A MULTIDISCIPLINARY POLICY APPROACH TO FOOD AND AGRICULTURAL BIOSECURITY AND DEFENSE

by

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B.S., Kansas State University, 1993
M.S., Texas A&M University, 1995

AN ABSTRACT OF A DISSERTATION

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Department of Animal Sciences and Industry
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Manhattan, Kansas

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Abstract

The U.S. agriculture industry is diverse and dynamic, plays a vital role in the nation's economy, and serves as a critical component in providing the global food supply. Agriculture has and always will be susceptible to threats such as pests, disease, and weather, but it is also threatened by intentional acts of agroterrorism.

One specific area of concern is foreign animal diseases (FAD) and the danger these diseases create for the U.S. livestock industry. Whether a disease outbreak is intentional or accidental, it could devastate animal agriculture and the food infrastructure and have a lasting impact on state, national, and global economies. One of the most economically devastating diseases that raise fear and anxiety in the livestock industry is foot and mouth disease (FMD).

A number of administrative, regulatory, and legislative actions have been implemented at state and federal levels designed to protect the agriculture industry and to prevent, prepare for, and respond to an accidental or intentional introduction of an FAD. However, the consistency, clarity, and long-term commitment of these policy approaches remains in question.

Effective policy decisions require a multidisciplinary approach that consider and balance science, economics, social factors, and political realities. A significant number of policy analysis tools exist and have been applied to animal emergency scenarios but few actually address the complexity of these policy dilemmas and provide information to policymakers in a format designed to help them make better decisions. Policy development needs to take a more multidisciplinary approach and better tools are needed to help decision makers determine the best policy choices.

This dissertation analyzes three FAD policy dilemmas: mass euthanasia and depopulation, carcass disposal, and vaccination. Policy tools are developed to address the multidisciplinary nature of these issues while providing the information necessary to decision makers in a simple and useful format.

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Dedication

This dissertation and every school project that came before it from kindergarten on is dedicated to my dad, Jack E. McClaskey, and my mom, Barbara Jean McClaskey. My dad taught me a love for agriculture, a desire to work with young people, a heart for all things canine, a passion for the Wildcats, a heartfelt appreciation for Kansas, and a toughness I appreciate every day. My mom made me think it was no big deal to be able to raise 6 kids, be a farm mom, teach at a university, have a hot meal on the table, get an advanced degree, read a good book every day, and never miss an important football game. It seems to me a dedication of my dissertation is the least I can do to say thanks.

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Preface

The majority of the content found in Chapter 3 was originally completed as a part of the March 2004 report prepared by the National Agricultural Biosecurity Center Consortium Carcass Disposal Working Group for the USDA Animal & Plant Health Inspection Service per Cooperative Agreement 02-1001-0355-CA (NABC, 2004).

Chapter 1 - Understanding Food and Agriculture Biosecurity Concerns

Agricultural biosecurity and agroterrorism are fairly recent terms in the agricultural industry vocabulary. Yet, threats to our agriculture production system and food supply are not new. Farmers and ranchers have been dealing with weather, diseases, and pests since the domestication of animals for food and the planting of crops to feed their families. Efforts have long existed to protect our food supply from accidental and intentional threats. However, the events of September 11, 2001, the anthrax postal attacks that followed, and on-going terrorist threats have increased attention to the potential of deliberate threats to the safety, integrity, viability, and sustainability of our food supply. More than 50 foreign countries have experienced naturally-occurring outbreaks of foot and mouth disease (FMD), classical swine fever (CSF), and highly pathogenic avian influenza (HPAI) since 9/11. The United States has seen four cases of bovine spongiform encephalopathy (BSE), along with chronic wasting disease (CWD) and epizootic hemorrhagic disease (EHD) in wild deer and elk populations, low pathogenic avian influenza (LPAI H7N2), one incidence of highly pathogenic avian influenza (HPAI H5N2), exotic Newcastle disease (END), and swine influenza (variant H3N2v).

The livestock and poultry industries could be devastated by numerous disease agents. These concerns, combined with other concerns related to emergency animal disease, emerging animal disease, transboundary animal disease, transmissible animal disease, and foreign animal disease (FAD) outbreaks around the world, have forced the livestock industry to focus on the issues surrounding an accidental or intentional devastating event. These threats affect farmers and ranchers, as well as the entire food infrastructure, and extend to consumers, investors, and government policymakers.

Food and agricultural biosecurity is the protection of the food and fiber industry from threats that are intentional, accidental, or natural. All types of threats are of significant concern, especially the potential threat of bioterrorism. Securing America's agricultural industry from agricultural bioterrorism was identified as an area of concern that needed attention and examination by scientists and policymakers long before the events of 2001 and it has received increased attention since 2001 (Adams, 1999; Foxell, 2001; Franz, 1999; Franz, 2005a; Horn &

Breeze, 1999; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003; National Research Council [NRC], 2002).

Nature and History of Agricultural Security Risks

To understand the risks related to agricultural biosecurity, it is important to understand the nature and history of the threat. The risk exists at all levels of the production chain from an attack on the livestock and crop sectors to adulteration of the food supply to introduction of a vector-borne disease. According to Hennessy (2008), biosecurity is "the protection of the economy, environment, and health of living things from diseases, pests, and bioterrorism" (p. 66). The concept of food and agricultural biosecurity encompasses protecting the food and agricultural industry from bioterrorism, as well as securing the agricultural system against all forms of natural and unnatural threats (Turvey, Mafoua, Schilling, & Onyango, 2003).

Defining bioterrorism, biowarfare, and agroterrorism

Intentional attacks include biowarfare, which is the act of a state government, or bioterrorism, which is perpetrated by a non-state actor. Carus (2001) defined bioterrorism as "the threat or use of biological agents by individuals or groups motivated by political, religious, ecological or other ideological objectives" (p. 3). Chalk (2004) defines agroterrorism as "the deliberate introduction of a disease agent, either against livestock or into the food chain, for purposes of undermining socioeconomic stability and/or generating fear" (p. 3). The World Health Organization (WHO) (2002) defines food terrorism as ". . . an act or threat of deliberate contamination of food for human consumption with chemical, biological or radio-nuclear agents for the purpose of causing death to civilian populations and/or disrupting social, economic or political stability" (p.4). Brown et al. (2005) defined agroterrorism as "the intentional use of a CBRNE weapon (chemical, biological, radiological, nuclear and explosive) against the nation's agricultural or food industries with the intent of destroying these resources and causing serious economic harm to the nation" (p. 3). In 2012, Yeh, Park, Cho, and Cho defined agroterrorism as "attacks with a variety of biological agents on commercial crops or livestock populations, either as targets in their own right or as vehicles by which to attack humans" (p. 536).

Bioweapons are a silent enemy because an attack is typically followed by an incubation period. It takes time before clinical signs appear and even longer before the disease is identified and mass casualties begin. The longer it goes undetected, the more devastating it becomes (Jaax, 2008). Numerous pathogens could threaten animal health and weaken or destroy animal production and a nation's economy. Biological weapons are often referred to as "the poor man's atomic bomb" (Blancou & Pearson, 2003, p. 433), making anti-crop and anti-livestock weapons seem "free at curbside" (Foxell, 2001, p. 114). If intentional, a multi-focal attack is the most likely to be devastating (Franz, 2005a). Multiple, simultaneous outbreaks are technically feasible and highly probable in an intentional attack, and this would be an immediate indication the disease is not naturally occurring (Elbers & Knuttson, 2013).

Historical attacks against agriculture

Segarra (2001) stated that, "Attacks against agriculture are as old as war itself" (p. 1). The use of food and agriculture as a weapon, target, or mode of attack remains a concern. In 590-600 B.C., the Athenians contaminated the Amphictyonic League's drinking water supply in the city of Kirrha. A Carthaginian general contaminated wine he left behind for the enemy allowing his army to catch them defenseless (Kennedy, 2007). In 149 B.C. in the Battle of Carthage, Romans poured salt on the Carthaginian crop lands and late in the 6th century a violent Jewish sect poisoned granaries (Lawson, 2000).

The first documented attack of bioterrorism against livestock occurred more than 1,200 years ago in Bavaria when a poisonous powder was used to kill cattle. Assyrians used rye ergot to poison livestock wells in the 6th century. Twelve cases of pathogens being used against livestock or food have been documented since 1912. During World War I, German operatives attempted to use glanders and anthrax against Romanian sheep, French cavalry horses, and Argentinean mules and livestock. While the overall success of their attacks is questionable, the Germans targeted Argentina, France, Mesopotamia, Norway, Romania, Spain, and the United States (Blancou & Pearson, 2003; Pearson & Salmon, 2005; Foxell, 2003; Dunn, 1999; Ban, 2000; Olson, 2012). The infection of Argentinian, French, and Mesopotamian mules with anthrax and *b. Mallei* leading to their subsequent death appears to be their greatest successes (Lawson, 2000). There is even a case of an American-born German operative living in Washington, D.C., who infected horses being shipped from Baltimore, Maryland, to French and British armies with glanders and anthrax. More than 3,500 horses were infected and rendered useless to the Allied troops (Foxell, 2001). The German goal was to infect draft horses, military cavalry, and food animals to disrupt transportation and supply lines. In World War II, despite

Hitler's ban on offensive bioweapons, Germany continued efforts to weaponize FMD. They conducted open-air trials on reindeer and domestic cattle on an island in a lake in northwest Russia (Ban, 2000).

Japan weaponized anthrax and Rinderpest against Russia and Mongolia in World War II. In 1944, the UK initiated Operation Vegetarian, a plan to drop 5 million anthrax cattle-cakes in enemy territory to wipe out dairy and beef cattle. More recently, the Rhodesian government used anthrax to destroy African cattle in the late 1970s (Ban, 2000; Blancou & Pearson, 2003; Dunn, 1999; Foxell, 2003; Pearson & Salmon, 2005). Mexican contract workers were accused by the USDA of deliberately spreading screwworm in livestock (Keremidis et al., 2013). From 1985 to 1991, Iraq weaponized anthrax and botulinum toxin, and the United Nations (UN) found proof of Iraq's program to develop camel pox (which may have been a surrogate for smallpox) as a weapon in 1995. In 1997, the Russian army used glanders against the Afghan mujahidin and their horses (Ban, 2000; Blancou & Pearson, 2003; Dunn, 1999; Foxell, 2003; Pearson & Salmon, 2005; Yeh et al., 2012). In 2011, a South African man was arrested and prosecuted for threatening to spread FMD in the US and Great Britain even though it was never proven he actually obtained the virus (Keremidis et al., 2013).

The crop sector is also susceptible to attack. During World War II, Germany dumped potato beetles in England and experimented with turnip weevils, turnip bugs, antler moths, potato stalk rot, potato tuber decay, and various weeds (Ban, 2000). In 1950, East Germany accused the US of scattering potato beetles over their potato crops (Ryan & Glarum, 2008). The Japanese explored the use of fungi, nematodes, and bacteria against grain and vegetable production in Siberia and Manchuria and are suspected of aerial dissemination that infected wheat and cotton fields. The US and Britain both had extensive anti-plant programs during World War II. The US even considered using a rice fungus in Japanese rice fields (Ban, 2000). In 1978, the Arab Revolutionary Council used mercury to poison Israeli oranges and jeopardize exports and the Israeli economy. Iraq weaponized wheat smut and experimented with aflatoxin for use against Iran in 1988. Israeli settlers sprayed pesticides on Palestinian grapevines in 1997 (Franz, 2005a; Pearson & Salmon, 2005; Center for Infectious Disease Research and Policy [CIDRAP], 2008; Foxell, 2003; Ban, 2000). In 2000, Israeli settlers allegedly contaminated Palestinian agricultural fields with sewer water with the intent to get them to abandon their land (Keremidis et al., 2013).

Biowarfare programs

A number of countries have historically documented, agriculture-focused biowarfare programs, including Canada, France, Soviet Union, Germany, Iraq, Japan, South Africa, UK, and the US. Egypt, Syria, and North Korea are suspected of having similar programs (see Table 1.1).

During World War II, the US studied animal diseases in cooperation with Canada and the UK. Mass production was investigated for anthrax, brucellosis, and glanders while defense strategies for Rinderpest, END, and fowl plague were also studied (Yeh et al., 2012). Starting in 1951, the US developed an anti-animal and anti-plant bioweapons program through the U.S. Army at Fort Detrick, Maryland. The U.S. Air Force also studied anti-plant weapons in Pine Bluff, Arkansas. The Central Intelligence Agency (CIA) later acknowledged efforts in this area as well. Field tests were run with wheat stem rust and rice blast fungus, and anti-animal pathogens were tested in feedlots in five states (Ban, 2000). The US had significant stockpiles of agricultural-focused bioweapons until the bioweapons program was disbanded by President Nixon in 1969 (CIDRAP, 2008; Franz, 2005a; Jaax, 2008; Monterey Institute of International Studies [MIIS], 2008; Pearson & Salmon, 2005). Cuban government officials have accused the US of attacks on animal, plant, and human populations with biological weapons in 21 different incidents. Investigations have shown, however, that the outbreaks and infestations were likely the result of a natural occurrence combined with an inadequate government response (MIIS, 2008; Ryan & Glarum, 2008).

The Soviet Union's biological and agricultural weapons development program has been documented as weaponizing a number of livestock and crop agents and was likely the most innovative and far reaching agricultural weapons program. The Biological Weapons Convention signed in 1975 aimed to end these weapons programs, but it is suspected that many programs continued past that time (CIDRAP, 2008; Foxell, 2003; Franz, 2005a; MIIS, 2008; Pearson & Salmon, 2005). Horn and Breeze (1999) stated that, "The Gulf War, the collapse of the former Soviet Union, and the end of apartheid revealed some surprising, well established bioweapons capabilities in Iraq, Russia and South Africa" (p. 10). Alibek and Handelmann (1999) noted that the Soviet bioweapons program *Biopreparat* had 32,000 scientists and staff, and 10,000 worked on anti-agriculture weapons. In comparison, the USDA Agricultural Research Service (ARS) had about 7,000 scientists employed in all aspects of agriculture research (Horn & Breeze, 1999; Jaax, 2008). Mass stockpiles of former Soviet Union weapons are likely to still exist and are poorly guarded (Roberts, 2005). Any country that continues to pursue a secret bioweapons program is most likely developing anti-agriculture weapons (Wheelis, 2000). One Soviet program, known as Ecology, was established by the Ministry of Agriculture and was focused on development of FMD, Rinderpest, CSF, ornithosis, and psittacosis for use specifically against the U.S. livestock industry (Lawson, 2000). The scientists who worked in these programs, the materials they created, and the techniques they developed have since been dispersed around the world, building a significant scientific understanding of agriculture bioweapons in rogue regimes and terrorist groups (Ban, 2000; Jaax, 2008). Officials from the former Soviet Union warned the U.S. government that Iran and other potential bioterrorists were attempting to recruit bioterrorism experts, especially those with experience in animal and plant pathogens. Finances could be influential, because the average Russian scientist made only $1,644 annually as recently as 2004 (Jaax, 2008).

Many smaller countries have also developed anti-agriculture bioweapons programs. For example, South Africa is believed to have developed anthrax as an agricultural weapon during the apartheid era (Lawson, 2000).

Actions by non-state actors

Biological, chemical, and vector-based attacks by non-state actors are important examples in understanding the ease of such attacks. As state-supported biowarfare programs have declined, non-state actors have shown increased interest in agroterrorism (Keremidis et al., 2013).

In 1952, the Mau Mau, a Kikuyu tribesmen terrorist society, used African bush milk to kill cattle in the White Highlands of Kenya (Ban, 2000; Foxell, 2003; Pate & Cameron, 2001). The Irish Republican Army attempted to intimidate the UK with the threat of an FMD release in the 1970s (Yeh et al., 2012). In 2001, ruling militants in Zimbabwe released FMD-infected cattle so they could take 4,600 white-owned farms and redistribute them to black owners. The cattle industry losses in Zimbabwe were estimated to exceed $70 million for the capital city of Harare and export markets to South Africa and Europe were halted. Economic impacts in neighboring Botswana were considered equally devastating (Ban, 2000; Foxell, 2003; Pate & Cameron, 2001). In 1970, the Ku Klux Klan poisoned cattle belonging to black farmers in Alabama (Kosal & Anderson, 2004). In New Zealand, a sheep rancher covertly imported rabbit hemorrhagic disease virus to use on the wild rabbit population who were eating his sheep's forage (Center for Domestic Preparedness [CDP], 2004; Jaax, 2008).

Table 1-1 *State Biowarfare Programs*

State	Status	Date	Disease
Canada	Former	1941-1960s	Anthrax, Rinderpest
Egypt	Probable	1972-present	Anthrax, Brucellosis, Glanders, Psittacosis, Eastern equine encephalitis
France	Former	1939-1972	Potato beetle, Rinderpest
Germany	Former	1915-1917, 1942-1945	Anthrax, Foot and mouth disease, Glanders, Potato beetle, Wheat fungus
Iraq	Known	1980s-present	Aflatoxin, Anthrax, Camelpox, Foot and mouth disease, Wheat stem rust, Wheat smut
Japan	Former	1937-1945	Anthrax, Glanders
North Korea	Probable	? – present	Anthrax
Rhodesia (Zimbabwe)	Uncertain/ Former	1978-1980	Anthrax
South Africa	Former	1980s-1993	Anthrax
Syria	Probable	? – present	Anthrax
United Kingdom	Former	1937-1960s	Anthrax
United States	Former	1943-1969	Anthrax, Brucellosis, Eastern & Western equine encephalitis, Foot and mouth disease, Fowl plague, Glanders, Late blight of potato, Newcastle disease, Psittacosis, Rice blast, Rice brown spot disease, Rinderpest, Venezuelan equine encephalitis, Wheat blast fungus, Wheat stem rust
USSR (Russia, Kazakhstan, Uzbekistan)	Formerly active; current status unclear	1935-1992	African swine fever, Anthrax, Avian influenza, Brown grass mosaic, Brucellosis, Contagious bovine pleuropneumonia, Contagious ecthyma (sheep), Foot and mouth disease, Glanders, Maize rust, Newcastle disease virus, Potato virus, Psittacosis, Rice blast, Rinderpest, Rye blast, Tobacco mosaic, Venezuelan equine encephalitis, Vesicular stomatitis, Wheat & Barley mosaic streak, Wheat stem rust

Note. Adapted from MIIS (2008), CIDRAP (2008).

This interest in agroterrorism by non-state actors was evident in the Arab Revolutionary Council's attack on Israeli oranges and the Israeli settlers attack on Palestinian grapes (Ban, 2000; Foxell, 2003; Pate & Cameron, 2001). In 1977, rebels in Uganda threatened to contaminate tea and coffee crops (Lawson, 2000). In 1985, the U.S. embassy received a threat that Sri Lankan tea exports had been contaminated with cyanide. Similar threats were made regarding Chilean grapes headed into the US being laced with cyanide, resulting in more than $333 million in losses to growers and exporters. In 1989, the Breeders organization claimed they bred and released Mediterranean fruit flies to protest pesticide use in California. Scientists were able to detect unusual populations of fruit flies and peculiar patterns of insect behavior, which indicated a likely intentional infestation (Ban, 2000; Foxell, 2003; Pate & Cameron, 2001).

An example where food terrorism was used against humans is the case of the Rajneeshee group in Portland, Oregon. In 1984, they intentionally contaminated salad bars with salmonella to influence voting turnout in a local election (Bledsoe & Rasco, 2002; Brown et al., 2005; Chalk, 2003; Chalk, 2004). In 1995, Aum Shinrikyo, a Japanese-based organization, used anthrax, botulinum toxin, and sarin nerve gas in multiple attacks (Ban, 2000; Foxell, 2003; Pate & Cameron, 2001).

CIA reports confirmed that the September 11 terrorists had received training in agriculture and showed interest in crop duster training, which is an excellent way to spread biological agents over crops or livestock (Collins, 2003; Roberts, 2005). During Operation Enduring Freedom, the U.S. military found al Qaeda instruction manuals in terrorist hideouts in Afghanistan, and hundreds of pages addressed agricultural terrorism (Kosal & Anderson, 2004; Monke, 2007; Jaax, 2008; Olson, 2012). Many were U.S. agricultural documents translated into Arabic (Crutchley, Rodgers, Whiteside, Vanier, & Terndrup, 2007). The manuals reportedly detailed the destruction of crops, livestock, and food processing facilities (Thompson, 2005; Olson, 2012). A recent post to a Jihadist Internet forum discussed the development and use of a biological weapon from *E. coli* (Hoffman, 2011). In a radical Islamic magazine, Shaykh Anwar Al Awlaki stated, “The use of poisons or chemical and biological weapons against population centers is allowed and is strongly recommended due to its great effect on the enemy” (Keremidis et al., 2013, p. s20).

On July 28, 2012, the Emergency Management coordinator from the Kansas Department of Agriculture received an update from the Counter Agro Terrorism Research Center (CATRC) stating that there had been a rise in the discussion of agroterror with a focus on “the tools and means to attack the food supply chain, drinking water systems and ventilation systems” on Jihadist websites in the second quarter of 2012 (Counter Agro Terrorism Research Center [CATRC], 2012, p. 1). Current trends indicate that agriculture continues to be an attractive target. Analysts indicated that terrorist groups focus on methods that cause significant economic damage. Olson (2012) concluded that the “evolving strategy of al Qaeda focuses on inexpensive but highly disruptive attacks in lieu of monumental ones” (p.1).

This dissertation will occasionally highlight examples of crop diseases, but the primary focus will be on animal agriculture. Most experts believe that animal agriculture is more vulnerable and at greatest risk for an intentional attack (Chalk, 2004; Monke, 2007; Parker, 2002) because livestock move frequently, have a higher individual value, and are more difficult to free from disease (Hennessy, 2008).

Animal Disease Outbreaks

There are a number of naturally or accidentally occurring disease outbreaks that are important when considering disease threats to animal agriculture. Periodic anthrax outbreaks in livestock have occurred in North America in the last 50 years including eight sporadic outbreaks in Canada from 1962-1991 and U.S. outbreaks in North and South Dakota, Texas, and Minnesota resulting in a few thousand livestock fatalities (Ackerman & Giroux, 2006). FMD was identified in Taiwan in 1997 and in Europe, South America, Asia, and Africa in 2001. HPAI outbreaks occurred in Asia, Europe, Canada, and the US beginning in 2003. A new H5 avian influenza strain appeared in Asia in 2011. Additional outbreaks with major economic impacts include CSF in the Netherlands, END in the southwestern US, CWD in Colorado and Wisconsin, Rinderpest in Africa, peste des petits ruminant (PPR) in India and Bangladesh, contagious bovine pleuropneumonia (CBPP) in Africa, Rift Valley fever (RVF) in the Arabian peninsula, and BSE in the UK, Canada, and the US (CIDRAP, 2008; Domenech, Lubroth, Eddi, Martin, & Roger, 2006; Franz, 2005a; Pearson & Salmon, 2005). In most of these cases, outbreaks were caused by human error, carelessness, or a lapse in security. The same results could be replicated with an intentional disease introduction (Collins, 2003). In particular, the FMD outbreak in the UK provides one of the best case studies for understanding the impact of a disease outbreak on the agricultural industry and a national economy. However, there are many diseases that could be catastrophic in an accidental or intentional disease outbreak.

Serious disease threats

The World Organization for Animal Health (also known as OIE, the Office International des Epizooties) identifies a number of transmissible diseases with the potential for very serious and rapid spread of serious socioeconomic or public health importance in the international trade of animals and animal products (CIDRAP, 2008; Office International des Epizooties [OIE], 2012a). Before 2004, the OIE categorized animal diseases in two lists: *A* and *B*. The former A-list diseases are of most concern. Since then, the OIE has combined all diseases into one list that is more in line with the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organization (WTO). The OIE classifies each disease equally, so they each have the same importance in regard to international trade (Monke, 2007). The OIE list is in Appendix A.

The Department of Homeland Security (DHS) recognizes more than 40 contagious FADs as a threat (SES, Inc., 2012). The Agricultural Bioterrorism Protection Act of 2002, a subpart of the Public Health Security and Bioterrorism Preparedness Response Act of 2002, identified pathogens that are of greatest concern (Federal Register [FR], 2002). The list has two parts: the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) only list (of concern to animals) and the APHIS and Center for Disease Control (CDC) overlap list (of concern to animals and humans) (Monke, 2007).

The list includes pathogens and toxins that have potential to threaten animal and plant health or related products. The listing of pathogens and toxins is influenced by the effect of exposure on health, production, and marketability; pathogenicity/toxicity of the agent; and the availability and effectiveness of pharmacotherapies and prophylaxis for treatment and prevention. Fourteen of the 15 diseases listed on the former OIE A-List are included on the APHIS list, except for RVF, which is on the APHIS/CDC list (FR, 2002).

The animal pathogens of greatest concern are highly contagious, infectious diseases that result in rapid disease spread and often high animal morbidity and mortality. They have high potential of imposing serious socioeconomic or public health consequences. In addition, such outbreaks would devastate international trade (CIDRAP, 2008; Franz, 2005b; Monke 2006).

Some pathogens are of greater concern than others. FMD is most often mentioned as a potential tool of an agroterrorist attack. It is easy to use, spreads rapidly, and can cause severe economic damage. FMD is not transmissible to humans. BSE is considered a select agent, but is not likely to be used in an attack (Jaax, 2008). Symptoms are slow to manifest and it may even go undetected. It can, though, be passed to humans in the form of variant Creutzfeldt-Jakob disease (vCJD). Even though it is unlikely to be used in agroterrorism, protecting against this disease is a matter of agriculture security. Diseases such as brucellosis, influenza, or tuberculosis are already widespread and do not receive much attention in the bioterrorism debate. In addition to FMD, CSF, and END, there are significant concerns about emerging diseases like Nipah virus, Hendra virus, and the H5N1 strain of avian influenza (Monke, 2007). Rinderpest, while it has a history in bioterrorism, was eradicated in 2011 due to the combined efforts of scientists, policymakers, veterinarians, and farmers (OIE, 2012a).

OIE has partnered with the Food and Agriculture Organization of the United Nations (FAO) to collaborate and strengthen efforts to build capacity and develop program strategies for dealing with FAD through regional alliances. Their Global Framework for Transboundary Animal Diseases identifies FMD as the greatest risk and highest global priority, followed by RVF and HPAI. PPR, CBPP, African swine fever (ASF), and CSF are recognized as top priorities with regional emphasis (Domenech et al., 2006).

Types of threats

A disease threat can be unintentional or intentional. If unintentional, the disease outbreak could be naturally occurring or due to an accidental introduction of a disease agent. If a disease outbreak is intentional, the disease introduction could be an act of terrorism or a criminal act depending on the circumstances. A terrorist attack could be domestic with special interest or political motivation or international by state, non-state, or loosely affiliated actors (Gilpen, Carabin, Regens, & Burden, 2009).

If the occurrence can be attributed to a natural outbreak, the disease is more difficult to track and trace to the original source. Simply announcing an infection could cause severe and immediate economic impact (Ban, 2000; Blancou & Pearson, 2003; CIDRAP, 2008; Franz, 2005b; Kelly et al., 2004). Strategic attacks on agriculture could have a more severe impact than accidental or natural disease occurrences (Yeh et al., 2012) and are “increasingly recognized as a national security threat” (Yeh et al., 2012, p. 536).

An unintentional outbreak, accidental infection, or deliberate attack can all have significant affects, even if just one farm or one animal is infected. Consider the single BSE case found in Washington in December 2003. One Holstein cow imported from Canada was diagnosed with BSE and it resulted in an export loss of more than $3 billion (Brown et al., 2005; Franz, 2005b; Kelly et al., 2004). This resulted in an immediate export ban and a 90% decline in exports. In 2005, exports were still 71.4% below pre-BSE export levels. The loss of high-quality beef export markets such as Japan and Korea who imported 56% of U.S. beef exports in 2003 was significant. The impact on domestic markets, however, was a decline of only approximately 1.5% (Lee, Park, Gordon, Moore, & Richardson, 2011). Interestingly, BSE is an example of a situation in which well-thought out policy choices made a positive difference. In 2011, only 29 cases of BSE were detected worldwide, which represents a 99% reduction since the peak of the disease in 1992. BSE testing policies developed since 2003 have made the industry less economically vulnerable to a BSE case. A single case of atypical BSE found in California in 2012 had little lasting impact on the economy (Clifford, 2012; Hollis, 2012).

Factors Related to an Intentional Attack

There are a number of factors related to the nature and potential of an intentional attack, including the motivation of attackers, the simplicity and low risk of an attack to the perpetrator, and asymmetry of an intentional attack.

Motivation behind an intentional attack

Perpetrators of agroterrorism could be politically motivated single-issue groups, organized crime groups, greedy individuals attempting to manipulate the commodity markets, radical ecologists, animal rights activists, religious fanatics, apocalyptic sects, opponents of biotechnology, malicious or mischievous copycats, lone wolves, traditional criminals, economic opportunists, political extortionists, hostile nations, non-state actors, environmental militants, disgruntled employees, industrial saboteurs, or individuals wanting to make a political statement. For some perpetrators, an attack may be a means to an end, or, for another, a means and an end. People for the Ethical Treatment of Animals (PETA), Earth Liberation Front (ELF), Animal Liberation Front (ALF), other animal rights extremist groups, and ecoterrorists may be willing to commit an act that devastates the livestock industry while encouraging consumers to rethink their food choices. Arson, animal liberation, assaults, extortion, firebombs, vandalism, and sabotage of livestock production and meat processing facilities are tactics used by groups like ELF and ALF in the past. Groups like these are not concerned with the economic impact. They want to dismantle an opponent (Casagrande, 2005; Gilpen et al., 2009; Heath, 2006; Keremidis et al., 2013; Olson, 2012; Parker, 2002; Yeh et al., 2012).

Ingrid Newkirk, PETA co-founder, noted that FMD would not be ghastly for animals since they are bound for death anyway, but it would awaken consumers. She stated she openly hoped FMD comes to the US, acknowledging it would bring economic harm to those who "profit from giving people heart attacks and giving animals a concentration camp-like existence. It would be good for animals, good for human health and good for the environment" (Elsner, 2001, p. 1). The British Animal Liberation Front has been accused of poisoning eggs, turkeys, and candy bars in order to stop crimes against animals (Yeh et al., 2012). According to the Federal Bureau of Investigation (FBI) Director Robert Mueller, crimes and terrorism committed by animal rights and environmental extremists are a top domestic terrorism priority (Jaax, 2008).

The goals of an attacker may include making money, stopping the planting of genetically modified crops, creating a market shift, exacting revenge, causing political upheaval, disrupting society, demoralizing a country, scaring consumers into changing their eating habits, blackmailing for political concessions, attracting attention to a cause, coercion, playing God, or creating an economic disaster. Their drive may be different, but their motivation is to disrupt the agricultural system with the greater goals of creating fear, economic disruption, and public distrust in the government (Cameron, Pate, & Vogel, 2001; Casagrande, 2000; Casagrande, 2005; Foxell, 2001; Hugh-Jones & Brown, 2006; Jaax, 2008; Manning, Baines, & Chadd, 2004). The UN, Interpol, and WHO agree that an attack on agriculture can create the meaningful psychological impact and government instability desired by extremists (Hugh-Jones & Brown, 2006). The Defense Science Board stated in 2002 that biodefense is the "single most significant modern challenge to U.S. government" (Jaax, 2011, p. 13).

Simplicity and low risk nature of attack

The skills required for implementing an attack on the food and agriculture system are rudimentary (Brown et al., 2005; Foxell, 2003). The attack can be nearly invisible, and symptoms may not be immediately apparent. It is even possible that an attack would go unnoticed for days, be difficult to trace, and may be hard to distinguish from a naturally occurring outbreak (Wheelis, 2000; CDP, 2004; Brown et al., 2005; Chalk, 2004; Myers, 2006).

In many cases, the diseases identified as the greatest risk have the ability to survive for several days or weeks in the environment (depending on temperature), are predictable in disease spread, and are easily available and reproducible. These most feared pathogens are easily disseminated, do not require an in-depth understanding of disease and animal health, are effective in small amounts, typically have low technology requirements, are easily transported in any type of container, and their use results in a greater moral acceptability than an attack on humans (Ban, 2000; Blancou & Pearson, 2003; CIDRAP, 2008; Franz, 2005b; Kelly et al., 2004).

Along with the lower moral barrier associated with an attack on the food system, A perpetrator faces little to no risk, few disincentives, and has little to lose from intentionally introducing disease to the food and agriculture sector. Few precautions are necessary, the technical obstacles are minimal, targets typically have low security, and a small attack can result in maximum impact. Pathogens are easily accessible from diseased livestock and crops around the world. No special process is required to weaponize the pathogens (Wheelis, 2000; CDP, 2004; Brown et al., 2005; Chalk, 2004). Because weaponization is considered one of the most significant barriers to bioterrorism, agriculture becomes a more effective target (Chalk, 2003). Ken Alibek, formerly known as Dr. Kanatjan Alibekov, the director of the Soviet bioweapons program, noted that many of the anti-agricultural weapons developed by *Biopreparat* were easy to produce, especially in comparison to bioweapons aimed at humans, and involved simple techniques that could be easily adopted by terrorists (Casagrande, 2000; Jaax, 2008). Not all anti-agricultural weapons would be easy to produce and distribute, but many such as FMD, anthrax, and wheat stem rust could be simple to prepare.

Biological agents are typically simple and inexpensive to obtain or produce. Infectious agents could be obtained from field clinical specimens and mass produced by multiplication using *in vivo* or *in vitro* methods. While the most likely biological attack is one that is relatively low tech in nature, scientific advances may open the door to more complex methods of assault. New techniques in biotechnology could allow for production of new microorganisms or transgenic pathogens with new characteristics. Some current production methods designed to increase volume, quality, and quantity, may increase stress levels in animals, which lowers their disease resistance and makes animals more susceptible to infection. Only health care has benefited more than the agricultural industry from genomic research and biotechnology. The same technologies used for the good of humanity can also be used to create destruction (Blancou & Pearson, 2003; Parker, 2002; Pellerin, 2000; NRC, 2002; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003; Jaax, 2008; Crutchley et al., 2007).

Brown noted that agroterror constituted an overlooked threat to America (1999). As the US becomes better protected from traditional, biological, or chemical attacks against the human population or infrastructure, agriculture and food systems become more vulnerable as terrorists shift their focus. There is also a greater potential for deniability by the perpetrator, and the likely response or retribution will be less vigorous (Noah, Noah, & Crowder, 2002).

Many FADs can be transmitted by animate or inanimate objects. The challenge increases when considering the magnitude and value of international travelers, mail, and products coming into the US. Nearly 500 million people arrived at American ports in fiscal year 2001, about 100 million were inspected by USDA, and more than 30% of items seized upon inspection are prohibited animal products or byproducts (General Accounting Office [GAO], 2002a). Increased international travel, the global marketplace, and increased imports result in more pathways for pests and diseases (SES, Inc., 2012).

Many experts have discussed that FMD could be easily gathered by contact with a sick or dead animal in South America or another country and smuggled into the US as manure stuck on the bottom of a shoe or fluid on a handkerchief (Brown et al., 2005: Jaax, 2008; Wheelis, 2000). It is possible FMD has been accidently brought into the US multiple times but has not come into contact with livestock (Swallow, 2012). Some experts have questioned whether the outbreak of FMD in Taiwan was intentional or accidental. A diseased pig was imported from China and it is difficult to determine if it was intentionally imported but accidently infected, or intentionally infected with the goal of disrupting the Taiwanese economy (Casagrande, 2005).

Asymmetric threat

An intentionally introduced agriculture disease is considered an asymmetric threat to America, intended to create instability of a social, political, and economic nature (Brown et al., 2005; Myers, 2006). Asymmetric threats are non-frontal attacks specifically defined by the Department of Defense Joint Staff as “unanticipated or non-traditional approaches to circumvent or undermine an adversary’s strengths while exploiting his vulnerabilities through unexpected technologies or innovative means” (Brown et al., 2005, p. 12). Asymmetry also implies an imbalance between the often minimal levels of effort needed by a terrorist in order for them to be effective compared to the massive effort needed to protect a nearly immeasurable number of targets (Hugh-Jones & Brown, 2006).

Stefan Wagner, a microbiologist, commented “the ingredients and recipes for an agroattack are already in place; the willingness and realization to actually use them is bound to increase sooner or later" (Chalk, 2000, p. 12). Agriculture has been called a bioterrorist's bull's-eye; a combination of the perfect weapon and the perfect target (McGinn, 2003a; Alibeck & Handelmann, 1999). The threat of an attack on agriculture deserves a factual approach, not just a hypothetical discussion. Congressman Rob Simmons (2005) remarked that the 9/11 Commission concluded the intelligence community suffered from a "failure of imagination" (p. 1) and noted that just because U.S. agriculture has not seen an attack in the past does not mean it cannot happen in the future.

During his resignation in December 2004, U.S. Health and Human Services Secretary Tommy Thompson highlighted the risks for agriculture by saying, "For the life of me, I cannot understand why the terrorists have not attacked our food supply because it is so easy to do…I worry every single night about it" (Brown et al., 2005, p. 76).

As world population expands to 9 billion in 2050, the demand for food will grow exponentially with significant increases in the demand for milk, meat, and animal-based proteins. The demand for meat is estimated by the OIE to expand by 76%, dairy by 62%, and eggs by 65%. Such growth will continually increase the industry's susceptibility (OIE, 2012, June 29).

Impact on U.S. Agriculture and the Economy

The security of the food and agricultural industry is critical to national economic security. Agriculture is the largest industry and employer in the US. More than one in six (18%) U.S. workers work in a job directly supported by the agricultural industry, 15% of the U.S. Gross Domestic Product (GDP) stems from agriculture, and the value of livestock commodities exceeds $105 billion annually (Franz, 2005a; Cupp, Walker, & Hillison, 2004; Government Accountability Office [GAO], 2005; Economic Research Service [ERS], 2008; SES, Inc., 2012). The industry is valued at greater than $300 billion, generates more than $1.25 trillion in agriculture-related activities, and employs 25 million Americans (CDP, 2004; Brown et al., 2005; Chalk, 2004; ERS, 2008). In 2011, cash receipts in agriculture increased by more than 15% to nearly $363 billion (ERS, 2013). These statistics account for only a fraction of agriculture's impact, because allied industries such as transporters, restaurants, and distributors are not included (Chalk, 2004). Roughly one fifth of America's economic activity is accounted for by food and agriculture when measured from inputs to consumer tables (National

Infrastructure Protection Plan [NIPP], 2007). The value of agriculture and the need to secure these resources cannot be overestimated (Ban, 2000; Connor, 2005).

The U.S. agriculture industry produces more food and exports more agriculture products than any other country in the world. Agriculture exports are predicted to exceed $65 billion per year in the next decade. More than 20% of U.S. agricultural production is exported (10.5% of livestock and 22% of crops) and nearly a million jobs are created by agricultural exports. There are only two areas of trade where the US exports more than it imports – agriculture and airplanes. The food and agricultural sector is the largest positive contributor to the U.S trade balance (Brown et al., 2005; Parker, 2002; Chalk, 2004; Cupp et al., 2004; Logan-Henfrey, 2000; Monke, 2007; CDP, 2004; ; Myers, 2006; ERS, 2008; ERS, 2013). Due to the increased cost of food, the value of agricultural exports in 2012 was more than $141 billion, which was a 100% increase from 2006. The positive value of the agricultural trade balance has increased by nearly 10 times from 2005 to 2012 (ERS, 2013). The food and agriculture sector creates "a positive trade balance of roughly $35 billion and thereby fueling the US economy" (NIPP, 2010, p.10). Horn and Breeze (1999) noted that, "It [agriculture] is an unequaled 'jewel in the crown' of this great nation" (p. 11).

Vulnerability of agriculture

While an attack on the food and agriculture systems may not be considered highly probable by some, the combination of the ease of an attack with agriculture's significance to the national economy makes it a significant concern. David Franz (2005b), former Director of the National Agriculture Biosecurity Center, stated that, "The likelihood of a bioterrorist attack, on humans or agriculture is probably very low – and risk is almost impossible to measure – but the potential impact is enormous: we cannot just look the other way" (p. 1). The agriculture industry would be one of the easiest industries in the US to disrupt and is highly susceptible to economic sabotage (Foxell, 2003; Brown et al., 2005).

The Gilmore Commission (2000), an advisory panel established by the RAND National Defense Research Institute under contract for the U.S. Secretary of Defense, found that, "... a biological attack against an agricultural target offers terrorists a virtually risk-free form of assault, which has a high probability of success and which also has the prospect of obtaining political objectives, such as undermining confidence in the ability of government or giving the terrorists an improved bargaining position" (p. 199). An attack could be focused on livestock, crops, processing facilities, food in the distribution chain, wholesalers, retailers, storage facilities, transportation systems, and agriculture and food research laboratories (GAO, 2003; Monke, 2007). Agriculture is a soft target with poor security and multiple entry points (Kohnen, 2000).

Yeh et al. (2012) summarized the vulnerability of the livestock industry to a biological attack into the following three reasons:

- "The majority of lethal and contagious biological agents are environmentally resilient, endemic in foreign countries and harmless to humans, making it easier for terrorists to acquire, handle and deploy these pathogens;
- With animals concentrated in fewer production facilities and frequently transported between these facilities, a single pathogen introduction may cause widespread infection; and
- The extent of human travel around the globe makes it difficult to exclude exotic animal diseases as possible biological agents" (p. 536).

Concentration of production agriculture

Animal agriculture's continuously changing structure to higher production concentration increases the industry's vulnerability to high death losses due to disease or disaster. A large percentage of commodity sales come from a relatively small proportion of production units and limited geographic areas (Foxell, 2001; Brown et al., 2005; Cupp et al., 2004; Chalk, 2004). A few geographic areas are especially vulnerable: cattle feeding in the High Plains region, including portions of Texas, Oklahoma, Kansas, Nebraska, and Colorado; swine operations in North Carolina, Minnesota, and Iowa; and poultry production facilities throughout the Southeast and on the East Coast. In these cases, infecting a small number of animals can cause a large disease footprint, which could wipe out production and sales at a high level. As an example, more than 70% of beef cattle are produced within a 200-mi circle within the High Plains, and 80-90% of grain-fed cattle are found in less than 5% of the country's feedlots and located in the Midwest and Southeast. More than 75% of hogs are in the Midwest (Foxell, 2001; Brown et al., 2005; GAO, 2005; Monke, 2007; Breeze, 2006). Ninety percent of poultry are in the Southeast (Jin, McCarl, & Elbakidze, 2009).

Overall, the Midwest is home to more than 24% of total agricultural production and is easily recognizable to potential agroterrorists as a prime target (Dykes, 2010). The First Congressional District of Kansas that is comprised of the western half of the state is the number one congressional district in the nation in the value of agricultural products marketed. There is significant interaction between the top three commodities of beef, dairy, and corn and the production sectors are highly integrated around animal feed consumption. A disruption in one production sector will quickly impact other sectors due to the high integration. In addition, agromovement, the routine transportation of livestock, grains, and processed food products, is rapid and expansive, adding to the industry vulnerability and potential economic impact of a disease outbreak (Dykes, 2010). It is estimated that 1,000,000 pigs are in transit every day in the US (Center for Food Security and Public Health [CFSPH], 2013a).

As of January 1, 2013, the US had nearly 90 million cattle, 66 million pigs, 6 million sheep (National Agricultural Statistics Service [NASS], 2013), and an estimated 40 million wild, cloven-hoofed animals all susceptible to a disease, such as FMD (Parker, 2002). The top four meatpacking firms in the US account for more than 65% of animal slaughter. In Canada, the top four firms account for more than 75% of livestock slaughter and more than 60% of poultry processing. But in the UK, the top 10 plants account for less than 40% of cattle slaughter, slightly more than 40% of sheep slaughter, and 60% of swine slaughter (Jin et al., 2009).

One infected animal introduced to a confined animal feeding operation (CAFO) can affect thousands of animals in a short time, resulting in a potentially devastating economic impact on producers and local, state, and national economies. There are livestock operations that own several hundred thousand head of cattle or hogs with thousands housed together in individual facilities and poultry operations with millions of chickens housed by the thousands in multiple facilities. Concentration in the slaughter and processing industry also makes the system vulnerable. These factors allow for fast and efficient spread of disease, will likely result in high number of animals to be destroyed, and make it challenging to secure entry points. However, concentration and scale allow a planned defense strategy that is focused on limited geographic areas and for the industry to be more resilient and responsive (Chalk, 2004; Crutchley et al., 2007; Monke, 2006; Zink, 2004).

Olson (2012) stated that, “The same factors that yield inexpensive and plentiful food by promoting maximum production efficiency also make American agricultural systems inherently vulnerable" (p.1). Vertical integration results in fewer, larger farms and centralized ownership. In the pork industry, the 40 top producers control 90% of production. It estimated that the 30 largest cattle feeding operations generate 50% of all beef products. Integrated production systems result in multiple entry points in the food chain for infiltration. The most likely targets would be intensive farming operations or feedlots, or a large number of small farms in close proximity. The infection of wildlife in agricultural areas is also a concern (Blancou & Pearson, 2003; Brown et al., 2005; Casagrande, 2002; Chalk, 2004; CIDRAP, 2008; Cupp et al., 2004; Foxell, 2001; Franz, 1999; Franz, 2005b; GAO, 2003; Kelly et al., 2004; Monke, 2007; Parker, 2002; Yeh, Lee, Park, Cho, & Cho, 2013).

In many developing countries or regions where agriculture is less concentrated, traditional, small-farming operations keep different species in close proximity which can lead to new outbreaks and pathogenic mutations across the species barrier. Thus, the combination of structures within the industry allows for the possibility that new pathogens can be created in areas with more traditional farming practices and more intensive production can lead to faster disease spread (Ackerman, 2006).

Additional factors adding to vulnerability

In addition to risks associated with high-density production, the vulnerability of animal agriculture is impacted by other factors. Open access production in low population isolated areas typically leads to insufficient biosecurity and surveillance, and few farms and ranches practice effective security measures. Agriculture utilizes large expanses of land that are difficult or impossible to secure. The limited genetic diversity of crops and food animals, the focus on the collection of aggregate livestock statistics rather than individual head data, and the extensive transportation system for livestock and food products add to the industry's vulnerability. As animals are marketed, they are often comingled with stock from other farms, which increases the potential for disease spread. The risk is also enhanced by livestock sales practices and centralized feed supplies. In addition, there is a shortfall in the training of producers and veterinarians to identify an FAD and weaknesses in disease detection systems. Because the US has been historically free of major FADs, vaccines are not routinely used. Producers are typically hesitant to report disease outbreaks for fear of income ramifications, and these passive reporting methods are accentuated by a lack of trust between producers and the government. Many Americans underestimate the economic and social importance of the rural and agriculture sectors which makes investing in agricultural biosecurity and defense less likely to be a priority to them (Blancou & Pearson, 2003; Brown et al., 2005; Casagrande, 2002; Chalk, 2004; CIDRAP, 2008; Crutchley et al., 2007; Cupp et al., 2004; Foxell, 2001; Franz, 1999; Franz, 2005b; GAO, 2003; Kelly et al., 2004; Monke, 2007; Parker, 2002; Yeh et al., 2013). Wade Moser, a North Dakota livestock producer, noted, "The livestock industry must overcome its distrust of government, and the government must understand the livestock industry better" (Koo & Mattson, 2002, p. 5).

Another factor that adds to the vulnerability of the livestock industry is the limited number of practicing large animal veterinarians and the decreasing number of veterinary students preparing for careers in the livestock industry (Crutchley et al., 2007; Swallow, 2012). Only 25% of veterinarians who belong to the American Veterinary Medical Association (AVMA) work with large animals and few have experience with FAD (Crutchley et al., 2007).

Consequences of an attack

The consequences of a large-scale animal disease outbreak would be far reaching. When an epidemic is introduced into a previously disease-free country, the effects on livestock productivity are dramatic. Direct and indirect costs for control and eradication will be significant. The entire agricultural industry and national economy will be affected, especially the import-export sector (Blancou & Pearson, 2003; Casagrande, 2000; Foxell, 2003; Monke, 2007).

Direct and indirect economic impacts

Consequences would include losses due to disease, efforts to contain the outbreaks, trade restrictions, and indirect effects to market and related industries, including demand shifts due to changes in consumer confidence. Direct costs would include expenses related to direct losses of crops and livestock, mortality, morbidity, loss of production, cost of diagnosis and diagnostic procedures, treatment, depopulation, disposal, welfare slaughter, market supports, surveillance, breeding restrictions, emergency vaccination, tracing of infected animals, establishment of short- and long-term quarantines and movement restrictions, and producer compensation. Further losses would result from idle production stages, damage to consumer confidence, land-value changes, disruption of markets, impacts on tourism and travel, trade disruption, and long-term loss of market share (Blancou & Pearson, 2003; Chalk, 2004; Monke, 2007; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003; NRC, 2002; Parker, 2002; Wheelis, 2000). Actual and perceived risks are likely to increase financial losses (Kohnen, 2000).

In addition, an attack on any one segment of the industry would impact other economic segments. For example, an FMD outbreak would affect the grain industry where every other bushel of U.S. grain is used for animal feed (Segarra, 2001). Approximately 70% of the world's feed grains are grown in the US and U.S. grain producers serve as the major supplier for the domestic and Canadian livestock industry. A North American FMD outbreak resulting in reduced demand for feed grains due to stamping out or lower consumption by diseased and recovering animals will result in a significant oversupply of feed grains in the global markets, destabilize grain markets for a long period of time, and disproportionately disrupt the economies of many developing countries who depend on imports (Heath, 2008).

An attack on just one farm would instigate movement stoppage, trade restrictions, and quarantines. The damage would be disproportionate to the size of the attack (Casagrande, 2005). An intentional attack designed to cause significant damage will involve simultaneous introductions at multiple production sites, creating even greater disruption (Pendell, Leatherman, Schroeder, & Alward, 2007). Even a blundered attack or a hoax would undermine government and consumer confidence (Ban, 2000; Foxell, 2001). Misleading or inaccurate information can also have an impact. A false report of FMD in Mexico attracted worldwide attention after a local newspaper claimed the disease had been identified and cattle were to be destroyed (Tabascohoy, 2011). When a false rumor of an FMD outbreak at a sale barn in Holton, Kan. hit the media in 2002, the cost to the national markets exceeded $50 million (Jaax, 2006; Jin et al., 2009). In New Zealand, government officials received a letter stating that a vial of FMD virus was poured over hay and fed to cattle and sheep on Waiheke Island. The letter threatened further releases and officials implemented their response plan. Direct costs exceeded $2 million (Mackereth & Stone, 2006).

The U.S. economic impact of an intentional or accidental FAD outbreak would be significant. The domestic impact, combined with the impact on international trade, would be devastating (Blancou & Pearson, 2003; Casagrande, 2002; Foxell, 2003; Franz, 2005b; Kelly et al., 2004). Agroterrorism is designed to cause economic destruction though diseases that damage a nation's ability to conduct international agricultural commerce (CDP, 2004; Wilson, Logan-Henfrey, Weller, & Kellman, 2000). In addition, the U.S. Department of Commerce found that the economic multiplier of exported agricultural products is 20 to 1. Because the economic loss would be so significant, some have designated such acts as econoterrorism (Parker, 2002).

Recovery from such events can take years as producers and the government work to regain domestic and international consumer confidence (Foxell, 2001). Recovery costs can actually be more than the costs of the outbreak itself (Keremidis et al., 2013). Such a method of economic destruction can be defined as low-cost/high-yield (Chalk, 2004) and should never be considered as low-probability or low-consequence (Yeh et al., 2013).

FMD as an example

According to Peter Chalk (2003), Taiwan's gross domestic product dropped by 2% nearly overnight due to trade embargoes implemented following the FMD outbreak in 1997. Total loss exceeded $5 billion. Long-term impacts show the overall loss may have reached $15 billion (Logan-Henfrey, 2000; OIE, 2012a; Owens, 2002). Current annual production losses from FMD worldwide and prevention costs from vaccination are estimated to exceed $5 billion (OIE, 2012, June 27). The FMD outbreak in the UK resulted in a $12-billion loss (GAO, 2003). In 2012, OIE estimated that the actual direct and indirect costs may have reached $30 billion (OIE, 2012, June 27).

Based on the U.K. outbreak of FMD, the cost of a similar outbreak in the US is estimated to exceed $24 billion in direct costs and up to $10 billion annually in the export market. This estimate does not include indirect costs (GAO, 2003). Price Waterhouse Coopers applied their estimated loss ratios derived from the U.K. FMD outbreak to predict a loss of up to $33.6 billion in the US based on a conservative estimate of animals being destroyed (Brown, 1999; Lautner & Meyer, 2003). Monke, 2007; In a study done using the National Interstate Economic Model, economic loss was projected to equal $23 to $34 billion primarily just in the reduction of domestic and international demand (Lee et al., 2011). A USDA study estimated the potential economic impact of an FMD outbreak as more than $60 billion (Knowles et al., 2005). The impact on individual producers would be significant while the aggregate impact on agriculture is less extensive due to shifts in economic welfare among different industry sectors. Closure of international markets and an adverse domestic consumer response would lead to the most devastating overall economic damage (Paarlberg, Lee, & Seitzinger, 2002).

A simulated outbreak in California was estimated to result in national agriculture economic welfare losses of up to $69 billion. In this case, every additional hour delay in detecting FMD was projected to result in 2,000 more cattle slaughtered and an estimated increased loss of $65 million (Carpenter, O'Brien, Hagerman, & McCarl, 2011). The economic and societal impacts of an intentional outbreak are expected to exceed those of an accidental outbreak (Jin et al., 2009). If an intentional FMD outbreak were introduced into five feedlots simultaneously, the economic damages are anticipated to be substantially greater than a single site introduction. In a 14-county region of Kansas, an FMD outbreak is projected to lead to the depopulation of 1.2 million cattle and the destruction of more than 987 million pounds of beef (Pendell et al., 2007). In another study based on a single Kansas county, a potential FMD outbreak that infected 60 farms resulted in projected operational costs of $1.4 million a week and an estimated $6.4 million loss to the county along with the expected loss of more than 4,000 jobs in manufacturing, retail, hospitality, and other jobs (Heath, 2013).

A study by the Center for Agricultural and Rural Development Food and Policy Research Institute estimated losses over 10 years due to an FMD outbreak in each agriculture sector. They estimated that the pork industry would lose $57 billion, beef would lose $71 billion, poultry would lose $1 billion, corn would lose $44 billion, soybeans would lose $25 billion, and wheat would lose $1.8 billion. Just in the pork and beef sector alone, job losses were estimated to exceed 58,000 jobs per year (Hayes, Fabiosa, Elobied, & Carriquiry, 2011). Other studies have estimated that the loss in trade would exceed $27 billion (Brown, 1999). The smallest outbreak can cause international trade damage. The National Defense University exercise predicted that an FMD outbreak that impacted only 10 farms would have an economic impact of more than $2 billion (Collins, 2003). A trade ban can have a larger and more long-lasting economic impact than the actual disease production losses. A disease outbreak will negatively impact a previously disease-free country's export reputation, and even after bans are lifted, it will be difficult to regain market shares (Junker, Komorowska, & van Tongeren, 2009). Canada spent $2 million in 1951 and 1952 to slaughter 2,000 animals to eradicate FMD, but the resulting embargoes cost $2 billion to Canadian farmers alone (1987 dollars) (Guterman, 2001; Kohnen, 2000).

In 2011 and 2012, the OIE reports there were 10 reported FMD outbreaks in previously disease-free zones or countries. Many of these were small outbreaks and did not result in extreme economic losses relative to a major outbreak, but the impact was still significant. In the last 15 years, more than $25 billion (based on 2011 US$) has been lost due to FMD outbreaks in countries that had been FMD free. This is combined with an annual estimated impact of $11 billon (range of $6 billion - $21 billion) in direct losses and vaccination costs in endemic countries. These estimates do not include losses due to trade restrictions, production losses when disease is present, or other FMD control and surveillance costs (Knight-Jones & Rushton, 2013).

FMD is not the only disease that will have a devastating economic impact. The CSF outbreak in the Netherlands in 1997 resulted in a loss of more than $3 billion (Logan-Henfrey, 2000; OIE, 2012a; Owens, 2002). The END outbreak in California from 1971-1973 resulted in the depopulation of 12 million poultry and direct costs of $56 million (Ackerman & Giroux, 2006). The 2002-2003 END outbreak in California resulted in an estimated loss of $1 billion (GAO, 2003) and depopulation of 2 million birds in California and Nevada (Ackerman & Giroux, 2006). Additional losses were incurred in Arizona, Nevada, New Mexico, and Texas during the same outbreak (Gilpen et al., 2009). Disease control is expensive but critical to minimizing loss as is evident with other disease incidents. The outbreak of HPAI in Pennsylvania in the mid-1980s cost $63 million for depopulation and decontamination and $200 million in indirect costs, but an economic analysis showed that without the eradication, the costs would have exceeded $5 billion and a significant portion would have been passed on to consumers (Ackerman & Giroux, 2006; Brown, 1999). Nearly five million birds were destroyed in response to the 2004 LPAI outbreak in Virginia (Ackerman & Giroux, 2006). When karnal bunt infected wheat crops in the southwestern US, it cost more than $250 million in lost wheat exports in 1996. Thirty-two countries banned U.S. wheat imports within one day (Owens, 2002).

Impact on consumer costs

The health of the livestock industry, specifically the lack of disease, results in higher productivity, increased profits for producers, and decreased consumer costs (Brown, 1999). Consumers typically spend less than 9.8% of their disposable income on food (including only 5.7% at home), which is one third to one quarter of the percentage many consumers pay around the world, and less than in any other nation. The percentage of disposable income dedicated to food purchases has decreased by 62% since 1933 (ERS, 2013). Efficient food production leads to inexpensive food policies, which allows funds to be invested in other areas, which creates a robust and vibrant economy (Brown et al., 2005; CDP, 2004; Cupp et al., 2004; ERS, 2013; Kohnen, 2000; Monke, 2007; Myers, 2006; Parker, 2002). As noted by former Kansas State University President Jon Wefald (1999), the true engine of America's prosperity is driven by the discretionary spending created by our nation's "ability to produce safe, plentiful, and inexpensive food" (Jaax, 2002, p. 50). The economic vitality of agriculture depends on being primarily free of disease. Any change in disease status would have devastating results (Brown, 1999). Jaax (2002) summarized that, "The very strengths that make our food production industry the envy of the world, also contribute to our vulnerability" (p. 53).

Economic, political, and social instability

An intentional disease introduction or other form of attack would create economic, political, and social instability. Mass panic would occur. The lifestyle and welfare of those involved in the agriculture industry would be immediately disrupted. Farms and ranches would be quarantined. Commerce within the industry would come to a dramatic stop (Chalk, 2000).

"Disease outbreaks in the past, both in animals and humans, have not only damaged people's health and livelihoods, on occasion they have wrought irreparable damage on entire societies, undermining long-held social beliefs and overturning stable political systems" (Ackerman, 2006, p. 358). Animals and human populations will recover but the cost and long-term impacts are significant (Ackerman, 2006).

An attack on the agricultural sector would impact more than just farms and ranches. Response exercises have demonstrated that no such event would be local – it would immediately become a homeland security event (Cupp et al., 2004; Dupont, 2003). The entire food supply chain would be affected, including retailers, consumers, and their checkbooks. Parker (2002) said an attack would "jeopardize consumer confidence, disrupt commodity markets and wreak economic havoc" (p. X). The effect would be felt across the country as consumers filled their regular grocery needs, "stretching from America's farm belts to its supermarket counters" (Foxell, 2003, p.101). Grocery stores in major U.S. cities typically stock a 7-day supply of food, so supply disruptions could quickly result in food shortages (Olson, 2012). In *The Turner Diaries*, a novel with violent and racist themes that has been associated with real-life militia violence, the author writes that the characters "began appealing to things they [the public] can understand, fear and hunger. We will take food off their tables and empty their refrigerators…" (Casagrande, 2000, p. 99).

Americans depend on a safe, affordable, and accessible food supply. Any change in those expectations would lower public confidence in the food supply, which would lead to a lack of trust and support for government. The U.S. agriculture industry's ability to consistently provide wholesome, inexpensive, and abundant food is a significant factor in the well-being of the citizenry and general prosperity of the nation (Chalk, 2004; Dunn, 1999; Franz, 2005b; Kelly et al., 2004). The agricultural industry has demonstrated its ability to manage and resolve a number of unintentional threats, including natural disasters, temporary shortages, infestations, disease, and food safety concerns. The resilience and responsiveness have earned the agriculture industry substantial consumer confidence (Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003; NRC, 2002). As President George W. Bush noted, "Agriculture ranks among the most crucial of our nation's industries, yet its reliability and productivity are often taken for granted" (Cheviron, 2005, p. 35).

U.S. citizens cannot imagine a scenario in which their food is scarce, expensive, or dangerous to consume. The U.S. agriculture industry is considered the most productive and efficient in the world. It reached this success even though relatively few people are connected to production agriculture (less than 2% of the workforce is employed in farming and ranching), which makes it relatively invisible to the public. While the move from an agrarian society to the industrial and information age has created a disconnection between consumers and their food sources, food still remains a necessary element of everyone's daily routine (Chalk, 2004; Monke, 2007; Parker, 2002).

The average U.S. city has no more than a 5- to 7-day supply of meat, grain-based foods, fruits, and vegetables. On average, most food product travels more than 1,500 mi and most meat travels more than 1,000 mi before it reaches the supermarket. An agroterrorist attack or an unintentional disease outbreak would raise the cost of food, impact family and individual budgets, and undermine confidence in government in ways that few other disruptions could (Brown et al., 2005; Chalk, 2004; Cupp et al., 2004; Foxell, 2001; Hennessy, 2008; Myers, 2006). Such events would impact the public's trust in government to protect the food supply and could change the relationship between government and its citizens. The public will likely blame an attack on the failure of the government rather than the vulnerability of the industry (Chalk, 2001; Chalk, 2004; Cupp et al., 2004). Just the claim of an attack can result in recalls, trade restrictions, economic loss, and negative publicity (Bledsoe & Rasco, 2002).

A loss of consumer confidence in meat and milk products would add to already devastating economic impacts of a disease outbreak (Heath, 2013). Consumers demand safe food products backed by a guarantee and increased government action without additional costs (Domenech et al., 2006). "Consumer demands will be for livestock products that are reasonably priced (food security), have little risk of disease (food safety), and are from systems that treat animals humanely (animal welfare)" (Rushton & Upton, 2006, p. 381). A survey completed in 2012 of 1,000 consumers of meat and milk products indicate 85% have heard of FMD, but 49% think small children can have FMD. Confusion with hand, foot, and mouth disease may indicate FMD should be referred to as hoof-and-mouth disease (Ahlem, 2013). Studies indicate that just the threat of agroterrorism would have a negative impact on food consumption behavior, and it is likely that it will take time for consumption to rebound following a threat. A bioterrorist threat will likely result in a more severe decrease in consumption than a naturally occurring threat will create. Any threat will reduce consumption, but is unlikely to completely eliminate consumption for most people (Just, Wansink, & Turvey, 2009). In general, educational efforts designed to allay consumer and public fears are poorly developed in regard to catastrophic events and in the case of an agroterrorist attack, the perpetrator can use anxiety and fear to their benefit (Crutchley et al., 2007).

A terrorist knows that a series of attacks against livestock, crop, and food products will undermine the public's belief in the government's ability to provide a safe food supply. The attacker does not have to cause devastation. If consumers question the government and its ability to protect and secure its citizens and the food supply, attackers will create panic, get publicity, destabilize the government, and affect the politics of democracy (Blancou & Pearson, 2003; Casagrande, 2002; Foxell, 2003; GAO, 2003). The response to such an attack can also cause the public to question the government. The mass depopulation and disposal of hundreds or thousands animals will create confusion, anger, anguish, and disbelief, especially because we have not seen massive disease outbreaks since the advent of television and the US public has limited visual points of reference for such a disaster (Brown et al., 2005; Chalk, 2001; Hennessy, 2008; Horn & Breeze, 1999).

Is the threat overstated?

While the majority of experts agree an attack on agriculture would be possible or even simple, Cameron et al. (2001) believe an "agricultural Armageddon" would face serious technical hurdles and require scientific knowledge and skills (p. 6). They claimed the threats of agricultural bioterrorism have been exaggerated and that an attack is unlikely. Amy Smithson, the director of the chemical and biological weapons project at the Henry L. Stimson Center noted in 2001 that terrorists have shown little interest in agriculture and "… have been interested in killing people” (Guterman, 2001, p. A20). In 853 cases of chemical or biological terrorism worldwide over 25 years, only 21 attacks were on agriculture (Guterman, 2001). Carus (2001) found 222 bioterrorism cases over 100 years with only 14 confirmed cases related to food or agriculture, but he did find that the attacks with a food or agriculture focus had steadily increased (Parker, 2002). One reason there have not been more attacks is because some terrorists may consider these types of attacks mundane and not as dramatic as other terrorist methods (Chalk, 2000; Chalk, 2004). It is also possible that an agroterrorism attack could be used in conjunction with a traditional terrorist attack to create greater disruption and dilute response efforts (Chalk, 2003).

In 2003, the Congressional Budget Office (CBO) reported that the nation’s economic loss due to an agroterrorism attack would be small due to the industry’s strong tradition of responding to weather, pests, and health events and the existence of commodity support programs. However, this estimate failed to account for the fact that farm products that account for two thirds of gross farms sales (meat, fruits, and vegetables) are not covered by commodity support programs (Monke, 2007). Cameron et al. (2001) believe the diversity of U.S. agriculture and the economy would make an attack insignificant and that discussing agricultural terrorism is sensationalist and could promote attacks. This highlights another debate about how freely methods of bioterrorism are discussed. James Stack, director of the Great Plains Diagnostic Center at Kansas State University, refers to this issue as the “transparency paradox” (Nelson, 2004, p. 2). It is a balance between informing and alerting the public for the purpose of preparedness and providing information that may aid in an attack or exaggerate fears (Jaax, 2008; Nelson, 2004). Pate and Cameron (2001) concluded that an agroterrorist attack would be too difficult because of too many technical hurdles, lack of concentration in crop and livestock production, extraordinarily sophisticated surveillance of crop and animal disease, and no evidence of motivation amongst terrorist groups to attack agriculture.

In reference to agroterrorism, Stephen Cunnion (2002) noted that, “Some have downplayed this type of bioterrorism, saying that since it has never happened and since it would take a concerted effort, it would be unlikely to occur. This may have been a safe supposition before the World Trade Center disappeared from the New York skyline. The same coordinated long-term planning necessary for the 11 September attack makes this type of terrorism a real possibility” (p. 2). The terrorist attacks of September 11, 2001, combined with unintentional disease outbreaks and their significant impacts have proven that these claims are naïve and limited in perspective. Most experts conclude that the economic and political threats call for more research, a more accurate economic assessment, and a more complete and coordinated policy approach that informs the public and policymakers about potential risks (Cameron & Pate, 2001; Pate & Cameron, 2001). In his testimony to Congress, Dr. Jerry Jaax quoted U.S. Representative Chris Shays, "Better to be scared by the improbable possibility, than be unprepared for the catastrophic reality" (Jaax, 2002, p. 52).

Robert P. Kadlec (1995), a professor of military strategy and operations at the National War College, said, "Using [biological weapons] to attack livestock, crops, or ecosystems offers an adversary the means to wage a potentially subtle yet devastating form of warfare, one which would impact the political, social, and economic sectors of a society…" (Madden & Wheelis, 2003, p. 155) and "potentially threaten national survival itself" (Chalk, 2001, p.9). The ripple effect of an animal disease outbreak would be wide and multi-faceted. The availability of disease agents and the simplicity of dissemination make this risk a distinct possibility. Such an attack is difficult to prevent and even more difficult to attribute and trace (Brown et al., 2005; Casagrande, 2002; Pearson & Salmon, 2005).

An attack on agriculture is not about killing animals. It's about striking at the heart of the economy and creating an economic assault (Franz, 2005a; Jaax, 2002; Jaax, 2008; Nelson, 2004). It is not about "imperiling our food supplies" (Breeze, 2004, p. 251). It is about terror, financial losses, and "mass slaughter and funeral pyres all day and every day on CNN and al Jazeera" (Breeze, 2004, p. 251). According to Breeze (2004), terrorists want to see "sweeping quarantines, mass slaughter and burning or burial of millions of carcasses under the ceaseless eye of television – together with staggering financial losses triggered by international trade embargoes" (p. 251). Horn and Breeze (1999) said an attack on agriculture is an attack on the entirety of America – "on all civil society, on our economy, our way of life, our values, and our course and choices as a nation" (p. 12).

Efforts to secure agriculture

While the US has strengthened its efforts to detect, prevent, and respond to bioterrorist attacks, "Agriculture is one area that has received comparatively little attention in this regard. In terms of accurate threat assessments and consequence procedures, the general farming sector exists somewhat as a latecomer" (Chalk, 2004, p. 1). The federal government has been seen by many as slow to recognize the vulnerability and significance of agriculture and to take appropriate steps of protection and preparedness (Monke, 2007; Nipp, 2004). The best method of preparation is prevention, and a government's willingness and ability to fund and provide necessary resources is a critical factor of preparedness (Yeh et al., 2012). According to historical experience, terrorists and other attackers will rely on a lack of preparation to help accomplish their goals (Appel, 2013; Keremidis et al., 2013).

Although it is clear that the impact would be significant from any level of attack, it is nearly impossible to protect all animals and plants. With the constant movement of animals and food products across borders, it is not feasible to examine and track all content. International preventative measures combined with national strategies and contingency plans will reduce the risk and limit the impact of an intentional or accidental introduction (Blancou & Pearson, 2003; Kelly et al., 2004).

Whether an agricultural disease emergency is intentional, natural, or accidental, the strategies for prevention, mitigation, management, and recovery are common to all scenarios. When preparing for the normal, emergency managers are also preparing for the abnormal. Emergency response should be seen as dual purpose in planning for both attacks and natural outbreaks (Hugh-Jones & Brown, 2006).

Limited historical governmental response

While the threat to agriculture is clear and well-documented, the threat of agroterrorism has not always been recognized in the U.S. federal budget, laws, or policy directives. For years, the government response to these threats was not a priority. As fears and discussion increased in the late 1990s, "little progress was made in preparing to either prevent or respond to attack" (Madden & Wheelis, 2003, p. 157). Horn and Breeze (1999), administrators at ARS, noted that America's vulnerability to a bioterrorist or biological warfare attack on agriculture had been "almost totally overlooked" (p. 9). As Dr. Randall Murch, Director of the Federal Bureau of Investigation's Agricultural Crime Laboratory, said "the U.S. government has not yet fully embraced the threat of agroterrorism" (Foxell, 2001, p. 127) and when referring to an attack on U.S. agriculture "it is not a question of if but when" (Foxell, 2001, p. 126). In 2005, FBI Director Robert Mueller said agroterrorism was "just starting to enter our collective consciousness" while acknowledging it as a real threat (Baker, 2005, p. 1).

Agroterrorism was not mentioned in President Clinton's 1998 Presidential Decision Directives 39, 62, or 63, which set counterterrorism policy and prescribed the protection of the nation's critical infrastructure (Casagrande, 2000; Gilpen et al., 2009; Horn & Breeze, 1999; Monke, 2007). Biological weapons used against livestock and crops were not included in the U.S. Code (Title 50, Chapter 40) definition of weapons of mass destruction (WMD) (Cameron & Pate, 2001).

Agriculture was incorporated into national anti-terrorist strategy after September 11, 2001, but less than $500 million was committed to the cause (Kelly et al., 2004). The threat of agroterrorism took on a new urgency because of the importance of agriculture to economic, political, and social stability. However, little attention was immediately given to the threat of agricultural biowarfare and bioterrorism. Nine days after the September 11 attacks, the General Accountability Office (GAO) issued a report on combating terrorism that did not address agricultural or food threats, and minimally involved the USDA. The GAO explained this by stating that agriculture was not designated a critical infrastructure of the US. If policymakers continue to believe the risk to American agriculture is small, they are putting the industry and nation at peril (Monke, 2007; Parker, 2002).

Congressional hearings and actions

1999 – Senate Subcommittee Hearing on Emerging Threats

The first Congressional hearing on agroterrorism was held in October 1999 before the Subcommittee on Emerging Threats in the Senate Committee on Armed Services chaired by Senator Pat Roberts (Monke, 2007). During the hearing, Roger Horn, ARS Administrator, discussed the USDA's recently developed six-part approach to dealing with threats against agriculture, including terrorism prevention and deterrence, international cooperation, emergency management planning, counterterrorism research, protection of critical infrastructure, and protection of the food supply (Cameron & Pate, 2001; Horn, 1999). The next Congressional hearing was not held until 2003 (Monke, 2007).

2000 - Congressional Budget

In the 2000 Congressional Budget, $10 billion were appropriated to combat terrorism, and less than $5 million were appropriated for agroterrorism prevention, which was significantly lower than requested (Cameron & Pate, 2001).

2001 - Agricultural Bioterrorism Countermeasures Act

The Agricultural Bioterrorism Countermeasures Act of 2001 was introduced in the fall of 2001. The legislation called for expanding agricultural research to protect domestic food supplies and established a coordinated program of agroterrorism countermeasures. The Agroterrorism Prevention Act of 2001 was designed to establish and strengthen the criminal code related to animal- and plant-related terrorism, and the Agricultural Terrorism Prevention Response Act of 2001 was focused on establishing better interagency and industry cooperation, communication, and training related to agroterrorism preparation and response. By December 2001, six different pieces of legislation had been introduced in Congress. While the introduction of these bills indicated increased interest, hearings were not held and the bills never left committee. The same fate awaited the Protecting the Food Supply from Bioterrorism Act and similar stand-alone legislation that was introduced in 2002 (Crutchley et al., 2007; Manning et al., 2004; Leviten & Olexa, 2003; Segarra, 2001).

2002 – Defense Appropriations, Homeland Security, Agricultural Bioterrorism Protection Act

In January 2002, the USDA received emergency funding through the Defense Appropriations Act which was the first time Congress allocated any funds specifically focused on agroterrorism after repeated USDA budgetary requests (Horn & Breeze, 2003; Leviten & Olexa, 2003; Manning et al., 2004; Monke, 2006).

The Homeland Security Act was enacted in 2002 in direct response to the September 11 attacks creating the Department of Homeland Security (DHS) and resulting in one of the largest governmental reorganizations in history. The overarching goals of the new cabinet level agency were to reduce U.S. vulnerability to terrorism, prevent terrorist attacks, and minimize damage and enhance recovery from terrorist attacks. Responsibility for agricultural border inspection and the Plum Island Animal Disease Center was moved to DHS (Crutchley et al., 2007).

In June 2002, both the U.S. House and Senate passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). This act incorporated many agricultural security objectives and one of its goals was to help protect the nation's agriculture from biological threats and enhance the safety of the nation's food supply. In subtitle B, known as the Agricultural Bioterrorism Protection Act, the Secretary of Agriculture was directed to develop a list of biological agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The USDA received increased budget appropriations, and was directed to work in coordination with DHS to protect agriculture. Appropriations and user fees for homeland security related to agricultural and food security in USDA and DHS more than tripled since 2001 and agriculture received about 2% of the total non-defense homeland security budget (Leviten & Olexa, 2003; Manning et al., 2004; Monke, 2006). Section 333 of this legislation was the first step toward the building of the new National Bio and Agro-defense Facility (Gilpen et al., 2009). In addition, this legislation made intentionally introduced anti-agriculture diseases to now be considered a WMD (CDP, 2004).

2003 – Senate Committee on Governmental Affairs Agroterrorism Hearing

In November 2003, the U.S. Senate Committee on Governmental Affairs held the second hearing devoted to the issue of agricultural security entitled, *Agroterrorism: The Threat to America's Breadbasket*. Committee Chair, Senator Susan Collins, noted that nothing is more at the heart of the U.S. economy than agriculture. While initial reviews might have made it seem that agriculture had nothing in common with the World Trade Center, they are both manifestations of a critical target – the economy. Collins noted at the time that agriculture was still virtually unprotected (Collins, 2003). Senator Daniel Akaka, known for his efforts to improve agricultural security, called for the passage of his two bills related to coordinating and confronting threats to agricultural security (Akaka, 2003).

2005 – Congressional Hearings

Congress held two hearings focused on agroterrorism in 2005. One was in the U.S. Senate Committee on Agriculture, Nutrition, and Forestry, and one was in the U.S. House Committee on Homeland Security, Subcommittee on Intelligence, Information Sharing, and Terrorism Risk Assessment. Testifiers noted significant progress in preparing U.S. agriculture for an attack, but concerns were expressed as well (Cox, 2005). Dr. James Roth (2005) stated that the nation continued to have "inadequate infrastructure for prevention, detection, response, and recovery from foreign animal and zoonotic diseases" (p. 32). He noted concerns on slow vaccine development, shortages of laboratory capacity, and human resource deficiencies (Roth, 2005). James Lane (2005), undersheriff from Ford County, Kan., agreed there was more work to be done, especially in the area of prevention. He called for a coordinated homeland security strategy against agroterrorism. Other testimony encouraged greater attention to other aspects of food supply in addition to animal and plant diseases (Reardon, 2005).

2006 – Congressional Field Hearings on Agricultural Biosecurity

In January 2006, the Senate Agriculture Committee held a subcommittee field hearing in Pennsylvania on the subject of agricultural biosecurity. In June 2006, the House Committee on Homeland Security held its second hearing on agroterrorism, this time in the Subcommittee on Prevention of Nuclear and Biological Attack, in a field hearing in Athens, Georgia. The hearing focused more on the threat of zoonotic disease than previous hearings (Linder, 2006). During that hearing, Dr. Corrie Brown identified three gaps in response efforts. First, Dr. Brown identified a need for a national strategy on food and agricultural defense. Second, food and agriculture still needed to be recognized as a national priority by DHS. Federal efforts and presidential directives were a good start, but follow up especially with state and local government was strongly needed. Third, funding at the state level was inconsistent and regionalization should be considered for funding and potential partnerships (Brown, 2006). Nearly 80% of food defense activities are at the state level, but only 5% of the bioterrorism-related funding allocated to states is related to food and agriculture (Brown, 2006). While many related pieces of legislation were debated in 2006, the only successful bill was the Animal Enterprise Terrorism Act. The law expanded criminal consequences for damaging or interfering with an animal enterprise and applies to foreign or domestic bioterrorism (Monke, 2007).

2007 – House Hearings on Agriculture and Homeland Security

In July 2007, the House of Representatives Committee on Homeland Security held an Emerging Threats, Cyber Security, and Science and Technology subcommittee hearing on the federal efforts to mitigate vulnerabilities in the food supply chain. Testimony focused on the performance of federal agencies in protecting the food and agriculture industry, and the committee heard from agency and industry representatives. Questions focused on perceived short-falls of agency preparation and response strategies (Langevin, 2007). The Management, Investigations, and Oversight subcommittee of the same congressional committee held a field hearing in Pennsylvania on partnerships to protect food and agriculture. Many of the questions focused on confusion over agency roles and responsibilities (McGinn, 2007).

2009 – Senate Hearing on Veterinary Profession

A U.S. Senate hearing in 2009 focused on the shortage of veterinarians in the federal workforce, the insufficient amount of large animal and FAD veterinarian expertise, and the impact these deficiencies have on animal health efforts (Sherman, 2010).

2010 – House Hearing on Biological Threats

In 2010, the Committee on Foreign Affairs in the U.S. House of Representatives held a hearing on *National Strategy for Countering Biological Threats: Diplomacy and International Programs*. In that hearing, agriculture received two mentions and neither was emphasized (Sherman, 2010).

2011 – Senate Hearings on September 11th Anniversary

In recognition of the 10th anniversary of September 11, the U.S. Senate Committee on Homeland Security and Governmental Affairs held a number of hearings related to homeland security. One subcommittee hearing focused on agro-defense and response capabilities against threats to the agriculture and food system from natural disasters and intentional attacks. Dr. Doug Meckes, Director of Food, Agricultural, and Veterinary Defense Division in the DHS Office of Health Affairs provided an update on DHS efforts to meet the objectives of HSPD-9 and their progress in coordinating with other federal agencies and state governments (Meckes, 2011). Senator Akaka (2011) made it clear that he was concerned about the ability of federal agencies to work with states and tribal entities, federal veterinarian workforce shortages, and general readiness of the country to “effectively respond and recover from an agricultural food event” (p. 2). A month later, a hearing was held before the full committee on the issue of biological threats, but there was little mention of agriculture threats (Lieberman, 2011).

2011– Food Safety Modernization Act

Congress overhauled the FDA statutory tools when it passed the Food Safety Modernization Act (FSMA) in 2011. The focus is on preventing foodborne illness, but also increases the agency’s ability to address all food safety issues, including intentional threats to the food supply. Specifically, the legislation addresses hazard analysis and preventive controls in food facilities, protection against intentional adulteration in primarily post-harvest operations, standards for produce safety, and national agriculture and food defense strategy. The FSMA directs the FDA and USDA to work with DHS to develop a new National Agriculture and Defense Strategy, which identifies goals related to preparedness, detection, emergency response, and recovery. The agencies are to articulate processes to achieve the goals, an implementation plan, a coordinated research agenda, and an approach consistent with existing strategies. This coordination is intended to address the concerns of federal agency ineffectiveness. The strategy was to be completed one year after enactment, but the agencies missed the statutory deadline and, as of the time of this work, have not yet produced a strategy. The agencies failure to produce the strategy has been blamed by some on Congressional funding (Woodlee, 2012).

Federal agency roles and presidential directives

The DHS was established in 2002 with responsibilities that included coordinating U.S. efforts to protect the country from agroterrorism. This role included border and transportation security, emergency preparedness and response, and science and technology (including animal disease research and development). While the USDA and the Food and Drug Administration (FDA) maintained primary responsibility for protecting the nation's food supply and received expanded responsibilities, DHS took over border inspections and the Plum Island Animal Disease Center. The National Security Council now recognizes agriculture and food safety in the preparedness framework against WMD (Brown et al., 2005; GAO, 2005; Parker, 2002).

HSPD–5 Incident Command System

Several Presidential Directives have brought attention to the threat of agroterrorism. Homeland Security Presidential Directive-5 (HSPD-5), issued in February 2003, called for a protocol of incident management and for all entities and individuals to work together in one response plan known as an Incident Command System (ICS). HSPD-5 also called for the creation of a National Response Plan (NRP) that was adopted in December 2004 and renamed the National Response Framework (NRF) (Brown et al., 2005; Dykes, 2010; Monke, 2007).

Science and Technology Blue Ribbon Panel

A Blue Ribbon Panel of international experts was convened in 2003 by the Office of Science and Technology Policy in the Executive Office of the President to identify priorities and research and development needs for FADs and biological terrorism aimed at livestock. They specifically focused on surveillance, epidemiology, vaccination and protection technologies, and detection, diagnosis, and forensic capabilities (Marburger, 2007).

HSPD-7 Critical Infrastructure

Parker (2002) noted in the National Defense University report that agriculture is a critical national infrastructure. Horn and Breeze (1999), representing ARS, made the same argument. On December 17, 2003, the President issued HSPD-7 which addressed Critical Infrastructure Identification, Prioritization, and Protection. This time, when critical infrastructure was identified, agriculture and food were at the top of the list and called for additional infrastructure protection measures (Brown et al., 2005; Dykes, 2010; Gilpen et al., 2009; HSPD-7, 2003; Monke, 2007).

HSPD-8 DHS support of Local and State Government Preparedness

Also in December 2003, HSPD-8 instructed the DHS to develop a national preparedness system and work more with local and state governments to help them prepare. Five mission areas of prevention, protection, mitigation, response, and recovery were identified as a part of the National Preparedness Goals. The preparedness goals included agriculture with emphasis on food contamination, FAD, and general agriculture and food target capabilities (Brown et al., 2005; Dykes, 2010; Monke, 2007; National Response Framework [NRF], 2013b).

HSPD-9 Defense of U.S. Agriculture and Food

On February 3, 2004, the President issued HSPD-9, entitled *Defense of U.S. Agriculture and Food*. The directive identified the food and agriculture systems as “vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or are intentionally delivered by acts of terrorism” (HSPD-9, 2004, p. 1). HSPD-9 (2004) established a national policy approach to “defend the agriculture and food system against terrorist attacks, major disasters and other emergencies” (p. 1) because an attack on U.S. agriculture could cause a health and economic catastrophe. The directive called for interagency cooperation and attempted to ensure DHS, USDA, Department of Health and Human Service (HHS), Environmental Protection Agency (EPA), the Attorney General, and the Director of Central Intelligence work together in their plans to prepare for, protect against, respond to, and recover from an agroterrorism event. It encouraged planning and policy efforts designed to keep the agriculture industry protected and viable. The directive outlined responsibilities in seven areas: awareness and warning, vulnerability assessments, mitigation strategies, response planning and recovery, outreach and professional development, research, and development (Brown et al., 2005; Dykes, 2010; GAO, 2005; HSPD-9, 2004; Monke, 2007).

USDA APHIS, in conjunction with Iowa State University, established The Institute for International Cooperation in Animal Biologics (IICAB) (an OIE collaboration center) in 1995 to study the efficacy, availability, and use of veterinary biologics. In 2002, the CDC established the Center for Food Security and Public Health (CFSPH) at Iowa State University. The development of resources and training materials, such as the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) documents, for the preparation for, response to, and recovery from animal health emergencies is a key component of their mission. IICAB and CFSPH are co-located (CFSPH, 2013b). HSPD-9 called for the establishment of university-based Centers of Excellence in agriculture and food security to provide scientific and technical expertise in meeting related research needs. In 2004, the Foreign Animal and Zoonotic Disease Defense (FAZD) Center was established at Texas A&M University and the National Center for Food Protection and Defense (NCFPD) at the University of Minnesota. In 2010, a Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD) was established at Kansas State University. FAZD and CEZAAD are co-leads for the DHS Program on Zoonotic and Animal Disease Defense (Kennedy, 2007; Zoonotic and Animal Disease Defense [ZADD], 2010).

Under HSPD-9, USDA and HHS, in coordination with EPA and DHS, are responsible for improving recovery procedures to stabilize agriculture and remove and dispose of contaminated animals, plants, and food products in coordination with state and local governments. The Directive also called for a National Veterinary Stockpile (NVS) of vaccines, antivirals, and therapeutics to be deployed within 24 hr of an outbreak, and a National Plant Disease Recovery System that calls for the development of resistant varieties within one growing season (Brown et al., 2005; Dykes, 2010; GAO, 2005; HSPD-9, 2004; Monke, 2007). Monke (2007) noted that presidential directives are not enforceable laws and can be changed without Congressional consent. Statutory parameters for an agroterrorism preparedness plan can only be established with Congressional action and the creation of public law. However, such actions may increase oversight and follow-through (Monke, 2007).

White House Science and Technology Council

In response to HSPD-9, the Foreign Animal Disease Threats (FADT) subcommittee was established under the umbrella of the White House National Science and Technology Council (NSTC) Committee on Homeland and National Security with agriculture biosecurity experts and policymakers from 13 federal agencies. The FADT subcommittee published their recommendations in January 2007. They identified FMD, RVF, HPAI, and END as the top priority diseases for research and development efforts. The need for the US to better understand disease spread and economic models when formulating policy, preparedness strategies, and response plans led the subcommittee to call for the development of an animal disease Modeling Operations Center and Modeling Research Center. An interagency Joint Agroterror Defense Office with the goal of directing interagency cooperation and strategic planning was also proposed in the President's 2007 budget request. The FADT subcommittee specifically identified vaccination and immunomodulation technologies as well as disposal and decontamination as priorities for research (Marburger, 2007). The GAO reported in 2011 that USDA APHIS and DHS continued to co-lead this interagency effort. The NSTC also includes a Decontamination and Disposal Working Group (Miller, 2012a). As of December 2013, the Office of Science and Technology no longer includes an FADT subcommittee as a part of the NSTC and agriculture is minimally discussed in the National Biosurveillance Science and Technology Roadmap published by the NSTC in June 2013 (National Science and Technology Council [NSTC], 2013).

DHS Food and Agriculture Sector Coordinating Council

DHS has the responsibility for coordinating U.S. efforts to protect national key resources and critical infrastructure (Runge, 2006). DHS considers threats to agriculture in the catastrophic category, which indicates significant economic and social disruption (McCarthy, 2005). As a part of the National Infrastructure Protection Plan (NIPP), the DHS created a Food and Agriculture Sector Coordinating Council (FASCC) to facilitate communications with the food and agricultural industries (Brown et al., 2005; GAO, 2005; Manning et al., 2004). The FASCC is comprised of key stakeholders and includes subcouncils of agriculture production inputs and services, animal producers, plant producers, processors and manufacturers, restaurants and food service, retail and warehousing, and logistics. This council and other sector coordinating councils are to work with their government counterparts to coordinate and enhance the protection of national infrastructures. The FASCC has been successful and used as a model for other councils (Monke, 2007).

USDA

The USDA considers food and agriculture security central to their mission. In testimony before the U.S. Senate, Deputy Agriculture Secretary Chuck Connor (2005) stated, “We seek to provide leadership on food, agriculture, natural resources, and related issues founded on sound public policy, the best available science, and efficient management” (p. 5). He noted the critical nature of USDA partnerships with other federal agencies and state and local governments (Connor, 2005).

The USDA and other federal agencies are charged with developing management plans and protocols for responding to terrorism, including agroterrorism. The USDA structures its animal disease response into seven segments:

- Prepare (training, intergovernmental coordination, equipment development and acquisition);
- Prevent (surveillance, examinations, high activity);
- Detect/Identify (clinical symptoms, field tests, disease confirmation);
- Contain (movement restrictions, quarantines, seizure of animals);
- Depopulate (humane destruction of conformed inspected animals);
- Dispose (removal of infected carcasses); and
- Recover (reparation, close outs, follow up, monitoring, surveillance) (CDP, 2004; GAO, 2005).

Each of these segments is critically important and requires significant coordination, effort, and resources. The 2004 Center for Domestic Preparedness report notes “animal carcass disposal and upstream euthanasia activities are very problematic at best” (p. 18). The larger the incident, the more difficult the containment, eradication, and disposal will be (CDP, 2004). In the case of a disease outbreak, like FMD, the USDA is responsible for leading overall incident management but may ask for support from other federal agencies. If the outbreak leads to a

Presidential emergency or disaster declaration, or if the USDA Secretary requests it, DHS will take over coordination of federal resources (Animal and Plant Health Inspection Service [APHIS], 2012c).

USDA established a formal USDA Biosecurity Committee in 1999 and worked with the National Security Council (NSC) to establish a NSC subcommittee on the risk to agriculture and the food supply (Horn & Breeze, 2003). In response to September 11, the USDA established a Homeland Security Council, Office of Food Security and Emergency Preparedness, and a sub-council for the Protection of the Food Supply and Agriculture. This subcouncil was directed to establish policy, monitor progress, provide border surveillance, and address threats, rapid response, and other issues related to protection, safety, and security of the food supply. This office has evolved into the Emergency Management and Homeland Security Branch of APHIS' Emergency Management, Safety and Security Division. Their 2005 budget request targeted funds for the Food and Agriculture Defense Initiative. The Food Safety and Inspection Service (FSIS) established a Food Security Action Team to manage all activities related to biosecurity, food terrorism, and emergency preparedness (APHIS, 2012c).

Under 7 USC §8306, known as the Animal Health Protection Act and part of the 2002 Farm Bill, the U.S. Secretary of Agriculture and the USDA have the responsibility to detect, control, and eradicate any pest or disease of livestock and poultry. The Act increased the penalties for threats and attacks against agriculture and moved agricultural security and defense laws in a positive direction (Noah et al., 2002). In addition, the Secretary was given the authority to declare an extraordinary emergency in the case of an FAD, seize, quarantine, destroy, and dispose of infected or exposed livestock to prevent disease spread (Monke, 2007; Environmental Protection Agency [EPA], 2006; Department of Homeland Security [DHS], 2013b). The Secretary can stop interstate livestock movement and take any measures to identify, control, or eradicate any disease or pest (GAO, 2002a). In addition, the Act increased the penalties for threats and attacks against agriculture and moved agricultural security and defense laws in a positive direction (Noah et al., 2002). Specifics of these activities will be determined cooperatively through the Incident Command System (ICS) in cooperation with state and local authorities (Brown et al., 2005).

The USDA also established the Strategic Partnership Program Agroterrorism (SPPA) initiative, a public-private partnership program with DHS, FDA, and the FBI to assess security vulnerabilities in the food and agricultural industry. It was designed to create collaboration with state governments and private industry for the purposes of identifying sector-wide vulnerabilities to an agroterrorist attack and developing mitigation strategies (Crutchley et al., 2007; APHIS, 2012c).

In 2004, the National Association of State Departments of Agriculture (NASDA) developed a cooperative agreement with USDA, Food and Drug Administration (FDA), and DHS with the intent to integrate federal and state response plans for agriculture and food emergencies, develop response plan templates, conduct emergency exercises, and develop guidelines for coordination between state and federal authorities (Crutchley et al., 2007).

Other agencies involved

The law enforcement and intelligence communities developed two programs related to agriculture: the Food and Agriculture Information Sharing and Analysis Center, and AgGard. These programs encourage information sharing between industry, law enforcement, and the intelligence community (Manning et al., 2004; Brown et al., 2005, GAO, 2005; Monke, 2007). The U.S. government has expanded research efforts by opening new federal laboratories, enhancing existing facilities, expanding laboratory networks, and planning the replacement of the Plum Island Animal Disease Center with a new National Bio- and Agro-Defense Facility (NBAF) (Monke, 2007). In 2009, DHS announced the selection of Manhattan, Kansas, as the location for the NBAF. It is expected to be operational by 2018 (Jaax, 2011).

The increased growth in agricultural security and extended responsibility to multiple entities has led to more than 200 different government offices, seven cabinet-level departments, and hundreds of state and local agencies involved with animal and plant health. This led the National Academy of Science's National Research Council in 2005 to call for the creation of an animal health czar and program consolidation (Fabi, 2005). While such consolidation has not occurred, this situation highlights the need for well-organized policy efforts. Consumers and agricultural producers need government agencies at all levels to speak with one voice (McGinn, 2003b).

Federal budget

While additional consideration and concern about protecting the food supply and agricultural industry from intentional and accidental threats continued to grow, these areas did not receive prioritization in federal funding and budget appropriations. "Despite the immediate flurry of attention [to protect the food and agricultural industry] following Secretary Thompson's warning [in 2004], federal funding designated specifically for agriculture and food defense has remained limited" (Myers, 2006, p. 175). In 2006, actual spending on civilian biodefense neared $5.4 billion, and $249 million (4.8%) was spent by the USDA (Hennessy, 2008). From 2001 to 2007, USDA and DHS agriculture homeland security appropriations tripled (Monke, 2006).

In 2008, the federal budget proposal for 2009 included $8.01 billion in federal funding for civilian biodefense. The largest increase was in the HHS budget, which included a significant increase for food defense initiatives for the FDA. The second largest increase was for the USDA Food and Agriculture Defense Initiative, bringing the USDA share to 3% of non-military biodefense funding and increasing funding specifically targeted to food and agriculture defense by 47% from the previous year (Franco, 2008). However, when the budget passed Congress, funds dedicated to the Food and Agriculture Defense Initiative were not included, but USDA APHIS, FDA, and the DHS Science and Technology Directorate Agriculture Thrust Area received new budget line items (Franco & Sell, 2012).

The federal government has moved toward funding all-hazards preparedness rather than threat-specific programs over the last several years and funding for some critical programs has declined. The USDA fiscal year 2012 budget for biodefense had declined by 63% to $92 million or 2% of all civilian biodefense funding (Franco & Sell, 2012). In fiscal year 2013 and the proposed budget for fiscal year 2014, USDA biodefense funding remained constant, but the percentage of overall funding fell to less than 1% in 2014 due to an overall increase in biodefense funding almost all credited to the construction of NBAF, which is part of the DHS budget (Sell & Watson, 2013).

Overall, in comparing funding over the last 10 years, the percentage of Homeland Security funding allocated to the Food and Agriculture Sector declined from 1.2% to 0.8%, which reflects a decline in actual dollars by $2 million, while overall funding increased by $25 billion (Painter, 2012).

Preparedness and response plans and guidelines

Several tools have been developed to aid in preparedness, response, and recovery from an emergency situation. These resources can prove helpful in understanding the appropriate response to a food and agriculture biosecurity emergency situation.

National Infrastructure Protection Plan (NIPP)

The food and agriculture sector was defined as critical to U.S. security because it provides "essential goods and services Americans need to survive" (NIPP, 2007, p.11). Government and private industry share responsibility for protecting U.S. food and agriculture critical infrastructure and key resources (CIKR). CIKR includes systems, assets, and networks. An attack targeting using food and agriculture infrastructure and resources would be devastating. Traditional security measures will not be sufficient, and a protection plan must focus on planning and preparedness. The NIPP provides the structure for integrating existing and future CIKR protection efforts into one program. The cornerstone of NIPP is the risk management framework, and risk is defined as potential loss, damage, or disruption to CIKR due to intentional or natural destruction, incapacitation, or exploitation (NIPP, 2007; NIPP, 2010).

The 2007 version of the NIPP was comprised of Sector-Specific Plans (SSP) that are focused on individual industries, but they were combined into one comprehensive SSP in 2010 (NIPP, 2010). The Food and Agricultural (FA) Sector is defined as the supply chain for food, animals, and animal products; crop production and seed, fertilizer, and related supply chains; and the post-harvest components of the supply chain from processing, production, and packaging through storage, distribution, retail sales, food service, and restaurant or home consumption. The USDA and HHS/FDA were identified in HSPD-7 as the Sector-Specific Agencies for the FA sector. The sector provides unique challenges in its protection because of the extensive, open, interconnected, diverse, and complex nature of the industry. The mission of the sector is to: protect the food supply from any attack that would threaten public health, safety, welfare, or the national economy; and provide a central focus to this dynamic sector while emphasizing protection and strengthening the U.S. capacity to supply safe, nutritious, and affordable food (NIPP, 2007; NIPP, 2010). The objective of the FA sector is to ensure the security, resiliency, and rapid restoration of U.S. agriculture and food systems in the case of an all-hazards event. "The sector will provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management" (NIPP, 2010, p. 2).

National Response Framework (NRF)

The NRF provides guidance to how the US conducts all hazard responses. It prescribes best practices for local to large-scale events that are natural, accidental, or intentional, and it builds on the National Incident Management System (NIMS), which outlines templates for managing incidents. NIMS provides guidance to all levels of government, the private sector, and non-governmental organizations in working together to deal with incidents. The NRF was published in January 2008, and replaced the previous 2004 and 2006 versions of NRP and the Federal Response Plan developed in 1992. The NRF is an integrated part of the larger National Strategy for Homeland Security. It provides a framework for prevention and disruption of terrorist attacks, identifies response and recovery plans, strengthens the nation's foundation to ensure long-term success, and protects the American people, critical infrastructure, and key resources. The NRF focuses on the goals of response and recovery from incidents (DHS, 2008b; DHS, 2013b; APHIS, 2012c).

The NRF establishes the process needed to meet the National Preparedness Goals (the Goal):

- Prevention – To have the capabilities to avoid, prevent, or stop a threatened or actual act of terrorism;
- Protection – To have the capabilities to secure the country against intentional acts of terrorism and natural or manmade disasters;
- Mitigation – To have the capabilities required to reduce loss of life and property;
- Response – To have the capabilities to save lives, protect property and the environment, and meet basic human needs after an incident; and
- Recovery – To have the capabilities to assist communities to recover effectively that have been affected by an incident (DHS, 2013b).

In the NRF, the USDA is identified as the lead federal agency in managing a large-scale animal disease emergency. The NRF includes an Emergency Support Function (ESF #11) of Agriculture and Natural Resources (Brown et al., 2005; Monke, 2007; EPA, 2006; DHS, 2013a). ESF #11 provides for nutrition assistance in disaster areas, control and eradication of animal and plant pests and diseases (specifically highly contagious or economically significant diseases), assurance of food safety and security, protection of natural and cultural resources and historic properties, and provision for the safety and well-being of household pets during an emergency response or evacuation. ESF #11 must be activated by the Homeland Security Secretary in the case of a food- or agriculture-related event that requires a federal response. It calls for an integrated federal, state, tribal, and local response (DHS, 2008b; DHS, 2013b).

In the area of disease response, ESF #11 provides for response efforts to be conducted in collaboration with state and private industries to ensure human nutrition; animal, plant and environmental security; and the security of American economy and trade. Animal disease response efforts dictate that animal depopulation efforts should be as humane as possible, stop disease spread, and limit the number of animals euthanized. The disposal of infected or exposed carcasses should use the methods most effective in stopping disease spread and least environmentally damaging. Economic and cost considerations are not addressed. The USDA Secretary has authority to appropriate the funds necessary to aid in disease control. If states do not adequately address disease outbreaks within their borders, the USDA may take action in those states (DHS, 2013a).

The NRF also includes *incident annexes* to address specific hazards and describe relevant policies and procedures. While the NRF was approved and annexes were identified in 2004, the Food and Agriculture Incident Annex was the last annex published (Monke, 2007) and was not published until late 2006. The Food and Agriculture Incident Annex describes the role of USDA, HHS, DHS, EPA, and other cooperating agencies in responding to incidents involving food and agricultural systems. It outlines the actions, roles, and responsibilities of a response effort. A food and agriculture incident may threaten public health, animal nutrition, food and livestock production, wildlife, aquaculture, soils, rangelands, and water supplies (DHS, 2008a).

A food and agriculture disease outbreak would cross jurisdictions and ignore state borders. The consequences would be severe; overwhelm state, local, and tribal responses; and may significantly challenge federal response capabilities. No single entity can act unilaterally in the case of a food and agriculture incident. The primary functions of the Food and Agriculture Incident Annex are to:

- Support effective and coordinated communication between all levels of government and responders,
- Minimize public health and economic impacts of an incident,
- Specify roles and responsibilities of all federal agencies and departments, and
- Provide transition efforts from response to rapid discovery (DHS, 2008a).

The annex identifies key elements of an effective response including control, containment, decontamination, and disposal. It provides HHS and USDA with direction to embargo, detain, seize, recall, or condemn affected food, animals, or plants (the control function). These agencies, in conjunction with the EPA, will provide technical assistance to state and local authorities in the coordination of animal carcass, food, and plant disposal (the decontamination and disposal function) (DHS, 2008a).

In March 2012, as a result of the emphasis in PPD-8, Federal Emergency Management Agency (FEMA) released working documents for comment including the National Prevention Framework, the National Protection Framework, the National Mitigation Framework and the National Response Framework. These followed the release of the National Disaster Recovery Framework in late 2011 (Caudle, 2012). These documents were finalized by May 2013 and supersede the 2008 NRF (NRF, 2013b).

A response that deters, mitigates, or neutralizes the effect of an attack reduces the appeal of agriculture and food as a target and helps protect the food and agriculture sector. The NIPP provides the pre-event state of the preparedness and response continuum and the NRF provides the post-event state activity coordination. Protection efforts must make agriculture a less attractive target (NIPP, 2007; NIPP, 2010).

National Animal Health Emergency Management System (NAHEMS)

The USDA APHIS has developed National Animal Health Emergency Management System (NAHEMS) guidelines to deal with highly contagious diseases, disease spread, return to normalcy in the agriculture industry, and returning the US to disease-free status.

NAHEMS was developed from the lessons learned from previous outbreaks. Specifically, the following components were considered vital to be incorporated into a successful response:

- A state-federal-tribal unified response with a focus on local leadership;
- Clear and realistic goals set by unified command;
- A quick and certain response from unified command;
- Clear communication to and understanding from stakeholders and responders on guidelines, strategies, and procedures;
- Acknowledgement that a timely and successful outcome will require a rapid up-scale of resources and capability to manage competing interests;
- Rapid diagnosis and FAD traceback is critical;

- A science-based and risk-management approach that "protects public health and animal health, stabilizes animal agriculture, the food supply, and the economy" (National Animal Health Emergency Management System [NAHEMS], 2012, p. ii).

In response to these concerns, the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) was developed. Its mission is to "raise awareness, expectations, and develop capabilities" related to FAD response (NAHEMS, 2012, p. iii). Goals of FAD PReP are focused on integration, synchronization, and conflict minimization in preparedness and response capabilities through clear and specific goals, guidelines, strategies, and procedures. It is based on the principles and systems of the NRF and NIMS, which should work in conjunction with NAHEMS. FAD PReP is considered a comprehensive strategy for preparedness and response for local, state, federal and tribal response efforts (NAHEMS, 2012; APHIS, 2012b).

Three key response goals in the event of an FAD are to:

1. Detect, control, and contain the disease;
2. Eradicate the disease while stabilizing the agriculture industry, food supply, and economy, and protecting public health; and
3. Provide science- and risk-based approaches to disease response (NAHEMS, 2012; APHIS, 2012a).

The type of federal-state-tribal intervention in a disease outbreak could follow under several situational examples, including:

- Emergency eradication lasting 12 months or less,
- Extended emergency eradication lasting more than 12 months,
- National animal disease control programs for long term disease situations,
- Individual state or tribal disease control programs, and
- Animal disease monitoring that requires no intervention (APHIS, 2012a).

The target of the NAHEMS strategy is to eliminate the disease in four months or less. If the disease remains for more than 12 months, response strategies change from regional disease eradication to a national disease eradication program. Control of animal disease is based on three principles:

- Preventing contact between susceptible animals and the disease agent (requiring quarantine, movement control, biosecurity, risk assessment, epidemiologic investigation, animal tracing, and accelerated slaughter);
- Stopping the production of the disease agent by infected and exposed animals (requiring euthanasia and disposal); and
- Increasing animal resistance to disease (including strategic vaccination and antiviral prophylaxis) (NAHEMS, 2005b).

The principles and related goals are best achieved by a control and eradication strategy. The selection of the appropriate strategy depends on:

- Disease transmission characteristics,
- Consequences of a disease outbreak (national security, food security, public health, animal health, environment, economics, regulatory impacts),
- Social and political acceptance of strategy,
- Scale of disease outbreak,
- Rate of disease spread,
- Accessible veterinary countermeasures,
- Available resources, and
- Domestic animal and wildlife disease management capabilities (APHIS, 2012a).

If a foreign animal disease diagnostician (FADD) classifies a premises as *highly likely* to have a highly contagious FAD (versus *unlikely* or *possible*), local response measures begin. Once the disease has been designated a presumptive positive or confirmed positive case, state and national efforts begin. The designated zone areas will be determined by the disease in question. An infected zone is designated around all presumptive and confirmed cases with the boundary extended at least 3 km (approximately1.86 mi) beyond the infected premises. A buffer zone of at least an additional 7 km (approximately 4.35 mi) should also be identified. The infected zone and the buffer zone make up the control area, which should be an area no smaller than 10 km (approximately 6.2 mi) beyond the infected premises and may be larger, especially initially. These zone boundaries apply to FMD and most other FADs. Boundaries will be modified based on agent characteristics, livestock movements, animal concentration, weather, prevailing winds, wild animal populations, processing options, and other commodities (APHIS, 2012a; NAHEMS, 2005b). Some research has indicated that doubling the radius of designated infected and surveillance zones could reduce the disease outbreak by 48% and, if vaccination is used, will yield a significantly smaller epidemic (Bates, Thurmond, & Carpenter, 2003a; Dykes, 2010).

The NAHEMS/FAD PReP companion documents included specific guidelines addressing euthanasia, disposal, quarantine and movement control, and cleaning and disinfection (NAHEMS, 2005b). NAHEMS documents were updated beginning in 2011 and industry response plan manuals have been developed (NAHEMS, 2011a).

Critique of federal efforts

The effectiveness of the structure of agricultural security and defense efforts has received critical reviews. Even though the US has taken steps to improve the nation's ability to respond to intentional disease threats, the agriculture and food industry remains highly vulnerable (Crutchley et al., 2007).

In 2005, the GAO identified that the DHS role in agroterrorism was confusing and they failed to take the lead in executing HSPD-9. In 2007, this theme continued as the DHS Office of the Inspector General indicated the size of the food and agriculture industry, combined with the complexity of government agency oversight, created significant challenges in protecting food and agriculture critical infrastructure. They further noted that DHS, USDA, and HHS all failed to meet their obligations to develop an integrated food and agriculture defense plan. This led the GAO to designate the Federal oversight of food and agriculture safety and defense as high risk. The structure of 15 agencies with more than 30 laws results in a number of management problems that reduces efficiencies, creates inconsistencies in oversight, and leads to ineffective coordination and inefficient resource use (Langevin, 2007).

The Bi-Partisan Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism evaluated U.S. government performance in 17 areas and gave the White House and Congress an *F* in December 2009 for its efforts in developing response capabilities against a biological attack and emerging disease outbreaks. They concluded in their report that the margin of safety was shrinking rather than growing. In addition, the commission noted that any future attack was more likely to be biological than nuclear (Sherman, 2010; Jaax, 2011; States News Service, 2013).

The presidential administrative change in 2008 led to refined homeland security efforts. In May 2009, the president merged the Homeland Security Council and the National Security

Council into one national security staff based on the concept that all homeland security issues were national security issues (GAO, 2011). A DHS review in February 2010 resulted in the issuance of Presidential Policy Directive 8 – National Preparedness (PPD-8). PPD-8 reaffirmed previous policy and called for an increased focus on preparation at all levels of citizenry with attention to greatest risks and capability-based approaches. The goals listed natural animal disease outbreaks, human-caused biological attacks, and food contamination as national-level threats. The greatest threats were defined as known threats with a distinct beginning and end, which left agriculture with less emphasis (Caudle, 2012).

The National Research Council (NRC) found that the nation has inadequate plans to deal with agricultural bioterrorism and that greater coordination between agencies is needed. The NRC acknowledges that a rapid, timely, well-organized response is critical to controlling an outbreak. They called for a national, comprehensive plan involving all potential partners that integrates deterrence, prevention, detection, response, and recovery (NRC, 2002; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003; Monke, 2007). Interagency cooperation amongst state, federal, and international health, food, and agricultural entities is necessary and critical. In most emergency and emergency table-top exercises after-action reports, one of the most noted shortcomings is lack of interagency coordination. Failures to work together increase costs and delay or dismantle effective response efforts (Hugh-Jones & Brown, 2006). Major James P. Dykes evaluated current government laws and policy and found that they do not adequately address agroterrorism (Dykes, 2010).

In a U.S. Senate hearing in 2011, Colonel John Hoffman from the National Center for Food Protection and Defense identified gaps between agency authorities and capabilities, and the variability between all levels of government as barriers to an effective food defense system. He noted that the lack of a “single, coherent, clearly delineated line of authority over our Nation’s food defense efforts” continues to be a significant concern (Hoffman, 2011, p. 4). Dr. Paul Williams (2011) noted that animal health management had found its leadership at the state level and there was reluctance to provide the support and commitment at the federal level for agriculture defense that had been provided to general food safety efforts. He highlighted the six years it took to get any agriculture sites on the critical infrastructure list and that about 1% of State Homeland Security Grant funds go to the agriculture and food sector (Williams, 2011).

State departments of agriculture hold primary responsibility for initial protection, response, and recovery to animal and plant diseases and pests, and state regulatory and laboratory resources are critical to the US. One of the most underfunded aspects of the U.S. agriculture and food defense strategy is the states (Kennedy, 2007). According to interviews with multiple homeland security officials from state departments of agriculture, funding from Homeland Security for food and agriculture sector defense was declining and inconsistent and state agriculture agencies were typically not a funding priority (Blackwood, 2010). Nearly 80% of homeland security grants that are distributed to states are funneled to the local level where there is no authority for agriculture as there is with public health, fire, and emergency services (Blackwood, 2010; Kennedy, 2007). Overall, State Homeland Security Grant Program funds have declined from $863 million in 2008 to $355 million in 2013, a decrease of 59% (Federal Emergency Management Agency [FEMA], 2013). In Kansas, the largest annual allocation designated to agriculture was in 2005 for $370,000 and the lowest was $30,000 in 2012 (personal communication with Sandy Johnson, Kansas Department of Agriculture Emergency Coordinator). Regional partnerships that have been created by states to respond to the lack of coordination on the federal level have provided some success (Williams, 2011). Another funding shortage lies with actual farmers and ranchers. While federal agencies are better staffed, equipped, exercised, and trained, few funds and efforts have made it to the farm level for safety, biosecurity, and defense (Filson, 2007) and it is unlikely that federal funds would be used for these purposes.

The GAO found similar program deficiencies in 2011. The lack of centralized coordination in the implementation of the nation's food and agriculture defense policy under HSPD-9 was a significant concern. This could lead to more vulnerability and less confidence in the agriculture industry's ability to respond to a major animal health or crop disaster. The GAO found that since the 2009 merger of the Homeland Security Council and the National Security Council, there was no longer any effort by the Council or DHS to collect information about the coordination of HSPD-9 and that interest in the food and agriculture defense policy had decreased from agencies and the Council. No department-wide strategy for implementing HSPD-9 exists at the USDA level. Moreover, the GAO noted that specific agency responsibilities regarding critical response activities such as depopulation and disposal were unclear, and problems exist with the implementation of NVS (GAO, 2011). This lack of coordination has caused some analysts to call for a complete reorganization of the system and creation of a single entity with responsibility for food safety and agriculture defense (Elliot, 2009). "The United States faces complex challenges that limit the nation's ability to respond effectively to an agroterror attack, including management problems in federal agencies that inhibit the effectiveness of protections against agroterrorism" (Myers, 2006, p. 191).

Senators Pat Roberts (R-Kan.), Jerry Moran (R-Kan.), Roy Blunt (R-Mo.), and Claire McCaskill (D-Mo.) introduced a resolution in February 2013 to remind their colleagues that protecting the safety, security, and health of U.S. livestock and commodities cannot be forgotten and that addressing the critical vulnerabilities in the food and agricultural industry needs to be a priority. They specifically call for the necessary resources to advance laboratory capabilities, vaccine development, research infrastructure, and achieving goals related to biosecurity and agrodefense (States News Service, 2013).

It is interesting to note that the European Union (EU) has more than 400 individual animal health related legislative acts. EU officials have announced the intent to develop a single, comprehensive, animal health law to replace the highly complicated collections of laws and regulations. The goal is to have one, coordinated policy in place by 2016 that will reduce the risk of negative economic, social, and environmental impacts of animal disease outbreaks or animal health events (European Commission [EC], 2013a).

FMD as an example

FMD is a "perfect" example of a disease that could be easily introduced to create havoc. The US has been FMD free since 1929 (GAO, 2003; GAO, 2002a). The biggest outbreak occurred in 1914 when it started at the Chicago Stockyards, spread to a national dairy show, and infected 22 states, more than 3,500 herds, and 172,720 animals. The stockyards were closed for seven months (Hullinger, 2013). FMD exists in 60% of the world's nations and is endemic throughout much of Africa, the Middle East, Asia, and South America. North America, Australia, New Zealand, and the Caribbean are considered disease free (GAO, 2002a).

FMD is caused by a small RNA virus and exists in seven serotypes. While it does not directly threaten human health, FMD is the most contagious disease of cloven-hoofed mammals such as cattle, sheep, and swine, and often results in severe economic losses. The disease is characterized by vesicular lesions on the tongues and lips, and between the hooves, and is shed in large quantities from these lesions and the upper respiratory tract of infected animals. Clinical signs range from mild to severe with possible fatalities among young animals. While most adult animals recover, they are left debilitated and with severe losses in regard to milk and meat production. It is easy to intentionally spread because the virus is extremely stable. It can survive on clothing, manure, soil, or straw for up to a month, can spread over 60 mi on the wind, and has an incubation period of 2 to 14 days. FMD spreads easily by direct contact between animals and through indirect transmission by fomites. It is considered 20 times more infectious than smallpox. An outbreak of FMD would require mass slaughter and disposal of millions of animals. Confirmation of the disease would immediately halt trade (Knowles et al., 2005; APHIS, 2002; GAO, 2002a). In addition, vaccination has not previously been considered an effective deterrent (APHIS, 2002; Wheelis, Casagrande, and Madden, 2002; Casagrande, 2002).

Virus transmission and response to vaccination differs between species. Cattle are highly susceptible to infection and are likely to show clinical signs but can also serve as potential disease carriers. Sheep can also serve as carriers and are less likely to show clinical symptoms. Swine are less likely to become infected but exhibit the most significant virus excretion. Vaccination is more likely to be effective on cattle and sheep than on swine (Backer, Bergevoet, et al., 2009).

FMD is “the most dangerous foreign disease” that could occur either inadvertently or intentionally in the US (Breeze, 2004, p. 251). Because meat and dairy products can also be infected, movement restrictions would apply to food products as well (McGinn, 2003b).

United Kingdom

Though the 2001 FMD outbreak in the UK was not caused by intentional introduction, it still serves as an example of the impact of a large-scale animal disease outbreak. The U.K. epidemic lasted 32 weeks, affected 44 counties, and infected more than 2,000 premises. The sheep, swine, and cattle industries were affected. More than six million animals were slaughtered, and the extent of the fiscal burden exceeded $14.5 billion (National Audit Office [NAO], 2002; Thomas, 2002). The government was shaken, national elections were postponed, and the food and agriculture governance system was restructured (Owens, 2002; Manning et al., 2002).

The UK found their contingency plans were not sufficient. The lessons learned from this experience called for increased surveillance, contingency plans with training, crisis management exercises, and decreased livestock vulnerability to minimize the impact of an outbreak. Post-outbreak evaluation found that decision-making analysis should be applied, policy decisions should be based on sound science, and an appropriate legislative and regulatory framework needed to be in place. If the policies and procedures are explained to all stakeholders before an outbreak, all players would be able to respond with greater certainty and speed to lower the negative impact of disease (Anderson, 2002; NAO, 2002).

In August 2007, the presence of FMD in Surrey was confirmed and the DEFRA response plan was initiated. An immediate national livestock stop-movement ban was implemented and infected and surveillance zones were established. It was determined the disease was caused through a leak from drainage pipes at the Pirbright Institute for Animal Health. Only two cases occurred (both within 10-km zone) in the 36 days before control measures were removed. Four days later another case was reported and control measures were re-established. In this period, six cases occurred before the restrictions were removed 3 months and three weeks later. DEFRA reacted with more speed and certainty, but confusion still existed over some aspects of the policy response (Anderson, 2008).

Taiwan

In Taiwan's most recent outbreak, the first two cases of FMD were reported on March 14, 1997. Within two weeks, 1,300 pigs in 15 western prefectures were infected, demonstrating how rapidly this disease can spread. This outbreak resulted in the loss of principal export markets, the elimination of 65,000 jobs, and a decrease in price of more than 60% in one week. Four million pigs accounting for 40% of the swine population were slaughtered, and direct costs were estimated at $379 million with an additional economic loss of more than $1.5 billion in lost trade (Ban, 2000; Carpenter, 2011).

Japan

An FMD outbreak occurred in Japan in 2000. In that case, culling and movement control strategies were implemented and Japan regained FMD-free status later the same year (Sugiura et al., 2001). FMD was detected again in 2010 in Miyazaki, Japan. Nearly 300,000 animals were infected and depopulated (Ontario Livestock and Poultry Council [OLPC], 2012; Muroga et al., 2012). A publicly owned seed bull farm that provided 90% of sperm used for cattle production in the prefecture was infected resulting in at least 5 years damage to the cattle industry (Nishiura

& Omori, 2010). The infection was believed to have occurred due to accidental introduction though contaminated people or goods from a nearby country. A combination of culling and vaccination-to-cull was utilized as burial locations were difficult to identify (OLPC, 2012; Muroga et al., 2012).

Movement controls were not taken seriously by local governments and individuals. As an example, unemployed workers spread the disease by traveling from the infected zone to other farms in new areas. Animals were transported over significant distances, which also spread the disease. The trucking and tourism industry were significantly impacted (OLPC, 2012). Officials estimated that recovery will take five years and the economic impact will exceed $3.5 billion. Japan did not receive FMD-free status until late summer 2012 (SES, Inc., 2012).

Paraguay

The Paraguay outbreak of FMD in 2011, the first outbreak in that country since 2002, caused significant concern for this region that is famous for their beef industry, especially due to the immediate trade restrictions implemented by countries such as Brazil. Officials quickly moved to destroy all exposed cattle so trading partners would see that the government was committed to ending the outbreak (Olazar, 2011).

South Korea

In late 2010, there was a significant outbreak of FMD in South Korea that extended into 2011. It is hypothesized that the disease was introduced by a Chinese or Mongolian laborer who was given a package of work clothes infected with FMD. More than 3.5 million cows and pigs were slaughtered, which represented 20% of the nation’s livestock. Production economic losses neared $3 billion (SES, Inc., 2012; Glionna, 2011; Ahn, 2012). Estimates indicate that costs exceeded $1.25 million per hour in outbreak response in South Korea, a country about the same size as the state of Indiana (Wide Area Recovery and Resiliency Program [WARRP], 2012).

U.S. FMD Response

Because of its large agricultural industries, the US is vulnerable to a disease outbreak or bioterrorist attack introducing an FAD, especially FMD. Such a situation would result in severe consequences. An intentional attack or accidental introduction of FMD in the US would have far-reaching effects and would extend to multiple sectors of society. The response to FMD must be well-thought out and highly coordinated amongst all stakeholders. Adequate infrastructure must be in place. Quick identification, control, slaughter, disposal, and indemnification policies must be in place (GAO, 2002a).

Historic U.S. FMD federal response policies called for prompt animal depopulation and disposal, and many states' regulations continue to dictate that all carcasses be buried within 24 hr. Such approaches create more mortalities than can be handled and indicates the need to consider vaccination. A balanced FMD response strategy would detect, contain, and control the disease quickly; stamp out FMD while stabilizing and protecting the economy, food supply, and public health; and provide science-based, risk-based approaches and systems that allow the continuation of commerce (Styles, 2011; Miller, 2012b; APHIS, 2012c).

For example, the traditional response to FMD requires immediate slaughter of all infected, exposed, and potentially exposed animals of susceptible species. A timely approach can stop the spread of disease, but the outbreak may have already spread over multiple states if not quickly identified. USDA officials estimated that an FMD epidemic in the US could spread to 25 states in five days or 35 states in 10 days. A National Defense University exercise predicted that FMD could spread to more than one third of the nation's cattle herds. Dr. Tom McGinn (2003a) projected the spread to 23 states before disease identification and 29 states by day eight. His projections called for the estimated destruction of 23 million animals. Another government table-top exercise resulted in 38 million cattle depopulated. These estimates emphasize the critical importance of rapid identification (GAO, 2003; Foxell, 2003; Dupont, 2003; Reardon, 2005).

Until recently, vaccination was not considered a part of a likely response plan. USDA APHIS now recognizes effective and appropriate disposal procedures, mass depopulation and euthanasia, and emergency vaccination as critical activities and tools for disease containment, control measures, and eradication. Efforts should focus on preventing contact between infected and susceptible animals, stopping virus production and reducing virus shedding in infected or exposed animals, which increases disease resistance of susceptible animals. Current strategies include both stamping out and vaccination protocols (APHIS, 2012c; Zack, 2013).

It would be difficult to meet disease containment goals in the defined timelines, which indicates that the modern challenges dictated by FMD require a new approach and further policy research. Minimizing depopulation and disposal will allow greater protection for the environment and food supply. It has been suggested a more sustainable approach would be to reduce stamping out, reuse animal products after vaccination, and recycle through rendering, landfilling, and composting (Styles, 2011; Miller, 2012b).

Policy Needs

Agroterrorism and FAD incidents pose significant, diverse, and complex problems. The size and breadth of U.S. agriculture, the simplicity of perpetrating an attack, and the diversity of the potential threats and perpetrators make complete prevention of an agroterrorism attack unlikely. Many unintentional events would have similar economic, social, and political effects. Therefore, policy responses to an agroterrorist event should be designed to limit the damage efficiently and effectively (Casagrande, 2000). The policies and procedures designed to guard against deliberate or incidental harm to an agricultural or food facility are known as food and agricultural biosecurity, agrosecurity, or agricultural defense (Brown et al., 2005, p. 4).

U.S. plans and policies

The ability of the US to quickly and effectively respond to an attack is a serious, continuing challenge. There are four areas where challenges remain:

- the need for rapid disease identification and reporting;
- effective communication, coordination, and cooperation;
- adequate response infrastructure and capacity;
- and a clear animal identification, indemnification, and disposal policy (GAO, 2002a).

The US can no longer consider an attack on the agricultural system as hypothetical; "hoping and complacency" cannot be considered an option (Applebaum, 2004, p. 49). The NRC (2002) acknowledged there are no easy answers (Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003). Being prepared for an attack provides the foundation needed to be prepared for an accidental occurrence (Brown, 2006). These are complex situations that call for multidisciplinary responses.

The current decision-making system is ambiguous. According to Franz (2005a), the US does "not have the validated intervention strategies that could be applied to our food production, processing, and distribution systems once an event has occurred. Existing strategies could make the problems worse" (p. 1). Government responses or policies that are short-sighted or obstructionist, such as limited surveillance or animal identification, can increase the negative impact of an FAD outbreak (Ackerman, 2006). Day-to-day decisions would be made using decision-trees that may be cumbersome and complicated (Segarra, 2001; Monke, 2007). Kastner, Sargeant, and Kastner (2005) concluded that such food and agriculture security strategies "must blend insights from multiple academic disciplines" and "by sewing together research from the fields of microbiology, sociology, economics, et cetera – indeed the list does and should go on" (p. 1).

For example, the WHO developed policy recommendations for dealing with an attack on food and calls for member nations to have systems in place for preparation, alert, and response that minimize public health risks from real or suspected agroterrorism. Their recommendations are focused strictly on public health and post-harvest food products. The WHO does not address an attack on livestock or crops (World Health Organization [WHO], 2002).

A working group on governance dilemmas identified the challenges faced by leaders and decision makers in dealing with a bioterrorism attack. While their focus was not on food and agricultural biosecurity, their findings still apply. The issues identified as high-stakes decisions are the inability to plan for every contingency; a pervasive uncertainty about the situation and response; unpredictable, rapid, and far-reaching impacts; scarcity of resources; practical difficulties of disease containment; and the impulse to avoid, stigmatize, and blame others triggered by fear and loss. Additional dilemmas relate to social trust, mutual confidence, and obligations amongst decision makers and other players. These factors are further complicated by instituting quarantine and movement orders while respecting individual freedoms, stabilizing the economy while disrupting commerce, restoring social confidence in the food supply, communicating in a crisis with creating chaos, using scarce resources fairly, maintaining credibility when decisions have to be made with limited information, and managing the situation with multiple jurisdictions involved (Schoch-Spana, 2004).

In order to meet these challenges, decision makers responsible for the development of food and agricultural security policy must integrate animal health, disease control, animal welfare, public health, economic impact, environmental impact, regulatory issues, logistical issues, physical security, geography, trade and border issues, public perception, risk communication, social and psychological impacts, emergency management, historical perspectives, and political realities.

Multidisciplinary policy approach and decision making

Government agencies and legislative bodies are faced with multiple policy questions related to threats against livestock and crops. The issues range from prevention to emergency response to producer compensation. To be sound and effective, the policy approach must be inter- and multidisciplinary. The goal in policy development should be to represent the entirety of the agricultural industry while providing useful information to policymakers. Policy decisions need to be made “quickly under challenging and changing circumstances” (Hayes, 2010, p. 3).

The OIE member countries have recognized that animal-related defense and protection is a “complex, multi-faceted public policy issue which includes important scientific, ethical, economic and political dimensions” and requires detailed vision and strategy that balances these issues (OIE, 2002, p. 1). It is also important to note that diseases that impact plants and animals result in significant reductions in food production that result in a threat to global food security (National Science Foundation [NSF], 2012).

Policies should focus on characterizing the biological and physical factors leading to disease spread, defining the likely scope, identifying economic and geophysical factors contributing to the spread, and developing a specific strategy for the outbreak. This approach allows emergency responders to “balance competing resources within a sound framework for decision making” (Heath, 2012, p. 61). This philosophy, combined with research focused on disease control strategies that are humane, economical, and that protect the environment and trade, will create better responses and more rapid decision making. For example, this may lead decision makers to determine when to depopulate, when to vaccinate, and when to let the disease become endemic. A “scorched earth” approach may not always be the most economical or the most humane (Heath, 2012, p. 61).

“The time has come for the animal and public health professions to enter into a debate on the socio-political impacts of the regulations and standards of disease control and to pursue policies that apply biological sciences to overcome the predicament of the 21st Century” (Heath, 2006, p. 417). Policy and decision makers need knowledge and communication to understand the situation and the resource needs in order to develop response strategies (Crnic, 2010). The public expects leaders to make decisions and take immediate action to address emergency situations (Myers, 2006).

The challenge is in balancing science and policy. Disease outbreaks should be scientific events rather than political stories, which is a lesson that can be learned from the U.K. FMD publicity. There is a natural conflict between science-based problem solving and policy development. If recommendations can integrate disciplines, then the policy will be more effective. Sound policy should be interdependent between economic, scientific, social, and political issues. As noted in a white paper published by the Council for Agriculture Science and Technology (CAST), scientific knowledge, political values, and cultural values are "imperfectly known and imperfectly separable" (Pearson & Salmon, 2005, p. 10). Moreover, the "decision making is often undertaken under the dim light of new and still-unfolding science" (Kastner, 2011, p. 2).

Many of the agrosecurity policy prescriptions in place – such as mass euthanasia, depopulation, and emergency vaccination – are expensive, resource-intensive, cumbersome, and time-consuming to implement. A coordinated strategy and strong leadership is needed to address all policies and procedures from prevention to casualty management. These policies require producers, consumers, government officials, processors, law enforcement, regulators, transporters, and others to reach consensus (Foxell, 2003). Policymakers must be attuned to these and other issues related to dealing with an FAD. Horn and Breeze (1999) stated that, "Current policies, procedures, and practices for epidemic pest and pathogen control must be reviewed paying special attention to changed public and media attitudes toward animal welfare, environmental quality, federal and state regulation, and the scientific bases for public policy" (p. 15). Policies must deal with the response and recovery while preserving freedom and an open society (Koo & Mattson, 2002). Policy and decision makers should be trained in economic analysis in order to understand the tradeoffs between strategies. Decision-making frameworks should be based on economic and risk-related principles (Jin et al., 2009). The dynamic nature of these decision processes and the globalization of the food and agriculture industry require leaders to take a multidisciplinary approach to policy development (Kastner, 2011).

Scientific, epidemiological, environmental, societal, international, and economic considerations, as well as agriculture's interdependence with society, should influence policy development (Evans, 2007). Policymakers need to understand the economic importance of agricultural security as they decide how to allocate efforts and resources. The US must understand the economic costs and benefits of interventions that allow the production system to return to normalcy (McGinn, 2003a). It is critical to have policies and procedures that allow for a quick and effective response that protects the agricultural industry and the U.S. economy (Huff, Meilke, & Turvey, 2003). However, these policy decisions are not simple or clear.

Policy development exists in a context of uncertainty and results are evaluated with scrutiny. Policymakers must base decisions on imperfect knowledge in complex situations. Science-based information and economic efficiency can narrow the scope of those decisions, but other factors must be considered. Decision makers must evaluate outcomes and choose policies to achieve the most desired outcome (Spradlin, 1997; Cahn, 2002; National Center for Environmental Decision Making Research [NCEDR], 2002). Decisions must be made rapidly based on available information and those decisions must be conveyed quickly and accurately to those who will implement the decisions (Geering, Roeder, & Obi, 1999). Uncertainty must not result in a lack of action or decision. Decision processes must be robust enough to function under these demands with sufficient timeliness (Dunn, Pollard, & Castinel, 2010).

Some believe that current procedures of mass depopulation and disposal during an FAD outbreak are archaic and outdated. In fact, some experts believe that the methods for containing an FAD – highly visible and expensive slaughter and disposal –increase the incentive for terrorists (GAO, 2005). As the world becomes more epidemiologically globalized, social values change regarding management of animal populations, and environmental concerns grow, new socially accepted responses must be considered (Evans, 2007). Breeze (2004) stated: "It will be the U.S. government, not a terrorist gang that is killing, burning, filling mass graves, and wreaking economic havoc nationwide" (p. 251). Damage can come from the government response, not just the disease itself. Poorly developed policies and procedures can be harmful, even causing the harm they were designed to prevent (Nipp, 2004).

"Whether a biological emergency turns into a disaster depends on how the government and the private sectors of the livestock industry react with regard to control and possible eradication of the disease outbreak" (Rushton & Upton, 2006, p. 375). The policy priorities range from minimizing economic impact while eliminating mass slaughter, to stamping out the disease and protecting international trade agreements. The US cannot choose if there is an unintentional or deliberate FMD outbreak, but the government can choose how to respond, which depends on national policy, preparedness, and the actions of first responders (Breeze, 2004). An underreaction can expand and extend the impact of the emergency and overreaction can lead to greater damage than the disease and control measures alone (Rushton & Upton, 2006).

The policy response will have a direct influence on the long-term impact of an attack or unintentional outbreak. Policy actions and resulting investments may lower industry vulnerability (Carpenter, 2011). Government policy should allocate resources with the goal of minimizing the overall cost to society (Hennessy, 2008). Any delays in action allow for disease spread, greater economic damage, and decreased public confidence (NRC, 2002; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003). Myers (2006) argued that the ability to respond quickly will be "directly proportional to the economic loss for the specific agricultural commodity" (p.191). Mitigation response strategies for an attack or unintentional outbreak need to be refined and developed (Jaax, 2002).

The existing challenges related to preparing for and responding to food and agricultural biosecurity threats are not due to a "lack of technology, but a failure of public policy" (Breeze, 2006, p. 272). The most devastating impacts in the case of an outbreak are likely to come as a result of the policy response. The policy response should not be focused solely on the domestic agricultural impact, but the international impact on trade, economic development, poverty, environment, public health, animal welfare, and wildlife conservation. The potential consequences will continue to grow as the food and agricultural industry increases in complexity and globalization. Yet, stakeholders and policymakers have little motivation to truly prepare for uncertain events that do not have political constituencies when current policy issues do. Policy must not only be driven by science-based information, but policy must be led by bold visions and must drive science and research. Strong policy and preparedness efforts will eliminate the vulnerability of agriculture and lessen the likelihood of an intentional attack or naturally-occurring outbreak (Breeze, 2006).

Planning and preparedness efforts

Policies, procedures, and regulations should ensure that the livestock industry is well-prepared to resist or minimize the effect of an attack. Effective policy and programs, along with a prepared society, are the best deterrents to an intentional attack (Kelly et al., 2004; Franz, 2005b). It is critical that all response plans encourage cooperation between state, local, and federal authorities, and that all levels of government are prepared. If the industry and government are prepared, terrorists are less likely to attack because their success becomes less likely (Leviten & Olexa, 2003; Brown et al., 2005).

Planning for a response and allocating scarce resources is more difficult when the probability of an incident remains controversial. Risk may be over emphasized or too much weight may be placed on past occurrences or lack of past history. Government policymakers can make systematic failures individually and collectively. In the case of food and agricultural defense, a conflict also arises because biosecurity is provided at many levels of government, but has centralized decision making. Agriculture, however, is decentralized and centralized decision making is difficult or impossible. Significant resources are needed to respond effectively. Quickly mobilizing resources can be difficult in a free society when tradeoffs are being made between individual rights and social good. Sacrifices will be necessary. A disease response is a "classic case of a public good" clarifying the critical role of government to take responsibility for the response efforts (Hennessy, 2008, p. 69). The 5th and Final Report of the Gilmore Commission (2003) called for clear processes that engage academics, business, all levels of government, and other stakeholders to develop and implement research to develop standards across many areas, including public policy. The American political cycle focuses decision makers on the near future, but policies to combat bioterrorism need to be institutionalized (Gilmore, 2003). This is also true of policies related to accidental and natural outbreaks.

Policies designed to respond to an FAD require "careful planning and diligent preparedness efforts" (APHIS, 2012b, p. v). Because interstate commerce and international trade will both be disrupted, the policies must ensure that the processes are rapidly deployable, scalable, and flexible. Conflicting interests and competing priorities that exist between stakeholders must be addressed. Science-based and risk-management approaches that are intended to protect food supply, stabilize the US economy, ensure public and animal health, and safeguard animal agriculture are necessary (APHIS, 2012b).

Federal, state, and local statutory authorities and responsibilities must be complementary in order for policy to be implemented effectively. Often, this may be complicated in cases where federal and state interests do not coincide. Stop-movement orders require the cooperation of multiple states. Local and state resources will be quickly exhausted on quarantine and remediation efforts, and a timely, synergistic response requires multi-agency exercises (Dykes, 2010).

Industry role

This situation is especially difficult for the agricultural industry to understand. Pearson and Salmon (2005) observed that, “Although some people may wish to avoid the world of politics – it needs to be appreciated and mastered by animal agriculture because it often reflects public opinion and human behavior….The animal agriculture industry needs to be better connected to the world around it and acquire a new cultural competence and political acumen to continue to be successful” (p. 10).

Industry collaboration is critical to the successful implementation of any policy response. Joint decision making and cost-sharing between government and industry representatives may need to be considered (Hayes, 2010). In addition, industry leaders need to balance all factors when responding to government policy proposals and government leaders need to better communicate policy alternatives and consequences to stakeholders. For example, policy proposals such as animal identification and traceability could aid in critical bioterrorism prevention and response mechanisms, but industry debate on these types of policies has traditionally focused on government overreach and concern over privacy of information, not the potential of a disease response tool. Government leaders and industry representatives have failed to reach agreement and farmers and ranchers have resisted implementation of such tools (Breeze, 2006; Gilpen et al., 2009).

In emergency situations, industry leaders should serve as potential consultants to the decision process and communication partners when dealing with farmers, ranchers, and the general public. However, clarification needs to exist in the role industry leaders play in advising policy decisions but not necessarily making the final policy decisions.

Expectations of the public

Policymakers and the agricultural industry may now better realize the importance of food and agricultural defense, but little is known about how consumers view agricultural biosecurity. A 2005 study conducted by the National Center for Food Protection and Defense indicated that consumers believe terrorism against the food supply is less likely than other threats, but that it deserves greater consideration. When asked to prioritize protecting the food supply, it was the number one priority on their list. It ranked above airlines, power grids, public transportation, and monuments. More than two thirds of respondents were *confident* or *very confident* their food supply was safe, but 62% were either *not very* or *not at all confident* the food supply was safe from terrorism (Stinson, Kinsey, Degeneffe, & Ghosh, 2007). Seventy-seven percent of consumers thought an act of food-related terrorism will occur in their lifetime (Dettmann & Stinson, 2006). Consumers consider the government to be the most responsible for protecting the food supply and funding food defense activities (Lorenzen et al., 2009).

The mechanics of dealing with an outbreak could also generate significant criticism from the public. Developing a response that is politically acceptable will be challenging when plans include culling and disposal. Even though depopulation is scientifically justifiable, the culling of a large number of animals, especially those not showing disease, will be controversial and will likely draw severe opposition. Mass burial or burning is likely to be just as contentious as mass euthanasia of exposed animals (Chalk, 2003; Chalk, 2004). Consumer reaction and public confidence in the government will be tested depending on the size of the outbreak and the eradication and destruction methods. As noted by Monke (2006), "The need to slaughter perhaps hundreds or thousands of cattle (or tens of millions of poultry) could generate public criticism if depopulation methods are considered inhumane or the destruction of carcasses is questioned environmentally" (p. 9). Of all response activities, mass eradication will be the most challenging and politically sensitive.

Public opposition has been a factor in previous cases, such as the mass slaughter and disposal during the FMD outbreak in the UK; the removal of millions of chicken carcasses in British Columbia, Canada, in 2004; and the use of wood chippers to dispatch chickens in California. In a case in Florida, the public debate and complaints from residents brought a judicial ruling that halted the removal of trees within a certain perimeter to stop the spread of citrus canker. It took 18 months and passage of a new state law before the injunction was lifted. By then, the infection was rampant (Monke, 2007; Hennessy, 2008). If the public is that upset about trees, the reaction to the destruction of live, uninfected animals may be more disruptive than previously considered.

Societal reaction to disease control, specifically mass depopulation, will likely fall into one of six categories:

- Waste of animal proteins when global food insecurity exists,
- Environmental damage due to carcass disposal,
- Natural aversion to mass animal killing of potentially healthy animals,

- Ability to depopulate large numbers of animals humanely,
- Animal suffering due to movement restrictions (Whiting, 2003; Swallow, 2012), and
- Psychological impact on farmers and ranchers (Swallow, 2012).

All alternatives need to be considered in the development of mass slaughter and carcass disposal policies (Monke, 2007).

Policy analysis

There are multiple approaches to policy analysis. Possible tools include:

- Cost-benefit analysis – a systematic means to enumerate all costs and benefits that applies dollar values to indirect and direct costs;
- Risk-based analysis – considers all related risks;
- Cost-effectiveness analysis – attempts to meet goals and objectives at the lowest costs;
- Decision analysis – structured consideration of alternatives typically using constructed models;
- Matrix analysis – uses a scoring system to compare alternatives;
- Case study analysis – use real life situations to compare possible policy alternatives;
- Focus group analysis – gather opinions and reactions to policy options; and
- Panel/rule-making approach – balance expertise to determine best policy (Spradlin, 1997; Cahn, 2002; NCEDR, 2002).

The goal of this dissertation is to investigate these agricultural security policy development challenges and apply various policy evaluation tools to three agricultural biosecurity dilemmas: euthanasia and welfare conditions in a large-scale animal disease outbreak, carcass disposal in a large-scale animal disease outbreak, and use of vaccination in a large-scale animal disease outbreak.

Euthanasia and Welfare Dilemma

Chalk (2004) said that containing a major animal disease outbreak would “necessitate the slaughter of hundreds of thousands of animals” (p. 8). Depopulation has been “a fundamental approach of veterinary and regulatory interventions for the effective biological containment and eradication of contagious diseases since the science and art of veterinary medicine began" (Evans, 2007, p. 201). However, a stamping-out approach, while typically effective at disease control and eradication, can lead to significant animal destruction, economic losses, environmental impacts, farmer and rancher psychological distress, negative societal reaction, waste of valuable protein, and animal welfare concerns (Willis, 2007).

In the case of FMD, current U.S. policy identifies an infected zone with a 3-km (approximately 1.86 mi) radius from the infected premises. It is expected that all infected and exposed animals within that zone will be slaughtered and disposed of by approved methods. Previously, it was required that all animals within a 6-mi zone would be depopulated (APHIS, 2010; APHIS, 2012c). State animal health officials and/or the USDA would wait for disease confirmation before beginning the slaughter process to avoid unnecessary panic (Knowles, 2005). If the disease spreads beyond the initial zone, quarantine and slaughter would continue until the disease is eliminated. This approach, when tested in the USDA's *Crimson Sky* test exercise, necessitated the slaughter of 38 million animals (GAO, 2005; Breeze, 2004). Many concerns were realized in the *Crimson Sky* exercise. The entire National Guard and the military were engaged in the response and ran out of ammunition in their depopulation efforts. PETA appeared on television to oppose the mass slaughter. All consequences had policymakers questioning mass depopulation and vaccine policies (Roberts, 2005).

The OIE notes that mass culling and destruction of animals often produce vehement public reactions. Owners of animals, other producers fearful of disease spread, animal welfare advocates, general public influenced by media photos and coverage, environmental organizations, and human rights advocates who see culling as a waste of edible food can all be expected to express their concerns (OIE, 2005). Problems that could lead to an animal welfare crisis within a crisis need to be identified. The emergency response should not be seen by stakeholders as more harmful than the disease outbreak itself (Zack, 2013).

If mass depopulation strategies are implemented, animals should be destroyed effectively and rapidly with as much emphasis given to animal welfare as the extenuating circumstances make practical (APHIS, 2012c). Slaughter, culling, and euthanasia policies will have significant welfare implications in an FAD outbreak or disaster. In an FAD outbreak, the eradication of the disease itself has welfare benefits by preventing suffering to potentially infected animals. Euthanasia alleviates suffering of affected animals, but may cause additional stress and suffering to potentially infected animals (Williams & Sheesley, 2002). The euthanization of large numbers of animals is likely to generate vigorous opposition from the public, as well as producers and animal rights activists. This opposition is likely to be even stronger when susceptible but non-symptomatic herds are depopulated (Chalk, 2004).

Some states, such as Illinois, cannot euthanize or dispose of animals without a cumbersome, lengthy process. They would need the federal government to declare an emergency to implement expected disease eradication efforts (O'Keefe, 2003). Compensation for destroyed animals, while originally implemented to encourage disease reporting, may also lead to a reduced incentive to farmers and ranchers to engage in disease control practices (Breeze, 2006).

The depopulation of animals for disease control or animal welfare is a complex issue and deserves significant investigation. The differences between a disease outbreak and a natural disaster add to the complexity and the need for further consideration of depopulation methods. Animal dispatch for welfare and disease control in the U.K. FMD outbreak caused great concern and has been vigorously discussed. The FAWC (2002) stated that "A balance must be struck between disease control and welfare, but welfare must not be set aside even in an emergency" (p. 9).

Animal welfare is often evaluated by the well-established *Five Freedoms*, a series of propositions encompassing an animal's basic needs. These freedoms are:

- Freedom from hunger and thirst by access to fresh water and diet to maintain full health;
- Freedom from discomfort by provision of an appropriate environment, shelter, and a resting area;
- Freedom from pain, injury, and disease by rapid diagnosis and treatment (or euthanasia);
- Freedom to express normal behavior by provision of sufficient space, facilities, and fellow species; and
- Freedom from fear and distress by ensuring conditions which avoid suffering (Farm Animal Welfare Council [FAWC], 2002).

These freedoms can guide the evaluation of animal welfare conditions during a large animal disease outbreak or disaster. Specific animal welfare issues that deserve future discussion include:

- Current policies and regulations related to depopulation and euthanasia at local, state, and federal levels;
- Technologies available for the euthanasia of animals for disease control or animal welfare;
- Current emergency vaccination policies and their relationship to the destruction of animals for animal disease control and welfare;
- Impact of different euthanasia technologies on animal welfare and animal behavior;
- Primary issues related to these technologies and their relationship to transportation and movement, disposal, economic impact, environmental effect, public relations, public health, and related industries; and
- Impact of certain mass destruction methods, laws, and policies on animal producers or caretakers.

In the case of a large-scale animal disease outbreak, when producers and consumers are already shaken, the mass depopulation of animals will be scrutinized by the public and the press. This has been evident in every major case of animal disease, from groups opposing mass slaughter to farmers fearing the loss of livelihood (Segarra, 2001).

Media coverage of any outbreak, especially a deliberate attack, will be substantial. Americans will see firsthand the impact of mass depopulation procedures and are likely to react negatively (Chalk, 2004). Previous mass euthanasia incidents, such as in the case of AI in California poultry flocks, received little coverage until there was evidence of wood chippers being used for animal depopulation (United Poultry Concerns [UPC], 2003). In South Korea, multiple news sources obtained photos and videos of live pigs being piled in trucks and buried alive in mass graves. Reports indicated that the government ran out of the neuromuscular drug used for euthanasia (Glionna, 2011; People for the Ethical Treatment of Animals [PETA], 2011).

The mass eradication techniques used in the UK to deal with the FMD outbreak received significant criticism. Many believed the government overreacted. One commentator, Simon Jenkins, exemplified the view of many in the public with his article, “This Wretched Cult of Blood and Money,” in *The Times* newspaper: “…Nothing in the entire history of the common agriculture policy has been so crazy. The slaughter is not declining but running at 80,000 a day…At the last estimate, 95% of three to four million animals dead or awaiting death…The obscenity of the policy is said to be irrelevant because of its success" (Chalk, 2004, p. 24). The image of a National Guardsman, government marksmen, or local law enforcement officer armed with high velocity rifles depopulating thousands of animals will not be a comforting sight (Wefald, 1999; Chalk, 2000).

Current approaches to an animal disease outbreak create animal welfare concerns related to animal movement, disruption of feed supply transportation, delay of slaughter at the appropriate production time, and mass slaughter. Animal depopulation as a welfare issue needs further consideration and review (Evans, 2007). The issues surrounding welfare are not just based on the method of euthanasia, but also the process of the response.

In addition to animal welfare, when apparently healthy or vaccinated animals are depopulated, ethical concerns linked to social values, environmental impacts, and global food security are also raised (Barnett, Geale, Clarke, Davis, & Kasari, 2013). Policy alternatives must be evaluated with all consequences in mind.

Carcass Disposal Problem

During a large-scale animal health emergency, the slaughter and disposal of infected and exposed animals is an instrumental part of controlling and eradicating the disease. Available technologies offer multiple options for disposal, including rendering, burial, incineration, burning, composting, chemical digestion, and other emerging concepts. Selecting the appropriate technology will depend on the cause of death, availability of necessary technology and resources, public health, environmental concerns, public perception, transportation needs, location, climate, regulatory issues, and economic concerns.

A complete and multidimensional policy strategy is necessary when planning for the disposal of livestock and poultry in the event of high death losses resulting from an intentional bioterrorism attack, an accidental introduction of dangerous pathogens, or a natural disaster. An important part of that strategy is the ability to dispose of large numbers of animal carcasses in a cost-effective and socially and environmentally effective manner (Adams, 1999; Casagrande, 2002; Deen, 1999, Parker, 2002). According to Nutsch and Kastner (2008), if the challenge of carcass disposal is not met successfully it will "spiral into major food agricultural security problems and result in devastating economic losses" (p. 1959) and environmental consequences.

The disposal of carcasses can be challenging. The easiest and quickest methods for disposal are burying in landfills and burning – both of which can draw public opposition. However, leaving carcasses out in the open can lead to increased disease spread and additional public discourse (Chalk, 2004).

As Segarra (2001) noted in the Congressional Research Service (CRS) Report to Congress, "the last line of defense and the costliest, is the isolation, control and eradication of an epidemic" (p. 8), which would include mass depopulation and disposal. Current USDA policy prescribes incineration, burial, or rendering as the preferred disposal method (GAO, 2005). Each of these disposal methods have challenges to their implementation, including disease spread, environmental impact, and public perception. In addition, producers may not be willing to cooperate. The USDA identifies burial as the fastest, easiest, and most economical method of disposal when it is feasible (GAO, 2002a).

The method of carcass disposal can impose heavy costs on society. Some methods could result in costs incurred by producers and society through environmental degradation, elimination of tourism opportunities, contamination of water supply, or the spreading of disease. The environmental impact of certain disposal methods could be permanent. Burial of carcasses will likely cause land used for pits to be lost for production for several years, which would affect producers' future economic well-being. Tourism can be affected by the images shown to the public of carcass disposal occurrences. If landfills are used, the county will be financially affected because landfills may reach capacity before expected. Estimating this impact requires a deeper look into the future use of land. These are significant costs that must be considered. The costs on producers, processors, and local communities for each disposal method should be considered. Regulations requiring contingency plans for rapid depopulation of livestock premises should be developed (Casagrande, 2002; Deen, 1999).

At times, location and technology availability may give producers and animal health officials little or no choice of disposal technology. Public health should always be a priority if an infective disease is involved. Biosecurity risks related to the livestock industry are also an important consideration. Short-term and long-term impact on the environment should also play a key role in the technology selection process. Economic considerations, including direct costs of the disposal methods must also be a part of the decision-making process.

Policy analysis must go beyond the direct costs of disposal (technology, equipment, transportation, storage, site acquisition, fuel, facilities, and labor) and must include other considerations, such as the impact on the environment, tourism, future land values, and other social costs. Direct costs should not be the only factor in a disposal policy evaluation. Economically attractive disposal methods may not meet regulatory requirements. The most cost-effective method may contradict regulations in place at the local, state, or federal level. Additional efforts are necessary to assess state-by-state regulations, investigate opportunities for states and the federal government to work together, have disposal plans in place before an emergency, and delineate clear decision making responsibilities. For example, to minimize direct costs, contracts with technology providers should be negotiated in advance. It must be clear who takes on this responsibility (Casagrande, 2002; Deen, 1999).

Timely disposal may be difficult with a large-scale death loss or depopulation. Resources may not be available for the actual disposal or the related costs. In the U.K. FMD outbreak, contingency planning should have considered additional issues, including the logistical problems related to the location of disposal facilities, size and species of animals, and access to farms. The UK could have planned to vaccinate healthy animals within the depopulation zone to postpone slaughter, or freezing carcasses to allow disposal to keep pace with animal deaths (Anderson, 2002).

The decision to implement a mass depopulation and disposal effort will have to be made in a short time and the execution must take place without delay. Success will depend on contingency plans and the related structures, policies, and infrastructures. Decision processes and partnerships must be pre-established (OIE, 2005).

To understand the dilemma, consider the development of an action plan for fighting FMD in California. The California Department of Food and Agriculture action plan states that all precautions should be taken to prevent disease spread and comply with environmental regulations during disposal of infected and exposed animals. While the state allows the governor to overrule environmental regulations in the case of an emergency, uncertainty over the long-term environmental impacts and public concern will likely delay even proven disposal methods (Ekboir, 1999).

The greatest logistical problem found in the California research is the disposal of carcasses. USDA APHIS states that burial is the preferred method of disposal when practical, and considers burning as an alternative. However, burial would require the digging of miles of trench pits that could not be disturbed for years. This alone imposes a major future cost for producers. Carcass burning would require more wood or other fuel than is available in a timely manner. The ability to use an air-curtain incinerator would be limited to equipment availability and could increase disposal time. Landfill use would be limited because of the need to mix with waste in a fixed portion and the cost imposed on the local communities of filling the landfill. Limited disposal ability and capacity will affect the spread of disease (Ekboir, 1999).

In the case of FMD, the virus can survive for long periods, so disposal must be done with in a manner that stops disease spread, minimizes negative environmental effects, and preserves animal protein when possible. On-site burial may be the least expensive and biosecure, but may be limited by environmental and geographical characteristics and regulations. Off-site burial, rendering, composting, incineration, and digestion may all be utilized in dealing with FMD (APHIS, 2012c).

The disposal of carcasses presents a number of unexpected challenges. To effectively meet the challenge of carcass disposal, public and private partners need to develop response plans well in advance. Multiple disposal methods may be utilized. Decision trees or action plan models need to be designed for local conditions and circumstances (Harper, DeRouchey, Glanville, Meeker, & Straw, 2008). Existing decision-trees used to guide policymakers do not always account for all circumstances and situations. In the UK, the media images of burning pyres caused a negative public reaction, burial had to be eliminated because of water tables and long-term land values, and, yet, an urgent decision was necessary because huge piles of dead animals were creating additional concerns (Foxell, 2003). The USDA APHIS and state animal health agencies have been charged with disposing of exposed animals in a sanitary and humane method (Dunn, 1999). The perspective also exists that the policy focus needs to move from one focused on disposal alternatives to one focused on an alternative to disposal (Evans, 2007). There is no perfect disposal method nor is there an alternative that would eliminate all disposal needs, so decision makers need to be armed with effective policies, procedures, and tools to make timely and effective decisions.

Vaccination

According to Roger Breeze (2004), the traditional response plan in the case of an epidemic animal disease began in 1711 when Pope Clement XI's physician, Dr. Lancisi, proposed quarantine and mass slaughter to deal with an outbreak of Rinderpest in the region's cattle. It is not until recently that vaccination has seriously been considered as a policy alternative in the case of a large-scale animal disease outbreak.

According to the OIE, eradication policies have existed to defend export interests and are economically motivated. In some countries, the public and policymakers have expressed opposition against economics being the top priority in implementing this strategy. Many producers may not be concerned about export markets, and animals may represent a more differentiated value than pure economics. To farmers, animals may represent the professional achievements passed on by their ancestors or personal, daily companions. Animals may also serve as beasts of burden, exist for ceremonial reasons, or represent a sign of wealth. In many of these cases, the export argument is not convincing, especially when animals that have not been infected are selected for culling. Prescribed compensation packages may not be able to replace the animals depopulated (OIE, 2005).

Trade bans implemented at just the mention of a disease outbreak make it challenging for policymakers to choose any approach other than stamping out (Willis, 2007). International trade rules do not reflect contemporary technology by penalizing vaccination, encouraging mass slaughter, and imposing antiquated standards to meet trade requirements (Breeze, 2004). Roth (2005) noted that animal vaccine development is much less expensive than human vaccines and can be approved for usage much quicker. Better technology in vaccine development needs to be used to expand vaccine capabilities (McGinn, 2003a).

The OIE indicates vaccination with or without eradication policy is preferred over mass destruction to contain a disease outbreak. According to the OIE (2005), the decision to conduct mass depopulation must be "carefully evaluated against available alternatives, environmental, socio-political and socio-economic concerns, trade implications as well as prevailing ethical and ethnic beliefs and preferences" (p. 1).

Vaccines can be used in a vaccinate-to-live policy, vaccinate-to-slaughter, or a vaccinate-to-cull policy. In a vaccinate-to-cull policy, vaccine would be used to limit infection and potential disease spread amongst animals that will eventually be depopulated (Kohnen, 2000). In a vaccinate-to-live policy, vaccinated animals would continue in the normal husbandry and marketing processes. This use of vaccines in the case of FMD would further jeopardize a nation's ability to reopen export markets. The OIE differentiates between countries that are FMD-free with and without vaccination. Most countries that are FMD-free without vaccination use a stamping out policy to guarantee the earlier opportunity to restore trade (GAO, 2005).

The USDA has traditionally preferred slaughter versus vaccination policies for FMD in the US because of international trade restrictions. Therefore, the US has not historically stockpiled vaccines or maintained a significant supply (GAO, 2005; Breeze, 2004). Breeze (2004) noted that, "In the past, US and other FMD-free countries have rightly calculated that their greatest profit could be obtained by not vaccinating their herds against FMD, because this allows producers free access to world markets with their most profitable products and handicaps other countries that use vaccine…..the most profitable option is not to vaccinate but to eradicate the disease by killing as many animals as it takes. This allows producers to reenter world markets much more quickly than if vaccine had been used" (p. 253). The number of animals involved, the size of the geographic region, and the spread of the disease will also change the economic impacts of vaccination versus depopulation.

In some parts of the world, vaccination has been used, but not always with success. In the case of the South Korea FMD outbreak, questions arose about vaccine effectiveness. The serotype *O* that infected hogs at the initial farm was the same serotype that the government had been vaccinating against for several months, and all the animals at the farm were vaccinated. One official noted that perhaps farmers could have vaccinated incorrectly or animals could have had immunity against the vaccine (Smith, 2011).

Even though vaccination has been proposed as a possible solution, it may be difficult to deploy vaccines in a timely manner. The process to get USDA approval to vaccinate is complex and difficult to implement during an FAD emergency. Officials have indicated a willingness to design a more rapid-decision making process, but they caution that there are many variables (including location, vaccine efficacy, and trade restrictions) and the complexity is ingrained in the policy (GAO, 2005).

In response to a GAO study, the USDA said that the NVS should be one potential component of the response. There are a limited number of diseases that can be treated by vaccines. Vaccinations may limit disease spread in areas adjacent to the outbreak or help reduce the shedding from infected animals (DeHaven, 2005).

By presidential directive HSPD-9, the NVS was authorized to enable vaccines to be deployed in 24 hr, but current vaccines stored for FMD would not be available for days as they would have to be sent to the UK for activation due to US regulations (GAO, 2005). There are seven serotypes of FMD virus and more than 70 subtypes. No single vaccine can counter all the serotypes, and current vaccines are designed for use prior to exposure. Vaccines can keep animals from acquiring disease, but not from being carriers. A vaccinated cow can carry disease agents in the throat for years after exposure (Kohnen, 2000).

In response to the presidential directive, the USDA has contracted with manufacturers for the development of strain specific vaccines in the case of FMD. The stockpiled vaccine materials and the contract agreements could result in strain identification and a tailored vaccine being developed in a few days. However, vaccines are only one part of the control strategy, and the USDA is likely to depend on a combination of vaccination and depopulation (Connor, 2005; APHIS, 2011d; APHIS, 2012a).

According to APHIS, a number of factors will be considered when selecting the appropriate strategy including disruptions to interstate commerce and international trade, acceptance of response strategies, scale of outbreak, rate of spread, vaccine availability, and resource availability. For example, a larger scale outbreak may quickly cause traditional depopulation and disposal efforts to get behind and exhaust resources, and vaccination may be used as either an alternative or delay tactic. The use of an emergency vaccination response will be determined by the incident commander, state animal health officials, and the U.S. Chief Veterinarian. The three epidemiological response principles defined by APHIS are to:

1. Prevent contact between FMD virus and susceptible animals,
2. Stop the production of FMD virus in infected or exposed animals and dispose of the carcasses immediately (as the disease will remain present on the carcasses for a long period of time), and
3. Increase the disease resistance of susceptible animals to the FMD virus or reduce the shedding of the FMD virus in infected or exposed animals (APHIS, 2011d; APHIS, 2012a).

APHIS has also identified five strategies for control and eradication:

- Stamping out (depopulation of infected and in-contact susceptible animals) with no vaccination,
- Stamping out modified with emergency vaccination-to-kill/cull (delayed depopulation and disposal),
- Stamping out modified with emergency vaccination-to-slaughter (delayed slaughter of eligible animals under USDA FSIS rules),
- Stamping out modified with emergency vaccination-to-live, and
- Emergency vaccination-to-live without stamping out (APHIS, 2011d; APHIS, 2012a).

USDA APHIS Veterinary Services (VS) personnel have indicated the two modified stamping out strategies or a combination of the two are the highly likely responses. Stamping out alone was characterized as a likely response and vaccination-to-live with no stamping out as a less likely response. No response action at all is considered highly unlikely (Zack, 2013).

NAHEMS guidelines note that vaccination-to-live, if all other factors are equal, would create the greatest benefit for animal survival and business continuity, but would have a detrimental impact on exports (NAHEMS, 2011d).

In July 2012, USDA and DHS announced the development of a novel vaccine for one of the seven strains of FMD. This vaccine does not use a live FMD vaccine for vaccine manufacture and can be used to differentiate an infected animal from a vaccinated one using common diagnostic tests. This was the biggest FMD research accomplishment in half a century. It can be produced safely in the US and becomes effective within seven days. This development created optimism in the industry about the ability to discover and produce additional vaccine (DHS, 2012, July 2).

This announcement immediately influences the policy making process and has the potential to lead to a complete paradigm shift in national and international policy response plans and policy development. Since a live vaccine is not used in the manufacturing process, then it can be legally manufactured in the US which can speed up the response process and more quickly stop disease spread. Because animals that have been vaccinated can be differentiated from those that have been infected, they can be identified as they are slaughtered, which allows trade restrictions to be lifted more quickly. It is important to note that as of December 2013, according to USDA APHIS official, no contracts have been signed by USDA for manufacturing of this vaccine and vaccine manufacturing in an emergency would still occur internationally (personal communication).

Summary and Next Steps

Agricultural biosecurity is a complex policy dilemma and deserves additional discussion in order to develop sound policy options. The next three chapters (2-4) will address these three policy areas – euthanasia, disposal, and vaccination – in greater detail. Chapter 5 will consider policy evaluation tools. Chapter 6 will outline and evaluate policy alternatives and considerations. Chapter 7 will provide a summary and conclusions.

Chapter 2 - Euthanasia and Welfare Implications

The destruction of animals for disease control is necessary in cases of suspicious or confirmed outbreaks of emergency diseases or diseases with considerable public health or economic impacts. The purpose of depopulation is to avoid the spread of the infectious agents and their products. Depopulation of a species in a certain geographic area should only occur when no other options are available, because many questions regarding stamping out policies exist. The impact on animal welfare of these options can be significant.

Euthanasia and depopulation, which can also be referred to as culling, dispatch, and destruction, are defined differently by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS) and the American Veterinary Medicine Association (AVMA). Euthanasia is the transition of an animal from life to death with as little pain and stress as possible. Mass depopulation deals with the destruction of animals quickly and efficiently while giving practical consideration to animal welfare (NAHEMS, 2011b; American Veterinary Medicine Association [AVMA], 2013a). However, for the purpose of discussion, the National Animal Health Emergency Management System (NAHEMS) guidelines and this document use these terms interchangeably.

Depopulation is used during a disease outbreak to prevent or limit disease spread by euthanizing infected and at-risk livestock and reducing the susceptible population. Therefore, depopulation policies help to protect the economic viability of the industry as well as protect animal and human health depending on the disease agent (NAHEMS, 2004; NAHEMS, 2011b).

Historical Experience

United Kingdom – Foot and mouth disease (FMD)

In 2001, the UK experienced a catastrophic outbreak of FMD. This outbreak is one of the best historical examples of a large-scale animal disease outbreak that led to the killing of the largest number of animals for disease control in more than 40 years. In June of 2002, the National Audit Office (NAO) published a summary on the 2001 Outbreak of Foot and Mouth Disease as reported by the Comptroller and Auditor General and as ordered by the House of Commons. In the UK, the Department for Environment, Food and Rural Affairs (DEFRA; formerly the Ministry of Agriculture, Fisheries and Foods [MAFF]) maintained lead responsibility for the FMD outbreak and policies related to infected or exposed animals. DEFRA's organizational structure in regards to Animal Health is comprised of a policy-making wing and an operational wing, the State Veterinary Service (SVS) (NAO, 2002; Anderson, 2002). The Cabinet Office Briefing Room (COBRA) was eventually given authority to make policy decisions related to disease control under the advisement of the Science Group and the Chief Scientific Advisor to the Government (Kitching, Thrusfield, & Taylor, 2006).

DEFRA's veterinary officers initially directed the operations. About a month after the outbreak was detected, it was determined that the SVS could not handle all aspects of the epidemic and additional organizational structures were created. Broadening the cooperative structure gave state veterinarians more time for veterinary work, including supervision of animal dispatch and disposal. Increasing the role of other agencies and departments took time, but other government entities, local authorities, voluntary organizations, and stakeholders made critical contributions to stopping the spread of FMD. The military was not immediately involved, but within a month they played a key role in assisting with the organization and logistics for slaughter, transportation, and disposal (NAO, 2002; Anderson, 2002).

The epidemic began in late January, lasted 32 weeks, impacted 44 counties, and affected more than 2,000 premises. FMD impacted the sheep, swine, and cattle industries. An average of 100,000 animals were destroyed and disposed of each day in a large and complex operation. More than 6 million animals were slaughtered over the course of the outbreak, including 4.2 million animals culled for disease control and 2.3 million destroyed for welfare (See Table 2.1). This data does not include newborn lambs and calves, because those numbers were difficult to estimate accurately (NAO, 2002; Anderson, 2002).

Killing and slaughter policy

The Royal Society for the Prevention of Cruelty to Animals (RSPCA) supported the slaughter of infected animals "to control the epidemic and therefore prevent the suffering of other animals" (Laurence, 2002, p. 864). In addition, the Farm Animal Welfare Council (FAWC), an independent advisory board established by the Government in 1979, does not consider the killing of animals to be a welfare problem if euthanasia is carried out humanely. However, the slaughter of large numbers of healthy animals did create ethical concerns. Killing animals that were likely to be infected was accepted, but the killing of animals unlikely to be infected was questioned. According to RSPCA, risk assessments reflecting the chance of infection should have been done to determine the need for destruction of the animals (Laurence, 2002). Scudamore, Pritchard, & Whitmore (2002) have argued that careful veterinary risk assessments were completed based on dispersal methods, geography, and weather patterns in order to inform contiguous cull policy.

Table 2-1 *Livestock Slaughter Figures Associated With the FMD Epidemic of 2001*

Animal	Total animals slaughtered	Additional information	Source
Sheep	5.5 million total • 3.4 million (disease control) • 1.6 million (LWDS) • 525,000 Light Lambs	Additional culling of 3-4 million lambs estimated	DEFRA MLC RPA
Cattle	759,000 total • 590,000 (disease control) • 169,000 (LWDS)	Additional culling of up to 100,000 calves estimated	DEFRA MLC
Pigs	432,000 total • 145,000 (disease control) • 287,000 (LWDS)	Additional culling of piglets not estimated because most pigs slaughtered were fattening pigs	DEFRA MLC
Others (includes goats and deer)	7,000 total • 4,000 (disease control) • 3,000 (LWDS)		DEFRA MLC

DEFRA: Department for Environment, Food and Rural Affairs
MLC: Meat and Livestock Commission
RPA: Rural Payments Agency
LWDS: Livestock Welfare (Disposal) Scheme
Note. Adapted from Crispin, Roger, O'Hare, & Binns (2002).

FAWC believes the scale of slaughter should be the minimum necessary for effective disease control. Moreover, "it is essential to separate the implications of the disease itself from those arising out of the conditions imposed to control the disease" (FAWC, 2002, p. 6).

Timely slaughter is critical to disease control. In the case of FMD, risk of disease transmission from carcasses is possible, but relatively low because the virus is not produced after death. This is not the case with prion disease outbreaks. DEFRA officials found themselves unable to keep up with slaughter needs and delays caused numerous problems. "The speed with which slaughter was necessary to control the disease and its impact on animal welfare raised concerns from a number of animal welfare organizations" (NAO, 2002, p. 69). Carcass disposal efforts need to be efficient to allow depopulation efforts to continue to move without delay or hindrance (Galvin, Blokhuis, Chimbombi, Jong, & Wotton, 2005). The public was also upset by poor welfare conditions that were blamed on DEFRA and their policies. The large numbers of animals to be destroyed placed a strain on resources for slaughter procedures and quality of the dispatch efforts (Laurence, 2002). Scudamore, Pritchard, et al. (2002) noted that all livestock depopulation was done under veterinary supervision and all complaints were handled expeditiously.

Various policy decisions were made during the crisis that impacted animal welfare. Because mass killing often occurred in the field, severe welfare challenges existed that do not exist in slaughter facilities. Field killing teams lacked proper training, experience, and supervision (NAO, 2002). Slaughter personnel were paid on a per animal basis (piece rate), instead of by the hour (Food and Agriculture Organization of the United Nations [FAO], 2002; NAO, 2002; Crispin et al., 2002). This policy was identified as "not consistent with welfare-friendly handing and accuracy" (FAWC, 2002, p. 12) by the FAWC. The RSPCA also found this payment policy to be detrimental, as it encouraged operators to cut corners and use poor slaughter procedures (NAO, 2002).

A 24-hr target was established for the destruction of all livestock on infected premises, and a 48-hr target was established for livestock slaughter on contiguous premises (NAO, 2002; Anderson, 2002). While diagnosis, culling, and disposal of infected livestock should occur as soon as possible, it is not clear that livestock on contiguous farms must be disposed of within 48 hr in order to delay disease spread (NAO, 2002; Anderson, 2002; Crispin et al., 2002). In fact, substantial delays occurred which resulted in some animals being destroyed after the incubation period for FMD had already passed (Crispin et al., 2002).

Most of the animals slaughtered were killed on farms. The location, conditions on the farm, age of the animals, and species all impacted the methods used. The three most common techniques were: captive bolt weapon followed by pithing or bleeding, free bullet weapon, and chemical (Crispin et al., 2002). Killing teams were neither well equipped nor well prepared at the onset of the outbreak. Bolt guns broke down regularly due to overheating, making it necessary to keep extra guns and ammunition on site. The effectiveness of captive bolts on sheep was also questioned, and recognized standards for equipment used for killing and slaughter still needed to be developed (FAWC, 2002). Large numbers of animals were culled and killed using methods that were not approved by statutory regulations. Several well-documented reports detailed illegal slaughtering and animal abuse at the time of depopulation (Crispin et al., 2002; Thomas, 2002). For most farming families, on-farm killing was traumatic, especially when the animals were not infected or directly exposed to FMD. This became a bigger issue to individual families when the 3-km kill-zones were not consistently implemented (Thomas, 2002). Welfare concerns were the result of "reduced killing options, inappropriate killing methods, and personnel not accustomed to working in disease control/field situations" (FAWC, 2002, p. 9). In addition, many uninfected animals were killed at slaughterhouses and their carcasses rendered (Laurence, 2002).

According to Scudamore, Pritchard, et al. (2002), analysis of the stamping out policy showed it to be most effective at reducing the number of livestock to be depopulated and determined that fewer animals were killed with a contagious cull than if vaccination-to-cull had been used as a response strategy. They argued that those who opposed the stamping out policy, such as RSPCA, did not understand the scale of the outbreak and the importance of a speedy and effective response. The killing of animals with any possible risk of infection is projected to lead to more rapid disease control and create a significant welfare benefit (Scudamore, Pritchard, et al., 2002).

The Welfare of Animals (Slaughtering or Killing) Regulations (WASK) provided the key controls for attempting to ensure humane slaughter. The regulations required the use of only licensed slaughtermen and audits by DEFRA's veterinarians. DEFRA stated that qualified veterinary inspectors maintained welfare standards at slaughter locations. However, one of the greatest factors leading to delays in slaughter and inappropriate slaughter methods was a shortage of veterinarians. RSPCA felt the veterinarians were stretched too thin and were required to cover too many slaughter facilities, too far apart. RSPCA also criticized the time taken by DEFRA to clarify instructions regarding pithing animals in addition to stunning, which resulted in animals regaining consciousness after stunning and experiencing pain and suffering (NAO, 2002; Crispin et al., 2002; Laurence, 2002). RSPCA was offered the opportunity to access slaughter sites and view slaughter techniques by reporting to the appropriate locations at infected sites for the necessary licensing and biosecurity protocols, but they did not choose to participate (Scudamore, Pritchard, et al., 2002). Little consideration was given to the logistics of killing large numbers of animals, especially young and late-term unborn animals. Some methods were also not acceptable because of the potential of disease spread, such as the use of exsanguination after stunning. Numerous reports of improper and inappropriate slaughter were documented by members of the public and the media, including broadcast television. Examples ranged from failing to sedate cattle prior to slaughter to shooting lambs with free bullets in an open field (Crispin et al., 2002). Other cases have been cited where cattle showed signs of consciousness hours after being stunned by a captive bolt pistol. No prosecution took place in regard to animal welfare, primarily because of the lack of forensic evidence (Laurence, 2002). Scudamore, Pritchard, et al. (2002) contended RSPCA showed no evidence of animals regaining consciousness and that their claims were based on unproven anecdotes rather than facts.

Methods of euthanasia were selected based on health and safety of all humans and animals on the premise to be depopulated, the availability of handling facilities, the type and behavior or tractability of livestock, and the plans and logistics of carcass disposal by a supervisory veterinary inspector. Concerns were expressed about some methods based on a lack of understanding about legality of use, but all methods were legal. The use of rifles and free bullets were seen as inhumane by some but actually required less handling and stress on animals, especially those not comfortable with close human contact (Scudamore, Pritchard, et al., 2002).

The slaughter of young lambs drew additional criticism. The most common process of euthanasia was the use of pentobarbital via the intracardiac route. While this technique does appear appropriate, further research is needed to evaluate the welfare impact. Another area of concern was that the epidemic began at the height of the gestation period in sheep. Many of the sheep killed were in late-term pregnancy and concerns existed regarding the stress level of unborn lambs when the ewes were destroyed. The RSPCA recommended that heavily pregnant animals should first be sedated with an agent that crosses the placenta prior to euthanasia (FAWC, 2002; Laurence, 2002). Views on the impact of euthanasia methods on animals *in utero* are divergent, but it has been found that death occurs shortly after the dam and that traditional methods are humane (Scudamore, Pritchard, et al., 2002).

While many animals were slaughtered on farms, hundreds of sheep were transported to another location for killing and mass burial. This created welfare implications when pregnant animals, post-parturient ewes, and neonatal lambs were transported. The Welfare of Animals

Transport Order establishes transport guidelines to reduce unnecessary suffering (Crispin et al., 2002), but the guidelines were not always followed.

FAWC offered a variety of recommendations on several topics related to kill and slaughter policy and animal welfare. They recommended that detailed strategies for on-farm killing in all species need further research and should be included an all contingency plans. Specifically, the use of captive bolt stunners in sheep needs further investigation as does the establishment of recognized standards for slaughter and killing equipment. The Government should establish a trained reserve of field slaughtermen to be rapidly deployed, complete with military issued "Green Cards," in disease situations. Members of these slaughter teams should be specifically licensed and should not be paid piece rates. Operational guidelines and organizational principles in a large-scale dispatch need to be more clearly defined (FAWC, 2002; FAWC, 2003a; FAWC, 2003b).

The legality of the government's decision to cull was questioned during and after the outbreak. In 2002, the Animal Health Act was passed establishing a legal basis for contiguous culling to respond to an animal disease outbreak (Anderson, 2008).

Movement restrictions and overstocking

Livestock production in Britain involves significant movement of livestock. At the onset of the epidemic, all movement transporting animals to and from wintering areas, between pastures, and to market were halted. As infected farms were identified, movement restrictions were placed on all farms within a 3-km radius. These widespread restrictions created additional animal welfare implications. Later, a licensure program was established to allow movement, but the process to receive a movement license was slow and bureaucratic (Crispin et al., 2002; Laurence, 2002). Any policy decisions regarding movement restrictions should include an assessment of animal welfare implications and provide for animal health experts to be available to producers subject to movement restriction (FAWC, 2002; FAWC, 2003a).

The welfare of animals was also impacted when they become overcrowded. For example, pigs in fattening pens became overcrowded because they could not be sent to market. This led to numerous welfare problems, including cannibalism. Examples included lambs covered in mud and cattle marooned on waterlogged ground. Animals were denied the opportunity to move from an overly grazed pasture to neighboring ungrazed fields, even when disease transmission was highly unlikely (Crispin et al., 2002; Laurence, 2002). Feed and fodder supplies were limited, and animals were in unsuitable, overcrowded locations with a lack of appropriate nutrition and resources (Royal, 2002). It became apparent that producers needed assistance from the government in alleviating the welfare problems resulting from the movement restrictions (Whitmore, 2002).

The Livestock Welfare Disposal Scheme (LWDS) was introduced to alleviate the worst animal welfare problems due to movement restriction and overstocking. This program involved the government reimbursing producers for stock and taking them away to slaughter. It was modeled after a disposal program designed to help deal with a classic swine fever outbreak in 2000 (Anderson, 2002). It was designed to be a last resort when the welfare of animals could not be maintained in any other manner and all reasonable farm management options has been exhausted (Whitmore, 2002). In some areas, killing for welfare far exceeded killing for disease control (Anderson, 2002). Because the initial financial values were overly generous, the demand for the LWDS exceeded its capacity and significant delays occurred in removing animals from poor welfare situations. Moreover, there was no effective priority system to determine which animals were actually in the worst welfare state (Laurence, 2002). It has also been claimed that some farmers intentionally made no effort to address animal welfare issues with the intent to get higher priority access to the LWDS. Basically, the compensation concept may have led to development of a moral hazard approach by some livestock owners (Whiting, 2003). Government programs, such as the LWDS, should address other avenues to support animal welfare, rather than simply disposal. The destruction of healthy breeding stock and unfinished animals should be a last resort. A government system utilizing "welfare vouchers" could be considered as well (FAWC, 2002, p. 15).

Crispin et al. (2002) summarized the welfare problems related to movement restrictions and overstocking. The issues included:

- inability to move periparturient animals, so that animals gave birth under unsuitable conditions with high maternal and perinatal mortality as a consequence;
- farms became seriously overstocked and there was a lack of feed, bedding, and shelter;
- conditions for hill pastured sheep deteriorated because of movement restrictions;
- the usual levels of husbandry could not be maintained and many farmers were placed under extreme stress as they could not look after their animals properly, and the stress

was exacerbated if welfare problems became so acute that the LWDS became the only option;

- the bureaucratic nature of licensing arrangements allowed little flexibility for veterinary-based decisions and often led to unacceptable delays (delays in issuing movement licenses resulted in many animals becoming eligible for the LWDS only); and
- LWDS became oversubscribed, resulting in further delays and animal welfare problems (cattle exceeding 30 months of age and mature males being kept under unsuitable conditions) (Crispin et al., 2002).

While movement licenses and restrictions were believed by some to be effectively managed and average turnaround time for a license was five days, it was a huge logistical endeavor. One of the most important lessons learned from the implementation of the LWDS and the management of movement restrictions was the need for all livestock businesses to maintain supplies to care for all their livestock for at least six weeks (Scudamore, Pritchard, et al., 2002).

Social impacts

The U.K. outbreak illustrates the significance of the psychological damage caused by the disease and the response. A number of psychological symptoms were prevalent from lack of sleep and appetite, to general depression and marital discord. Some practitioners have estimated that 50% of patients affected during the FMD outbreak required antidepressants. Many sent their children away so they did not witness the euthanasia and disposal. Normal daily life was severely disrupted. Quarantines and limited movement added to the stress, as did the loss of income and the need to cut back on household expenses and renegotiate loans (GAO, 2002a).

Vaccination policy

The policy in the European Union (EU) for controlling FMD allows for the use of emergency vaccination as a part of a stamping out policy when FMD has been confirmed on an extensive level and vaccination would help eradicate the disease. In the Netherlands, where the outbreak was much smaller, emergency suppressive ring vaccination was used in conjunction with later slaughter of the animals. It allowed slaughter and disposal to be managed better. However, it is not expected that a vaccinate-to-kill policy would have been effective in Britain and likely would have resulted in a larger number of animals being slaughtered. Some consideration was given for a vaccinate-to-live policy in Britain during the outbreak, but it was controversial (NAO, 2002). Specifically, vaccination was considered during the first two weeks of the outbreak, but it was determined that the outbreak was too wide spread for vaccination protocols to be implemented. It was subsequently considered at least 10 more times during the outbreak, and was eventually approved for use in Cumbria and Devon. However, key stakeholders, including farmers, veterinarians, consumers, retailers, and food manufacturers, were not sufficiently supportive, so vaccination was never used. It was not feasible to obtain their support at the height of the outbreak (Scudamore, 2007). Emergency vaccination should have been discussed as a part of contingency plans before the outbreak (NAO, 2002).

A vaccination policy may have significant welfare implications. It could be possible to depopulate an infected premise and ring vaccinate to stop the spread of disease. This type of policy could be effective in preventing and reducing the spread of disease, while culling fewer healthy animals.

Trade and usage restrictions

FMD had a significant economic impact on the U.K. livestock sector. Restrictions on the potential usage of infected and at-risk animals lowered the value of livestock. RSPCA contended that reduced value of livestock negatively impacted the care they received from their owners. Thus, any event that reduces the fiscal value of livestock could potentially reduce their welfare and create a link between the loss of domestic and international markets and the welfare of livestock (Laurence, 2002).

Summary of welfare concerns from U.K. inquiries

Concern for animal welfare needs to be at the center of contingency planning for any future disease outbreak. The plan needs to establish procedures that maintain animal welfare standards even during an emergency situation. There is no alternative to culling animals that are infected or directly exposed, but limiting the number of non-infected animals depopulated should be a goal. Culling can have a positive welfare impact if it shortens the disease outbreak and limits movement restrictions. However, culling practices should not cause increased stress and anxiety to animals. This includes the recognition that keeping animals alive, simply for the sake of keeping them alive, is unacceptable if they are denied access to food or acceptable living conditions (Royal, 2002; Department for Environment, Food and Rural Affairs [DEFRA], 2002).

A vaccinate-to-live policy means fewer animals will need to be culled, but the welfare cost associated with increased movement restrictions needs to be considered. Animals should be kept on the farm, and farmers need to maintain responsibility for their care and welfare. A welfare disposal scheme should be a last resort, and a compensation program may actually work opposite animal welfare. Farmers faced with compensation schemes can "provide a disincentive for them to take responsibility for looking after their animals and may also create a false market" (DEFRA, 2002, p. 45). All future contingency plans must address the welfare problems summarized in the following paragraph (DEFRA, 2002).

Local inquires in Cumbria, Devon, and Northumberland combined with the lessons learned identified by Iain Anderson and the Royal Society included the recognition of a variety of significant animal welfare issues (Anderson, 2002; NAO, 2002; Thomas, 2002). This list of problems was summarized by Crispin et al. (2002) to include:

- delays in the slaughter of infected animals;
- unsuitable on-farm and off-farm conditions for slaughter (poor handling and restraint facilities);
- animals awaiting slaughter were kept close to and in sight of those being slaughtered;
- incompetent animal handling and inhumane slaughter (inexperienced handlers, unskilled slaughter teams, lack of training, lack of compassion, failure to pith slaughtered animals);
- policy of paying slaughtermen for each animal they destroyed (piece-rate basis) led to a lack of care;
- inadequate veterinary supervision;
- failure to kill animals effectively (particularly associated with use of barbiturates and stunning procedures) resulting in animals that subsequently regained consciousness;
- unsuitable slaughter methods, failure to follow the DEFRA guidelines on facilities, handling, equipment, and use of sedatives (the most frequent problem was the selection of unsuitable weapons and ammunition that failed to kill the animal at the first attempt);

- animals escaping, being chased and wounded by slaughtermen using free bullets (examples shown on television of ewes and lambs in Monmouth, South Wales, and cattle at Knowstone in Devon, England);
- transport of unfit animals (heavily pregnant animals being transported to slaughter, some giving birth en route or whilst being slaughtered); and
- late-term and full-term fetuses dying of anoxia and circulatory collapse because the mother was dead (Crispin et al., 2002).

Future contingency plans

On December 1, 2003, DEFRA released the Foot and Mouth Disease Contingency Plan for public comment. This plan followed the release of an interim report in 2002, and responded to the issues raised in the FMD inquiry reports. The purpose of the plan was to guide the actions of the government in dealing with another foreign animal disease (FAD) outbreak or emergency (DEFRA, 2003).

The plan calls for the use of an emergency vaccination strategy to control the spread of FMD, with a focus on vaccinate-to-live policies when possible, even for use as the key control strategy (DEFRA, 2003). DEFRA states that protective vaccination (vaccinate-to-live) should be used when veterinarians believe the disease can be contained by stamping out infected and exposed premises, a defined group of animals can be protected, or rare breeds need protection. It would also be advantageous if the population density of susceptible animals is high, swine are the main species involved, a high risk of airborne spread exists, the disease origin is unknown, the disease is spreading rapidly, and the outbreak distribution is widespread. Suppressive vaccination (vaccinate-to-kill) should be considered as a method of delay when the number of animals to be destroyed exceeds the disposal capacity (DEFRA, 2003).

The contingency plan creates an animal welfare forum to address specific areas of animal welfare concerns during an outbreak. The plan calls for ensuring the welfare of all animals when movement restrictions are established and that all emergency on-farm slaughter follows WASK regulations. Animal owners will receive more advice and instructions in dealing with welfare issues, and animal welfare issues will be addressed early in the event of a disease or outbreak. DEFRA recommends that animals should be kept alive and healthy if possible. While animal health is the responsibility of the farmer, the government could offer assistance in movement licensure or in a fodder scheme. However, DEFRA called for the Government to not offer any compensation for animals destroyed, although they would pay for collection and disposal. “Any animal welfare disposal scheme would be an option of very last resort as it is clearly undesirable to slaughter animals unless absolutely necessary” (DEFRA, 2003, p. 38).

In the case of an FMD outbreak, the EU “requires slaughter of all susceptible animals on infected premises, and provides for culling of susceptible animals on epidemiologically linked holdings, as well as culling of susceptible animals on holdings where FMD is suspected” (DEFRA, 2003, p. 90). In the UK, law allows for slaughter of “animals affected or suspected of being affected with FMD, animals which are believed to have been exposed to FMD infection, and animals to prevent the spread of FMD, e.g. a ‘firebreak’ cull” (DEFRA, 2003, p. 90). In regard to the prevention cull, dispatch may be required to protect geographic areas of high livestock density. The power to assess such situations is defined by the Disease Control Protocol. “The Government is committed to using the new slaughter powers only where this is justified by the level of risk of the disease spreading and on the basis of sound veterinary, epidemiological, and scientific advice” (DEFRA, 2003, p. 92). Vaccination should be considered before slaughter powers are used (DEFRA, 2003).

A 2005 report from the NAO reviewed plan changes and discussed the application of lessons from the outbreak. The U.K. contingency plan is considered one of the most thorough and complete available. The current plan calls for the explicit consideration of emergency vaccination. The European Directive on FMD requires all exposed and infected animals be culled and emergency vaccination be used as an additional measure. The decision to vaccinate is complex and would have to be made in the face of uncertainty. The FMD contingency plan includes a vaccination decision tree. The supply of vaccines has been substantially increased, and vaccination will most likely serve in a much more prominent role in a future outbreak (NAO, 2005).

DEFRA commissioned development of a decision support tool on alternative disease control strategies to help with future policy decisions. A cost-benefit analysis based on an epidemiological model and a spreadsheet calculation model was completed to examine four FMD control strategies, including a base strategy comprised of culling of infected premises and dangerous contacts and the addition of a contiguous cull, vaccination-to-live of cattle, and vaccination-to-live of cattle and sheep. The location of the initial outbreak, virus strains, and resource constraints were used as variables in the analysis. Researchers concluded that due to the influence of a large number of parameters on size and costs of an outbreak that there is no clear, always applicable lowest cost alternative. Culling was concluded to be more cost effective in low- or medium-density livestock populations, with low virus infectivity, under nationwide trade restrictions, with necessary resources allowing for timely depopulation and disposal, or when effective traceback systems exist. In opposite scenarios, vaccination was estimated to be more cost beneficial in high density areas (Risk Solutions, 2005).

Other countries – FAD outbreaks

Nearly 300,000 animals were culled in the 2012 FMD outbreak in Japan, including more than 125,000 that had been vaccinated but were still considered at risk (Hagerman, McCarl, Carpenter, Ward, & O'Brien, 2012; OLPC, 2012). The primary euthanasia method was tranquilization and injection, but electrocution and CO_2 methods were also used. These methods were time consuming and labor intensive, and, when combined with a shortage of individuals trained to administer injections, slowed the process (OLPC, 2012). Large numbers of animals were culled in FMD outbreaks in Taiwan, the Netherlands, and Korea. In these cases, depopulation was used for disease control method, combined with movement restrictions (Hagerman et al., 2012). Taiwanese farmers and meat processors supported a culling approach, while the Taiwan's Council of Agriculture favored vaccination due to the related social, economic, and political ramifications of mass depopulation. Since farmers' indemnity payments were higher than the market value they would have received for healthy animals, it is believed some farmers intentionally introduced FMD at their farms (Crnic, 2010).

In South Korea, an FMD outbreak in 2010-2011 led to the culling of large numbers of animals amid several animal welfare concerns. Some cattle and farm-raised deer were injected with small doses of succinylcholine, a neuromuscular blocking drug used for euthanasia, at levels that caused paralysis but did not render them unconscious before being buried in large mass graves. A number of incidents of pigs being buried alive were reported by the public, farmers, and the media. Government officials did admit there was a shortage of drugs that led to live burials, but denied any animal cruelty. The emotional impact on farmers and the public was substantial leading Buddhist prayer monks to hold prayer sessions for the animals. Workers were treated for post-traumatic stress, tourism to affected areas declined substantially, and online petitions declaring South Korea in violation of their agreement with the World Organization for Animal Health (OIE) earned thousands of signatures (Glionna, 2011; Mesmer, 2011). Animal rights groups reported that more than 1.2 million head of animals were buried alive, not including an estimated 2.7 million chickens exposed to avian flu during the same time (Vegan.com, 2011; Huffington Post, 2011).

During an FMD outbreak in Paraguay in 2011, government officials ordered the depopulation of 1,000 head of cattle to stop the disease. Beef is their second largest export product and accounts for nearly $650 million in the small, rural country. Officials decided to destroy the exposed animals in public view in the community of Sargento Loma to send a clear message to their trading partners that the animals had been eliminated and that the government was serious about stopping the disease. Officials also denied farmers' requests to consider compensating the producers for the animals destroyed (Olazar, 2011).

In the 1997 outbreak of classical swine fever (CSF) in the Netherlands, 10 million pigs were depopulated. Nearly 75% (7.3 million head) were culled for animal welfare reasons rather than disease control (Garner et al., 2007).

United States – Disasters and disease outbreaks

While the US has not experienced a disease outbreak proportional to the FMD outbreak in the UK, there are situations that offer similar animal welfare learning experiences. Hurricane Floyd in North Carolina led to animal emergency and welfare implications, as did the outbreaks of avian influenza (AI) in Virginia, exotic Newcastle disease (END) on the West Coast, and chronic wasting disease (CWD) in the deer populations of Wisconsin and Colorado.

Avian influenza

In 1983, highly pathogenic avian influenza (HPAI) H5N2 led to the destruction of 17 million birds in Pennsylvania with costs exceeding $61 million (Benson et al., 2007). In 2002, the low pathogenic avian influenza (LPAI) H7N2 outbreak in Virginia resulted in the depopulation of 4,743,560 turkeys and chickens at 197 facilities and cost $160 million (Benson et al., 2007; Kingston et al., 2005). More than 900,000 additional birds were slaughtered for disease control (Kingston et al., 2005). Any flock with clinical evidence of infection (positive results on one or more screening tests) was considered a positive flock and was depopulated. Any negative flock with a clear epidemiological link to a positive flock was also depopulated.

The goal was to depopulate all birds on quarantined farms within 24 hr of a positive declaration (Kingston et al., 2005). Carbon dioxide gas was the primary method of euthanasia. Birds were confined in tight pens and covered with black plastic. Gas was then released under the plastic. Smaller pens were used to decrease volume of gas and chance of birds escaping. In some cases, young live birds were double stacked on top of dead birds (Puffenbarger, 2003). LPAI H7N2 resulted in the destruction of 328,000 chickens in the Delmarva region in 2004 (Benson et al., 2007).

In these cases, considerations and challenges in the euthanasia method selection process included variations in the size of birds, diversity in types and sizes of poultry houses, minimal number of personnel with mass depopulation experience, staff emotional and physical fatigue, use of temporary employees, providing temporary and permanent staff appropriate training, communication with personnel who were not native English speakers, worker safety, morale of employees and others, biosecurity, time restrictions, and no "proven method of humane and efficient mass euthanasia, given the constraints of the outbreak control policies" (Kingston et al., 2005, p. 730).

California – Exotic Newcastle disease

END is a contagious and fatal disease that can affect all bird species. It is one of the most infectious diseases that can affect the poultry industry and affects the respiratory, nervous, and digestive systems. END spreads through direct contact and contact with bodily fluids. The only way to destroy the disease is by rapid depopulation of all infected flocks and establishing strict quarantine policies. END threatens not only commercial operations, but pet bird and backyard poultry operations as well. The USDA APHIS fact sheet on END offers no recommendations on the euthanasia methods that should be used (APHIS, 2003; California Department of Food and Agriculture [CDFA], 2003).

California experienced an outbreak of END in October 2002. It first affected backyard poultry farms in California and expanded to commercial operations and into the state of Nevada. More than 600 veterinarians were involved in dealing with the outbreak (CDFA, 2003; Singer & Dawn, 2003). Birds in positive flocks as well as negative flocks with a proven epidemiological link to a positive flock were quarantined and depopulated. Negative flocks in neighborhoods where disease infection was believed to be imminent were also destroyed. All quarantined birds were to be euthanized within 24 hr after positive declaration. A successful mass depopulation effort was one in which all birds were handled humanely, euthanasia agents were delivered in quantities sufficient for rapid anesthesia, and anesthetic induction promptly resulted in 100% mortality rates (Kingston et al., 2005).

It became obvious that the euthanasia of these animals was a concern. The California poultry industry was criticized for breaking anticruelty measures in animal dispatch and disposal. Poultry producers were accused of ineffective use of gassing methods, live burial, and putting live chickens in wood chippers (UPC, 2003; Singer & Dawn, 2003).

In one case during the END outbreak, a veterinarian is accused of telling a large poultry farm that it would be appropriate to throw 30,000 live hens into industrial wood-chipping machines in February 2003 (UPC, 2003; Singer & Dawn, 2003). According to a complaint by the San Diego County Department of Animal Services, hens (dead and alive) were loaded into a front-end loader, dumped into the receiving hopper of the chipper, pushed into feed wheels which crushed them by a hydraulic ram, fed into pulverizing device, and destroyed by rapidly rotating metal hammers (UPC, 2003).

These types of practices are clearly working against the welfare of the animals and certainly do not set well with the public. In a Gallup survey in May 2003, 62% of Americans supported strict laws concerning treatment of farm animals (Singer & Dawn, 2003). The California Department of Food and Agriculture (CDFA) has developed guidelines and training programs for emergency euthanasia and is assisting in the development of protocols to ensure the safety of animals in disaster situations (CDFA, 2003).

These are just a few examples of emergency situations that can affect the livestock industry and welfare of large populations of animals. Other natural disasters, such as floods, droughts, and blizzards, can all have devastating impacts on animals and may result in welfare implications beyond the disaster itself. In addition, other disease outbreaks, including bovine spongiform encephalopathy (BSE), CSF, and CWD, create welfare implications and the need for contingency planning. Many of these disasters will require mass euthanasia efforts. In the following sections, euthanasia polices and methods of euthanasia are described with a focus on the animal welfare impact.

North Carolina – Hurricane Floyd

Hurricane Floyd devastated North Carolina late in the summer of 1999. The disaster had significant impacts on all areas of North Carolina, including the livestock industry. Major animal welfare issues were related to companion animals, farm animals, and wildlife. The public was called upon to rescue, feed, and dispose of many endangered or killed animals. Farmers were left with questions when being evacuated from their farms. They did not know if they should take their animals or leave them, leave barn doors open or closed, or ask for help. More than 750,000 turkeys, 2,107,000 chickens, 28,000 pigs, and 1,180 beef cattle were killed. Hundreds of dogs and cats were rescued and about 30 were reported killed. Closed roads and limited access to highly populated animal locations made rescues difficult. While owners could take reasonable steps to protect their animals, the animal population still needed attention as it would in any emergency response. North Carolina organized the State Animal Response Team (SART) to help manage and deal with future animal emergencies (McGinn, 2003b).

One major lesson learned in the Hurricane Floyd disaster was the need for contracts to be used in depopulation and disposal efforts. North Carolina calls for all animals to be disposed of in 24 hr, and contracts can help insure all equipment, personnel, and supplies are available. North Carolina calls for bid-pricing to be done on a per animal basis (Wilson, 2003a). Others have argued that pricing should be done by the hour, so that individuals are not motivated to move through animals quickly without focusing on their welfare.

Current Policies and Guidelines

As a member of the OIE, the US agrees to follow standards established and approved by member countries. The OIE standard for disease eradication in dealing with FMD, HPAI, and CSF is stamping out. OIE defines stamping out as the killing of affected animals, animals in the herd suspected of being affected, and animals in other herds that have been exposed by direct or indirect transmission. All susceptible animals, both vaccinated and unvaccinated, on infected premises would be depopulated under the OIE policy. If the outbreak cannot be contained in the Containment Zone, the OIE recognizes other response strategies may be implemented. The OIE should be notified if a modified stamping out policy that includes the use of vaccination without subsequent culling is used (NAHEMS, 2005b; APHIS, 2012a).

The goal of the U.S. stamping out policy is to euthanize all infected and susceptible animals on infected premises within 24 hr of exotic or emergency disease identification. In many cases, animals on contact premises (animals have been directly or indirectly exposed) will also be euthanized in the same time frame. The species most likely to shed the disease will be the first to be euthanized. Public concerns over the policy will need to be given appropriate attention and response (NAHEMS, 2005b; APHIS, 2012a). Lori Miller with USDA APHIS noted in May 2012 that "if euthanasia is required, improved, more humane methods are being developed" (Miller, 2012b, p. 13).

APHIS intends to comply with all recommendations for depopulation outlined by the American Veterinary Medicine Association (AVMA) and by OIE Terrestrial Animal Health Code Chapter 7.6 (NAHEMS, 2011b). OIE and APHIS response goals include the implementation of strategies to spare animal lives if appropriate and legal, but, otherwise, call for optimized depopulation which focuses on animals that are suffering, aesthetically acceptable euthanasia methods that fit the needs of the situation, and an attempt to minimize the emotional and psychological impacts on farmers, ranchers, and the public (APHIS, 2012a).

National Animal Health Emergency Management System

The USDA APHIS Veterinary Services (VS) Unit has established mass depopulation and euthanasia guidelines and standard operating procedures as a part of the NAHEMS. The NAHEMS guidelines for euthanasia are designed for use in a major animal health emergency. They are considered guidelines and can be used by other agencies at different levels of government to develop policies and deviations may be possible depending on circumstances (NAHEMS, 2004).

The goals of euthanasia in an animal disease emergency are to:

- provide humane treatment of animals at all times from disease identification through destruction;
- select an acceptable form of euthanasia that can be administered quickly, effectively, and humanely;
- minimize the emotional and psychological effect on animal owners, caretakers, families, and the public;
- prevent adulterated food products from entering the food chain;
- prevent or mitigate disease spread; and
- provide aesthetically acceptable humane euthanasia to affected animals as quickly and efficiently as possible (NAHEMS, 2011b).

As the goals have been revised, greater emphasis has been placed on mitigation of disease spread and protection of the food supply, with less emphasis on providing aesthetically acceptable humane euthanasia (NAHEMS, 2005b; NAHEMS, 2011b).

Depopulation should be performed by qualified and trained professionals in a speedy, safe, and most humane way possible (NAHEMS, 2004). In order to provide humane treatment, lactating cows must be milked or dried off if they are not immediately destroyed. Sick or injured animals must receive appropriate care, comfort, and medical treatment following veterinary guidelines prior to depopulation (NAHEMS, 2005b).

Incident Command System

All of the NAHEMS guidelines are developed to be used at three levels: a local/limited response, a regional response, and a national response. In all cases, animal health personnel must be prepared to work with the entirety of the emergency management community. The state-based or nationally coordinated model created to outline this response effort is referred to as the Animal Emergency Response Organization (AERO) model, based on the emergency management ICS (NAHEMS, 2004).

The euthanasia unit is a part of the AERO Operations Section and coordinates all euthanasia activities, including communication with producers, appraisers, incident command, and the disposal unit. The unit leader takes the lead in managing euthanasia protocols and procedures, humane animal handling methods, and safety precautions. The unit leader will assign team members and team leaders and will work closely with the animal welfare unit. The animal welfare unit is also located in the operations section and includes veterinarians and animal care inspectors who serve in an advisory capacity and ensure all animals are treated and euthanized humanely (NAHEMS, 2004; NAHEMS, 2011b).

Policy considerations

In the case of a highly contagious animal disease, immediate large-scale euthanasia efforts are necessary to control the production and transmission of pathogens. Because eradication efforts must be timely, clear policies and familiarity with procedures are essential. There are several factors critical to successful depopulation efforts, including humane considerations, documentation, gaining public support, and minimizing owner and personnel stress. All affected animals should be euthanized in a manner that minimizes pain and stress, and should be rendered unconscious as soon as possible. To meet this objective, the skilled use of the most humane, quickest methods is necessary (NAHEMS, 2004; NAHEMS, 2011b). Timely and effective depopulation will reduce disease transmission and the at-risk susceptible population. The dilemma occurs because the goal of rapid depopulation may not be compatible with animal welfare and elimination of animal distress (McReynolds, 2013).

Economic factors may also play a role in determining the appropriate depopulation strategy. As an example, Paarlberg, Seitzinger, Lee, and Mathews (2008) considered the economic impacts of an FAD with an emphasis on depopulation control strategies. They used a combination of epidemiological and economic models to assess the impact of an FMD outbreak originating on a small hog farm in the U.S. Midwest. Disease control strategies that were predicted to reduce the duration of the outbreak were considered the most effective. Depopulation of infected herds and those herds with direct contact within 1 km of the infected herd, depopulation of infected and direct contact herds and herds with indirect contact within 1 km, and depopulation of all herds within 1km of infected herds were compared. Depopulation of all animals within 1 km was estimated to consistently reduce the outbreak to less than a quarter and was considered the most effective. Radii of 3 and 5 km were also considered but results did not vary significantly from 1 km (Paarlberg et al., 2008). Chapter 4 includes discussion of several comparison studies that evaluate the impact of multiple disease control strategies, including depopulation and vaccination.

For a stamping-out approach to be effective, a number of prerequisites exist, including clearly defined infected zones, capabilities to quarantine and implement movement control, political and community support, well-trained personnel, legal authority, ability to slaughter humanely and dispose of carcasses appropriately, interagency cooperation and assistance, fair and timely compensation to farmers and ranchers, and community rehabilitation programs (Geering & Lubroth, 2002).

In the case of a large-scale outbreak, the veterinary workforce available in the US would be insufficient to meet the needs of a stamping-out approach. The logistical and environmental concerns combined with the workforce shortage make USDA and DHS consider such an approach potentially infeasible (GAO, 2009). Environmental contamination and exposure of other animals or humans should be considered when methods and substances are being selected (McReynolds, 2013).

A major animal health emergency will attract significant media attention. Personnel must work with the public and the media to gain their support. Efforts must be made to raise public awareness of the necessity of euthanasia for disease eradication. The humane aspects of the procedures must be emphasized. The media can be asked to document the presence of animal care experts and animal welfare group representatives to reassure the public. Experts and groups must be included at the beginning of the response and educated about the policies and procedures. Any use of controlled substances must be documented (NAHEMS, 2004; NAHEMS, 2011b). Information should be provided to animal welfare and animal rights groups simultaneously with the general public, and no one other than official personnel should be allowed on site (NAHEMS, 2011b).

Even if euthanasia is indisputably necessary, it does not make the extinguishing of animal life easy or less stressful. Personnel should be selected for the team only if they have the necessary experience and skills. Team members should be observed for signs of stress and be offered breaks, duty shifts, and counseling. Regular meals, adequate sleep, and frequent breaks are highly encouraged. Psychological counselors should be made available to all staff assisting in the process. APHIS noted the potential of compassion fatigue, a form of posttraumatic stress disorder (PTSD), and other PTSD cases in individuals working in an emergency situation. It is recommended that veterinarians likely to be involved in emergency response be trained in psychological first aid (NAHEMS, 2004; NAHEMS, 2011b).

Critical incident stress debriefing should be offered and possibly even mandated. It is advised that livestock owners and their families not be present for the euthanasia procedures, especially if there are children or others with strong emotional bonds with the animals. Quarantine procedures may limit the family's ability to leave the premise, but every effort should be made to move them if possible. The owners should receive complete information and explanations about policies and procedures and have all their questions answered without exception. Community mental health professionals and religious leaders may need to be on site to assist with problems as they arise (NAHEMS, 2004; NAHEMS, 2011b).

Guidelines, Methods, and Welfare Implications

Animal welfare must be a consideration in development of animal disease control response plans, in regard to depopulation as well as transportation and general care (Galvin et al., 2005). “Generally, the less handling, movement, transport and similar interference with the animals to be killed, and the shorter the time this process takes, the better for the animals” (Scientific Veterinary Committee [SVC], 1997, p. 4).

Euthanasia methods must be administered in such a way as to minimize stress, pain, anxiety, and fear in the animal (American Association of Swine Practitioners [AASP], 1997). Producers and government representatives have an “ethical and moral responsibility” to provide animals a humane death without additional pain or suffering (Rietveld, 2003, p. 1). When selecting a method of euthanasia, decision makers must consider human safety, animal welfare, restraint requirements, practicality, operator skill requirements, cost, aesthetics, location limitations, and tissue diagnostics (AASP, 1997; Rietveld, 2003; Center for Animal Welfare [CAW], 2003; American Association of Bovine Practitioners [AABP], 2000). The method of euthanasia selected must be appropriate for the species involved and meet professional standards (NAHEMS, 2004). Public perception must also be considered, especially in the case of mass euthanasia.

World Organization for Animal Health

The OIE identifies 10 general principles to consider when killing animals for disease control:

1. Personnel must be trained and competent in the humane killing of animals.
2. Operation procedures should be considered to adjust for welfare, aesthetics, costs, operator safety, biosecurity, and environmental impacts.
3. Killing should occur as soon as possible, and normal care and husbandry should be continued until time of death.
4. Animal handling and movement should be minimized and follow welfare guidelines for such movement.
5. Restraint of animals should be minimized before killing, but sufficient to provide for effective application of the method and safety of the operator.
6. Methods selected should result in immediate death or loss of consciousness, which lasts until death.
7. Young animals should be killed first for welfare purposes, and infected animals first for biosecurity purposes.

8. Animal welfare, operator safety, and biosecurity should be continuously monitored.
9. A written report must be completed detailing all procedures implemented.
10. These principles should also be applied in the case of a disaster or mass culling for reasons other than disease (OIE, 2007b; OIE, 2012c).

American Veterinary Medicine Association

In the 2013 Edition of the AVMA Guidelines on Euthanasia, techniques are defined as either acceptable, acceptable with conditions, adjunctive (should not be the sole method used), or unacceptable (Shearer, Griffin, Reynolds, & Johnson, 2013; AVMA, 2013a). Acceptable indicates the method, when used independently of any other method, will consistently produce a humane death. Acceptable with conditions indicates that a method may require certain conditions in order to consistently result in humane death, can create greater opportunity for operator error or safety hazard, is not scientifically well-documented, or requires a secondary method to be used in combination. These methods are considered equivalent to acceptable methods when all criteria are met. Unacceptable methods are seen as inhumane in all situations or pose a substantial human safety risk (AVMA, 2013a).

Specifically in the case of mass euthanasia during an animal health emergency, the AVMA Guidelines on Euthanasia acknowledge euthanasia options are limited (Alphin, Rankin, Johnson, & Benson, 2010). "Under unusual conditions, such as disease eradication and natural disasters, euthanasia options may be limited. In these situations, the most appropriate technique that minimizes human and animal health concerns must be used" (APHIS, 2012c, p. 5-37). Previous AVMA Panels on Euthanasia noted the need for additional research and guidance on euthanasia methods for animal emergencies and mass depopulation efforts. While some acceptable euthanasia techniques may be appropriate for mass depopulation, not all depopulation methods may be appropriate for daily euthanasia activities, such as the use of water-based foam as a tool for depopulation of chickens. When the updated AVMA guidelines were released in 2013, the decision was made to create separate documents on Mass Depopulation and Humane Slaughter because applicable methods may not always fit under the traditional euthanasia technology guidelines (Shearer et al., 2013; AVMA, 2013a). At the time of this dissertation, a draft of the mass depopulation document was not available.

The most appropriate depopulation technique needs to minimize human and animal health concerns. The most likely options include CO_2, gunshot, penetrating captive bolt, and cervical dislocation. Any method considered should be on the AVMAs acceptable or, at minimum, acceptable with conditions lists. Acceptable with conditions (previously referred to as conditionally acceptable) methods may not produce humane death, so those methods should only be used when all acceptable options have been considered and determined to be infeasible. There may be viable methods that have not been reviewed by the AVMA. Some AVMA-approved methods are not practical in a mass euthanasia situation. The role of proper training in minimizing animal pain and stress cannot be overemphasized with any method (NAHEMS, 2004; NAHEMS, 2011b; AVMA, 2013a).

Considerations for method selection

In addition to the general considerations for method selection, other aspects need to be considered in a mass euthanasia situation. In regard to personnel, the availability of sufficiently trained professionals with the necessary experience and skill must be considered. The attitude of the personnel is also critical; they have to take personal responsibility for handling all animals in the most humane manner possible. Personnel safety must also be considered. The emotional impact of the method on personnel, owners, and observers should also be considered. Euthanasia should be conducted in a location that ensures public safety and is removed from public view. The site of euthanasia will also be influenced by the desire to limit potential disease spread, protection of property and other animals, and availability of facilities and equipment. Proper handling and restraint is critical to minimizing animal pain and distress, as well as personnel safety (NAHEMS, 2004).

The AVMA Guidelines identified a number of considerations as important when evaluating methods of euthanasia in any scenario. The NAHEMS guidelines and the OIE guidelines specifically note important considerations in the case of mass euthanasia and the selection of depopulation methods. These considerations are listed in Table 2.2

The sequence of euthanasia should take into consideration the risk the animals have for continuing to spread disease. The priority for euthanasia should be: (1) animals with greatest chance to spread disease (swine shed FMD in a greater concentration than cattle), (2) animals showing clinical disease signs, (3) animals having been in contact with diseased animals, (4) animals in areas determined to be of high risk, and (5) animals susceptible to the disease of concern. The sequence will be influenced by humane and handling issues. Before euthanasia, animals must be appraised for eventual compensation (NAHEMS, 2004; NAHEMS, 2011b).

Table 2-2 *Considerations for Selection of Euthanasia Method*

AVMA	OIE	NAHEMS
• Ability to induce loss of consciousness and death with minimal pain and distress (previously stated as without causing pain, distress, anxiety, or apprehension); • Time required to induce loss of consciousness; • Reliability; • Safety of personnel; • Irreversibility; • Compatibility with intended animal use and purpose; • Documented emotional effect on observers operators; • Compatibility with subsequent evaluation, examination, or use of tissue; • Drug availability and human abuse potential; • Compatibility with species, age, and health status; • Legal requirements; • Environmental impacts of the method or disposition of animal remains; • Ability to maintain equipment in proper working order; and • Safety for predators/scavengers should the carcass be consumed (AVMA, 2001; AVMA 2007; AVMA, 2013a).	• Minimal handling and movement of animals; • Ability to stay on infected premises for depopulation purposes; • Species, number, age, size and order of depopulation; • Methods and costs; • Housing, husbandry practices, location of animals, and accessibility to farm or ranch; • Training of personnel; • Availability and effectiveness of necessary equipment's; • Time needed to complete depopulation; • Access to necessary facilities; • Biosecurity and environmental concerns; • Health and safety of personnel; • Legal issues; • Location of nearby premises with animals; • Ability to remove, dispose and destroy carcasses; and • Minimize negative welfare impacts on the animals. (OIE, 2012c).	• Ability of method to quickly induce consciousness and death with minimal pain, stress, or anxiety; • The number of steps required in the process, or economy of manipulation; • Availability, reliability and irreversibility of method; • Training and expertise available; • Disease virulence and risk of spread; • Personnel safety; • Biosecurity; • Legality in the jurisdiction; • Ability to implement with appropriate professional standards; • Species, size, and weight of animals; • Number of animals; • Premise location; • Housing, facilities, and location of animals; • Need for specialized equipment; • Public acceptance; • Weather conditions; • Environmental concerns and hazards; • Animal restraint requirements; • Sample contamination; • Disposal plans; • Compatibility with plans for carcasses (evaluation, disposal, or utilization); • Other considerations to meet the unique characteristics of the situation (NAHEMS, 2004; NAHEMS, 2011b).

Note. Adapted from AVMA (2001), AVMA (2007), AVMA (2013a), OIE (2012c), NAHEMS (2004), NAHEMS (2011b).

General welfare implications

Dr. Temple Grandin identified five basic causes of animal welfare problems in slaughter plants. These can be applied to any emergency euthanasia experience as well. They are:

- Stressful equipment and methods,
- Distractions that impeded animal movement,
- Lack of operator training,
- Poor equipment maintenance, and
- Poor condition of animals (Grandin, 1994; Grandin, 1996).

Grandin also notes that the single greatest factor in maintaining good animal welfare is the attitude of the handler and decision maker. Therefore, all animal emergency plans must consider animal welfare in the decision and policy process. Ethical considerations must be included, especially when dealing with healthy animals. In addition to the killing itself, handling should be as stress free as possible. The degree of restraint, handling methods, and level of human activity necessitated by the euthanasia method will all impact the animal. The animals' previous experience with human handling, tolerance of humans, and degree of domestication will have an influence on the welfare effect of the method used and should be considered in method selection. All handling and killing policies must follow animal welfare regulations at the local, state, and federal levels (AVMA, 2001; Grandin, 1994; Grandin, 1996; AVMA, 2013a). "Judicious use of euthanasia is essential to achieving appropriate welfare" (Department of Animal Welfare [DAW], 2002a).

Euthanasia methods must result in immediate death. A short period (no longer than 20 seconds) of muscle contraction may occur. It is essential that death be confirmed by absence of breathing, heartbeat, and blinking response (corneal reflex) before disposal. Animals should be monitored for several minutes following dispatch (CAW, 2003; AVMA; 2001; DAW, 2002a).

"The need to minimize animal distress, including fear, anxiety, and apprehension, must be considered when determining the method of euthanasia" (AVMA, 2001, p. 674). Even in the case of a disease outbreak and imminent mass euthanasia, livestock should receive humane handling. They should be provided appropriate shelter from the weather, feed and water at least once every 24 hr, and facilities should be clean and safe. Transportation should be humane, safe, and low stress. Animals should be moved at normal speeds with limited use of prodding equipment. No methods to move animals that increase pain or stress should be utilized (Emory, 2003).

It should be the goal of mass depopulation efforts to provide humane handling throughout the process. The Food Safety and Inspection Service (FSIS) defines a systematic approach to humane handling as "a focus on treating livestock in such a manner as to minimize excitement, discomfort, and accidental injury the entire time they hold livestock in connection with slaughter" (Food Safety and Inspection Service (FSIS), 2013, p. 4).

Types of Euthanasia

Euthanasia can occur in one of three ways:

- Hypoxia, direct or indirect;
- Direct depression of neurons necessary for life function; and
- Physical disruption of brain activity and destruction of neurons necessary for life (AVMA, 2001).

The first group of agents utilized for direct or indirect hypoxia cause loss of consciousness at various rates. Loss of consciousness should occur before loss of motor activity to ensure a painless and distress-free death. Agents that cause muscle paralysis before loss of consciousness are not considered acceptable. Some muscle activity can occur as a reflex and is not perceived by the animal. The second group of agents induces loss of consciousness by depressing nerve cells of the brain. Vocalization and muscle contraction may occur during the first stage of anesthesia. Loss of consciousness is followed by death, attributable to cardiac arrest or hypoxemia. With the third group of agents, rapid loss of consciousness is induced by physical disruption of brain activity. This disruption can occur as a result of concussion, direct brain destruction, or electrical depolarization of neurons. Death is a result of killing the animal by an adjunctive method or the destruction of the mid-brain centers controlling cardiac and respiratory functions. Loss of consciousness can be followed by muscle movements in the animal, of which it is unaware (AVMA, 2001).

Physical methods

While most physical methods of euthanasia are aesthetically displeasing, they may be the most appropriate and humane methods available and may provide the most rapid relief of pain and suffering. The most humane methods may be in direct conflict with the most aesthetic methods (AVMA, 2013a).

Mechanical devices may stun or kill by laceration, crushing, shock waves, or temporary cavitation. Personnel must be well trained and sensitive to aesthetic implications. Most physical methods are considered conditionally acceptable (AVMA, 2001). Physical methods, such as neck dislocation or decapitation, should only be applied to poultry species (SVC, 1997). Penetrating captive bolt and gunshot are the most practical methods in mass euthanasia of animals 200 pounds or larger (NAHEMS, 2004; NAHEMS, 2011b).

According to the AVMA, "When properly used by skilled personnel with well-maintained equipment, physical methods of euthanasia may result in less fear and anxiety and be more rapid, painless, humane, and practical than other forms of euthanasia" (2013a, p. 34-35).

Penetrating captive bolt

A captive bolt gun is powered by gunpowder or compressed air and penetrates the skull causing concussion and trauma to the cerebral hemisphere and brainstem. Adequate restraint (or an animal that is incapacitated by injury) and accurate placement are critical to achieving sufficient brain disruption to cause sudden loss of consciousness and subsequent death. The welfare implications of the restraint process, shooting position, and feasibility warrant greater consideration of animal welfare. Effective euthanasia is dependent on both the concussive force and brain penetration (SVC, 1997; AVMA, 2001; AVMA, 2013a; DAW, 2002a; DAW, 2002b). Multiple projectiles are recommended for large ruminants. A device that delivers some compressed air unto the skull after the bolt will increase efficiency (AVMA, 2013a).

Penetrating captive bolt is an acceptable and practical method for cattle, horses, sheep, swine, and poultry when followed by pithing or bleeding. It is an effective method for slaughter houses, research facilities, and farms. Its advantages are that it induces immediate unconsciousness and reduces the need to move livestock if a mobile process is used. However, the disadvantages are that it is aesthetically displeasing, problems may occur if equipment is not maintained or used properly, post-stun convulsions can be dangerous in large animals, it is difficult to use with agitated animals, the guns can overheat, and damage to brain tissue may limit diagnostic capability. Air-injection captive bolt may not be used on animals entering the food chain because of the concern that specified risk material will contaminate the meats (OIE, 2012c; AVMA, 2013a). An adjunct measure (exsanguination) is recommended for use to guarantee rapid death and eliminate the possibility the animal could regain consciousness. Hiring individuals who use captive bolt methods at local slaughter plants would ensure the necessary experience and handling (NAHEMS, 2004).

USDA APHIS has invested in research at Iowa State University on a portable pneumatic captive bolt device to be used for mass depopulation of beef and dairy cattle. It includes auto-pithing by air injection, ensures a high fatality rate, removes carcasses through a side-drop stanchion, and is being designed to work with a center-line conveyer system. At Oklahoma State University, researchers funded by USDA APHIS have evaluated the use of the Cash (pistol grip) Special Extended Captive Bolt for use in depopulation of small cattle herds in remote locations. This system has also been explored for use with swine with both penetrating and non-penetrating heads (Styles, 2012).

Gunshot

If properly placed and performed by highly skilled personnel, a gunshot can provide a humane and immediate death. Fire-use regulation and the safety of nearby public, personnel, and other animals need to be considered. The use of a firearm may be the most humane choice if the animal is only partially mobile and movement to a restraining chute would cause additional suffering (AVMA, 2013a; DAW, 2002b). The firearm should be aimed such that the projectile enters the brain. If the projectile destroys most of the brain, loss of consciousness and death is immediate. Occasionally, the brain may not be destroyed, and the unconscious animal will need to be bled immediately. However, bleeding animals is not likely possible in a disease control situation. Using hollow point or soft nose bullets enhances the expansion on impact and results in greater tissue destruction (SVC, 1997; DAW, 2002a; DAW, 2002b; AVMA, 2013a).

Depending on the situation, gunshot may be the most practical and logical euthanasia method. It is considered suitable for cattle, sheep, goats, and pigs. The advantages of gunshot include that it is quick, effective, requires minimal restraint, can be used from a distance, and can be implemented with agitated animals in open spaces (OIE, 2012c). Disadvantages include danger to personnel, unpleasant aesthetic impact, difficulty to perform, legal barriers, limited availability of trained personnel, potential for non-lethal wounding, and non-availability of brain tissue for future research (OIE, 2012c; AVMA, 2013a). If animals can be restrained, penetrating captive bolt is a preferred method. Gunshot should not be used for routine euthanasia (AVMA, 2013a).

In the case of both gunshot and captive bolt, the presence of a uniformed law enforcement officer on location where firearms are being used will help allay public concerns. All individuals using firearms must be approved in writing by the incident commander. If gunshot is the approved method, the NAHEMS guidelines dictate appropriate caliber of firearms, type and weight of projectiles, velocity, muzzle energy, and other specific recommendations (NAHEMS, 2004). Military and law enforcement professionals may be designated to assist with gunshot euthanasia upon Governor's request. Most state highway patrols would have the necessary equipment and training. Public perception is likely to be of concern, as will be the noise level. The use of silencers may be advantageous for animal stress, public relations, and personnel emotional response. In cases where open range euthanasia must occur, it may be possible to use anesthetic darts followed by euthanasia (Jones, 2003). Canadian researchers have noted that .22 caliber bullets may result in poor penetration, deflection, and bullet fragmentation at a distance of 82 ft (25 m) (Shearer et al., 2013). Researchers at Kansas State University have studied appropriate caliber and ammunition to be used at a distance of 30 ft. Further research is anticipated on live animals and in noise suppression (Styles, 2012).

Stunning (blunt force trauma)

Stunning can be performed by a blow to the head, non-penetrating captive bolt, or electric current. It must be followed immediately by a process that ensures death (SVC, 1997; DAW, 2002a).

Non-penetrating captive bolt induces immediate onset of unconsciousness and will cause death in neonates and poultry. The mobility of the equipment is an advantage. However, disadvantages include that consciousness can be regained quickly in non-neonates, birds need to be moved from cages and restrained, poor gun maintenance can lead to issues in use, post stun convulsions can create difficulties, agitated animals create additional challenges, the gun may overheat, and bleeding may be a security risk (OIE, 2012c). While some sources indicate non-penetrating captive bolt is acceptable and will induce an unconscious state in ruminants, horses, and swine (SVC, 1997; DAW, 2002a), the OIE recommends it be used only for poultry, and neonate sheep, goats and pigs weighing up to 10 kg (22-23 lbs) (OIE, 2012c).

To stun, an animal must be immobile, incapacitated by injury, or restrained in a chute. The process involves using a heavy hammer or maul to impose a stout blow along the front of the skull between the eyes and ears. It should only be used if a single blow delivered to the skull can cause immediate depression of the central nervous system and destruction of brain tissue, including stoppage of all life processes, especially heartbeat and respiration (AVMA, 2001; DAW, 2002b). A blow to the head with a blunt object is an acceptable method of euthanasia for neonatal animals with thin craniums (young pigs). The anatomic features of the specie determine if a blow to the head is acceptable. Personnel must be properly trained and aware of the aesthetic implications (AVMA, 2001; DAW, 2002a). Blunt trauma has been found conditionally acceptable by AVMA for pigs less than 3 weeks of age, but it is not recommended by the OIE (NAHEMS, 2011b). Electrical stunning has been used for stunning dogs, cattle, sheep, goats, hogs, fish, and chickens. It involves applying an electrical current across the head of the animal to induce a temporary loss of consciousness (SVC, 1997; DAW, 2002a).

Cervical dislocation

This technique is often used for small animals, especially poultry, and is believed to be humane if performed by well-trained operators. The goal is to separate the cervical vertebrae from the skull. It is commonly done by hand with a stretching process that causes concussion in the brain leading to loss of consciousness. Loss of consciousness may not be immediate, but does occur rapidly. Neck stretching results in death by cerebral ischemia, and neck crushing results in death by asphyxia. It is a quick process to perform, and the remaining tissue is not contaminated. Cervical dislocation is not an aesthetically pleasing method, and rapid induction of unconsciousness requires that personnel have mastered the necessary technical skills. Even with proper application, the animals will convulse for several seconds to minutes after death. The welfare concerns are due to questions regarding its effectiveness and consistency, and the use of pliers must be avoided. Little scientific research has been done to confirm the humaneness of this method (SVC, 1997; AVMA, 2001; AVMA, 2013a; Gullett, 1987). Cervical dislocation is non-invasive and can be performed manually. Personnel need to be well trained, will become fatigued, and will face health and safety concerns. It is also more difficult with larger birds and creates greater stress on animals from handling (OIE, 2012c).

Electrocution

Death by electrocution occurs by using alternating current to induce cardiac fibrillation and cerebral hypoxia. Because animals may not lose consciousness for 30 seconds, operators should first render the animals unconscious by an acceptable process, such as electrical stunning.

In some cases, an effective one-step process is used for sheep and hogs. Euthanasia by electrocution is economical, does not contaminate the tissues, and is humane (if the animal is unconscious) (AVMA, 2001; AVMA, 2013a). There is little biosecurity risk, but a reliable supply of electricity is necessary, electrodes must be applied correctly to be effective, and it is physically demanding (OIE, 2012c).

There are a number of disadvantages to euthanasia by electrocution, including the fact it is dangerous to operators, time-consuming per animal, aesthetically unfavorable, and often ineffective in small animals. Restraint may be challenging and purpose-built equipment and trained personnel are necessary (AVMA, 2013a; OIE, 2012c). Often in field conditions, a considerable number of animals are not effectively stunned and require a second stun. This process is not appropriate for animals under 1 week of age (SVC, 1997). OIE considers electrocution suitable for calves, sheep, goats, and pigs over 1 week of age (OIE, 2012c). Appropriate equipment and personnel training are required, and electrocution techniques that apply electrical currents to the head first are unacceptable (AVMA, 2001). An electrified water bath can be used for poultry species if the strength of electric current is high enough to kill animals immediately. Each bird in the bath must receive the minimum required current and pre-kill shocks must be non-existent (SVC, 1997). There are cases where birds hanging from shackle lines were flapping their wings and missed the electrical water bath and death was not induced (Raj, 2008). Mobile equipment to be used in the mass euthanasia of poultry has been developed and should be considered in the case of a large scale poultry disease (NAHEMS, 2004). Meat Processing Systems, Inc. has developed a mobile electrocution unit for swine mass depopulation that can process 600 head of swine per hour. It was used in Poland in 2011 and USDA AHPIS National Veterinary Stockpile (NVS) is planning to acquire units retrofitted for the U.S. market (OIE, 2012c).

Water-based/fire suppression foam

This method has been developed for mass emergency poultry depopulation. USDA APHIS conditionally approved its use with floor-reared birds infected with a potential zoonotic disease or rapidly spreading infectious disease in 2006 (Benson, Alphin, Dawson, & Malone, 2009). The advantages of the foam method are its speed, minimal animal handling requirements, and low personnel needs. In the 2007 AI outbreak in Virginia and West Virginia, foam was utilized as a method of depopulation by both a large, skid mounted system as well as hand held foam generating system connected by hose and nozzle to a water and foam supply. It was an effective method, and especially successful when combined with composting as a disposal method (Flory & Peer, 2009). Foam physically induces hypoxia rather than hypoxia being induced through a reaction to a chemical gas. Several firefighting foams meet biodegradability requirements and may be suitable for use. The foam process also adds water to the remains, thus aiding in composting (Benson et al., 2007).

Foam is generated by medium or high expansion generation equipment to create a blanket of foam over the birds. Foam leads to a rapid onset of airway occlusion which brings about cessation of heart and brain activity. Its use reduces the number of personnel needed and limits human exposure to the disease. Water-based foam has been proven effective on turkeys, broilers, quail, chukar, and ducks. Because waterfowl are capable of holding their breath, additional exposure time is required. Exposure time remains fairly consistent with foam, unlike gassing where the number of birds increases time needed for exposure until cessation of activity. Foam requires significantly less time to cessation than CO_2 with similar stress effects (Benson et al., 2009).

Dry foam has also been developed that includes an inert gas (Benson et al., 2009). Some research has indicated that dry foam with an inert gas that causes unconsciousness prior to death may be more humane than water-based foam. Water-based foam can create welfare concerns as it can be seen as a form of suffocation. Because time to unconsciousness indicates the length of time an animal may suffer, methods have been compared to determine if there are significant differences between gas and foam. Researchers have found that there is no need to add CO_2 or inert gas to the foam because either method still results in the bird being killed by the foam consistently (Alphin et al., 2010). However, in comparing foam to the traditional use of CO_2 gas, researchers found that with ducks 5 to 9 weeks of age, onset of unconsciousness, brain death, termination of cardiac activity, duration of bradycardia, and time from bradycardia to unconsciousness were all shorter with CO_2 than foam. When tested with ducks 8 to 14 weeks of age, there were no significant differences except with brain death and duration of bradycardia, which were faster with CO_2. When atropine injections were used with foam, all observed physiological responses were faster (Caputo et al., 2012). Foam is no more stressful than gas when comparing corticosterone levels and foam becomes faster than gas as number of birds increase (Benson et al., 2007). Animal rights activists continue to express concern over the humaneness of foam as a depopulation method and refer to researchers who have indicated that birds show escape behavior, are difficult to observe when enveloped in the foam, and may just eventually get worn out and suffocate (Davis, 2006). USDA APHIS has concluded, when comparing gas and foam, there are comparable times to death with similar behavioral responses and cortisol concentrations (Styles, 2012).

There are currently two types of foam systems, a high expansion foam system developed by the University of Delaware, and a medium expansion foam system developed by the North Carolina Department of Agriculture. A third type, a compressed air foaming system, is under development at Texas A&M University that uses less water, acts as a disinfectant, and could be used with caged birds (Styles, 2012). While not listed in the AVMA Guidelines on Euthanasia, AVMA issued a policy document in 2013 supporting the use of water-based foam if appropriate conditions are met. It can be used in cases of floor-reared poultry, HPAI infected poultry, animals infected with a rapidly spreading disease that cannot be contained by traditional means, or poultry housed in structurally unsound buildings that are unsafe for humans to enter. The policy clarifies that while water-based foam is an acceptable method of mass depopulation, it is not an acceptable form of traditional euthanasia (APHIS, 2012d; AVMA, 2013b).

Decapitation

Severing the head from the body induces immediate central nervous system depression. It can be used for poultry that are too large for cervical dislocation. The equipment used (heavy knife, machete, hatchet, or bolt cutters) must ensure the spinal cord is severed. This method is considered acceptable with conditions if used in appropriate settings and performed correctly. It induces rapid loss of consciousness and does not chemically contaminate the brain tissue. The necessary handling and restraint can be distressful, and the guillotine process is aesthetically displeasing. In addition, questions regarding the electrical activity in the brain following decapitation remain controversial (AVMA, 2001; AVMA, 2013a). Decapitation can occur inadvertently if neck dislocation is carried out with force (SVC, 1997). The NAHEMS guidelines do not include decapitation (NAHEMS, 2004). OIE does include decapitation and identifies the advantage as being effective without required monitoring. Biosecurity risks are created by contamination of working area with bodily fluids and the animals feel pain if consciousness if not immediately lost (OIE, 2012c).

Microwave irradiation

Focused beam microwave irradiation is a humane euthanasia method for small research animals if appropriate instruments are used. The process rapidly halts brain enzyme activity while maintaining the anatomic integrity of the brain. Loss of consciousness occurs quickly, but instrumentation is expensive and only appropriate for small animals (AVMA, 2001; AVMA, 2013a). The NAHEMS guidelines do not include microwave irradiation (NAHEMS, 2004).

Thoracic (cardiopulmonary, cardiac) compression

Thoracic compression is applicable to avian euthanasia when other methods are not practical. It can also be used with small wild animals. The method involves stopping the heart and lungs by pressure from the operator's hands. The technique is rapid and does not contaminate the carcass. Some research indicates it can cause substantial pain and distress, but field biologists have used it and have argued it to be apparently painless. Thus, the level of distress is questionable, and it is not aesthetically pleasant. It is considered unacceptable unless animals are deeply anesthetized or insentient (AVMA, 2001; AVMA, 2013a). The NAHEMS guidelines do not include thoracic compression (NAHEMS, 2004).

Kill traps

In many cases, kill traps do not meet effective euthanasia criteria. They are often used for the collection and killing of small, free-ranging mammals for commercial, scientific, property protection, or human safety purposes. They are considered controversial, because they do not always provide a rapid loss of consciousness or stress-free death. New technologies being used in kill traps result in a faster loss of consciousness. Live traps combined with another euthanasia method may be more preferable, but the human contact associated with live traps may actually be a more stressful experience (AVMA, 2001; AVMA, 2013a). The NAHEMS guidelines do not include kill traps (NAHEMS, 2004).

Maceration

The use of a mechanical apparatus with rotating blades or projections that causes immediate fragmentation is known as maceration. It results in immediate death and can handle large numbers quickly. It requires specialized equipment, the tissues may create a biosecurity risk, and cleaning the equipment can lead to contamination. OIE indicates it can be used for day-old poultry and embryonated eggs (OIE, 2012c). AVMA indicates maceration can be used on poultry up to 72 hr old (AVMA, 2013a). In addition, according to the Center for Animal Welfare at UC-Davis, maceration in a high-speed grinder imposes a rapid death and is considered humane for disposing of young chicks and embryonated eggs. Only grinders designed for poultry disposal should be used, and they must be properly maintained and loaded (CAW, 2003).

Advantages include instantaneous death, limited risk to workers, and ability to kill large numbers quickly. Disadvantages include that special equipment is needed, equipment must be kept in excellent condition, personnel must be well trained, macerated tissue could create a biosecurity risk, and public reaction is likely negative. A backlog of chicks must be avoided as suffocation, injury, and distress will occur if birds pile up prior to maceration (AVMA, 2013a).

Adjunctive methods

Exsanguination and pithing are used in combination with other methods to ensure death, but these methods should not be used independently from other methods. Exsanguination involves bleeding out the animal by puncturing the vena cava or cutting the brachial or carotid arteries and should be used in combination with stunning or on unconscious animals. Pithing is done by inserting a pithing rod or tool into the entry site created by penetrating captive bolt or bullet. It should not be used for ruminants due to the concern that specified risk material may contaminate meat. Adjunct measures can be used in combination with stunning or other methods that render the animal unconscious, but should never be used as the sole method (AVMA, 2001; AVMA, 2013a; DAW, 2002a).

Chemical methods – Inhalants

In order to be effective, any gases inhaled by an animal much reach a certain concentration in the alveoli. The AVMA (2013a) notes that the suitability of an agent depends on whether an animal experiences distress between the time it begins to inhale the agent and the time it loses consciousness.

A few considerations apply to all inhalant agents. The considerations include:

- Exposing the animal to a high concentration of the inhalant is more humane and loss of consciousness is more rapid.

- The equipment used for delivery of inhalant must be working properly and in regulatory compliance.
- Most inhalants are hazardous to humans.
- Agitation is more likely in cases where the animal has decreased ventilation and alveolar concentration rises slowly.
- Neonatal animals are resistant to hypoxia and take longer to die than adults.
- Equipment with rapid gas flows can make noises that cause animals to experience distress.
- Time to unconsciousness depends on displacement rate, container volume, and concentration.
- Inhalants must be in pure form with no contaminants or adulterants and should be produced with an effective displacement rate and concentration.
- Chambers need to be leak free, and layering and loss of agent must be avoided.
- Animals should be penned with similar species, safely restrained, and kept in chambers that are clean and not over-populated. Every effort should be made to reduce any distress felt by the animals prior to euthanasia.
- Reptiles, amphibians, and diving birds and mammals can prolong the time between taking in the inhalant and losing consciousness, because of their ability to hold their breath.
- Death must be verified (AVMA, 2001; AVMA, 2013a).

While the use of chemical methods seems more humane than most physical technologies, it is effectively limited to intravenous administration because broadcast application endangers humans, the environment, wildlife, and other animals. In the case of mass euthanasia, chemical methods also create additional dilemmas with carcass disposal (NAHEMS, 2011b).

Inhalant anesthetics

Anesthetic vapor is inhaled causing the cessation of respiration followed by death. A few of the most common inhalant anesthetics are ether, halothane, methoxyflurane, isoflurane, sevoflurane, desflurane, and enflurane. Because it works rapidly, halothane is the most effective inhalant for euthanasia. Factors impacting the choice of an inhalant include blood solubility, potency, vapor pressure, odor (animals may hold their breath), and speed of induction. Each characteristic varies per inhalant. The animal should be exposed to the inhalant in vapor form in a closed chamber. Nitrous oxide (N_2O) can be used in conjunction with an inhalant to speed anesthesia, but should not be used independently. One advantage of these inhalants is their appropriateness for small animals. In addition, most of them are nonflammable and nonexplosive under normal conditions. There are several methods for administration, and they can be used independently or in a two-step process. The disadvantages are that the animals may struggle or become anxious during inhalation, ether is both flammable and explosive, inhalants can often be dangerous to humans, and it creates tissue residue in food-producing animals (AVMA, 2001; AVMA, 2013a). It is possible for animals to go through an excitement phase with vocalization and appearance of struggling or to seizure as the anesthesia takes effect. This can be disturbing to personnel (Gullett, 1987).

Carbon dioxide

Inhalation of carbon dioxide (CO_2) at high rates induces a rapid anesthetic effect. It can be an effective method for small or young animals (piglets, poultry). Effective CO_2 anesthesia results in the same signs as those associated with surgical anesthesia (loss of withdrawal and palpebral reflexes) and cause an abrupt loss of consciousness and subsequent death due to respiratory arrest (AVMA, 2013a; DAW, 2002a). CO_2 can be administered through multiple methods, including placing animals in a gas-filled container, use of a containerized gassing unit, and introducing gas into an existing structure, such as a poultry house (OIE, 2012c).

Use of a gassing container means birds will have to be caught and carried by their legs to the container, which creates an additional welfare concern. It is also important that birds do not die due to compression or suffocation because too many live birds have been dropped into the container without adequate intervals in between loads (Raj, 2008).

The time between inhalation and loss of consciousness will decrease with higher concentrations of CO_2 or if the animal is immersed in the full concentration of CO_2 immediately (AVMA, 2001). Practical experience with poultry indicates that animals should be immersed in a maximum concentration of CO_2 as rapidly as possible to reduce reaction to the gas and time to loss of consciousness. However, some research indicates that inhalation of CO_2 at high concentrations can be distressing to animals by creating carbonic acid on the nasal mucosa, so more research is necessary regarding the welfare aspects of the induction phase (SVC, 1997;

AVMA, 2013a). For welfare purposes, it is important for systems to be operated so that birds are not directly hit by the cold gas being delivered at high pressures into a facility (Raj, 2008).

Advantages of carbon dioxide include that its rapid, analgesic, and anesthetic effects are well documented; it is readily available, inexpensive, nonflammable, non explosive, and poses minimal hazard to personnel; there is no accumulation of tissue residues; and it does not distort corticosterone concentrations. However, because CO_2 is heavier than air, animals may climb above the exposed area if the chamber if not completely filled. Some animals (fish and burrowing and diving mammals) are extremely tolerant to CO_2. Some species may experience significant distress. In addition, exposure to CO_2 may take longer to induce euthanasia than other methods and is more appropriate for some species than others (SVC, 1997; AVMA, 2001; AVMA, 2013a). Swine, as an example, demonstrate transient muscle spasms prior to death, which is likely a physiologic response rather than a sign of stress. Stress gene negative pigs exhibit less intense spasms than stress gene positive pigs (AASP, 1997).

In the case of mass euthanasia, the limitation is usually in the existence of chamber or troughs that allow for animals to be totally submerged. In no case, should dry ice, fire extinguishers, or chemically generated CO_2 be used (NAHEMS, 2004). Liquid CO_2 was used in an AI outbreak in British Columbia in 2002, but that action was criticized for delivery method, efficiency, and humaneness. Since then, there have been improvements in gas delivery manifold, and whole-barn gassing is considered more humane and biosecure than methods that require significant handling such as mobile chambers (Turner et al., 2012). OIE identifies CO_2 as acceptable for use with poultry and neonatal sheep, goats, and pigs, depending on method selected (OIE, 2012c).

It is difficult to reach a rapid and consistent CO_2 concentration in field conditions (Alphin et al., 2010). USDA APHIS has invested in the development of a modified atmosphere killing (MAK) trailer for portable gassing of small flocks of chickens, and they have funded the development of on-farm and mobile gassing units for swine at North Carolina State University (Styles, 2012).

Carbon monoxide

Carbon monoxide (CO) is also a colorless and odorless gas. CO induces unconsciousness and death through cerebral anoxia (SVC, 1997). It is nonflammable and only explosive in concentrations greater than 10%. Exposure to CO leads to fatal hypoxemia by combining with hemoglobin and blocking the uptake of oxygen. The recommended CO source for euthanasia purposes is commercially compressed CO in cylinders, while CO from chemical interaction or exhaust fumed from gasoline combustion engines are not considered acceptable. In research with dogs, some agitation and vocalization occurs prior to loss of consciousness, but tranquilization with acepromazine decreases these types of responses. CO leads to an unconscious state without pain or extensive discomfort. The animal appears to be unaware of the onset of hypoxemia, and death occurs rapidly if concentrations of 4 to 6% are used. However, CO is highly toxic and difficult to detect, causing significant hazard to personnel (AVMA, 2001; AVMA, 2013a).

CO is considered acceptable for individual or mass small animal euthanasia if compressed CO is used and guidelines are closely followed (AVMA, 2001). The chamber where animals are exposed should be designed, constructed, and maintained to ensure animals can be supervised and will not be at risk of injury (SVC, 1997). In the case of mass euthanasia, CO would be effective if large, air-tight chambers are available. Due to the human hazards, use of CO must be closely monitored and no delivery method other than industrial CO cylinders should be considered (NAHEMS, 2004).

Nitrogen and argon

Both nitrogen (N_2) and argon (Ar) are colorless, odorless, nonflammable, and nonexplosive, and they can be used with swine and poultry in an oxygen-excluding manner (SVC, 1997; AVMA, 2013a). They are used for euthanasia by placing the animal in a closed container that is either pre-filled or filled rapidly with gas that induces death by hypoxemia. Dogs exposed to N_2 lose consciousness within 76 seconds if N_2 concentration of 98.5% is achieved within 1 min. They have a tendency to hyperventilate before losing consciousness, and they experienced vocalizations, gasping, convulsions, and muscular tremors following loss of consciousness. Researchers concluded the method induced death without pain. However, in a study conducted with rats, they showed signs of stress and panic prior to becoming unconscious and insensitivity to pain was questioned. Researchers exposed swine and poultry to Ar and found that the exposure did not appear to cause distress. In fact, it was found to be humane for chickens. Both Ar and N_2 are readily available, and the hazards to personnel are minimal. However, the level of stress experienced by the animal is in question, and exposing the animals to a low concentration of oxygen before death can cause recovery. Ar and N_2 should only be used if low concentrations of oxygen are reached quickly, animals are heavily sedated, and the chamber poses no possibility for injury (AVMA, 2001; AVMA, 2013a). Typically, birds are unable to detect the presence of N_2 or Ar (Alphin et al., 2010).

These gases are suitable for use with poultry and neonatal sheep, goats, and pigs. N_2 or inert gas such as Ar can also be mixed with CO_2 and used in a gas-filled container or containerized gassing unit on the same species (OIE, 2012c). This combination is seen as a more humane gassing procedure and causes less bird reaction when compared to CO_2, but requires an airtight container and is impractical in large poultry houses (Alphin et al., 2010).

Hydrogen cyanide

In research done in Europe, hydrogen cyanide was tested and found to result in rapid death for poultry. However, there are clearly worker safety and human health risks (Raj, 2008). There are considerable welfare concerns related to the use of hydrogen cyanide, because it causes violent convulsions prior to loss of consciousness and death, and it blocks the oxygen uptake causing respiratory difficulties. Birds also develop rapid rigor making for difficulty in removing carcasses from cages (Raj, 2008; SVC, 1997). It is used in certain member states in the European community (SVC, 1997).

Chemical methods – Lethal injections

The most rapid, desirable, and reliable euthanasia method is the use of intravenous injections that do not cause fear or distress in the animal. Death, unconsciousness, or central nervous system depression is caused by anesthetic or sedative drugs. These injections cause either a narcotic overdose or paralyze life functions with the use of a pharmaceutical agent. The animals should be restrained prior to injection and may require sedation (AVMA, 2001; DAW, 2002b; OIE, 2012c). The use of a syringe and needle is perceived as more refined and humane than some of the other methods (NAHEMS, 2004). If the injection process or necessary restraints cause the animals distress or put the operator in danger, then sedation, anesthesia, or other methods would be preferred. If intravenous injection is not a feasible choice, intraperitoneal administration is acceptable if the agent is nonirritating and does not contain neuromuscular blocking agents. If the animal is heavily sedated and insensible, intracardiac injection is also acceptable (SVC, 1997; AVMA, 2001). All other injection methods (e.g., intramuscular, subcutaneous, etc.) are considered unacceptable (AVMA, 2001). These methods are most commonly used in small species, although they could be used in all species (SVC, 1997).

Any product used for lethal injection must be recognized as humane and effective (NAHEMS, 2004). Injection euthanasia can be the most precise and provides the best public image. It does require a veterinarian for administration as well as drug availability in a timely manner (Meyer, 2003). The carcasses should never enter the food chain and must be disposed of in accordance with local, state, and federal laws and regulations (AVMA, 2013a). Contaminated carcasses create a risk for wild animals or other domestic animals. Lethal injection may be used with small numbers of any species, including cattle, sheep, goats, pigs, and poultry (OIE, 2012c). It should especially be considered with pet livestock (equine, pot belly pigs, goats, llamas, etc.), young animals, and pets (Meyer, 2003). In poultry houses, anesthetic or poisonous agents can also be mixed with poultry feed or water, but the feed must be palatable and not bitter to taste. To get birds to eat adulterated feed may require forcing them to fast for a period of time beyond appropriate from an animal welfare perspective. Killing may need to follow for birds that are anesthetized, but not killed (Alphin et al., 2010; OIE, 2012c; Raj, 2008).

Barbituric acid derivatives

Barbiturates are acceptable for euthanasia if administered intravenously, and they are desirable if they are potent, long-acting, stable, and inexpensive. They depress the central nervous system in descending order, and unconsciousness is reached rapidly with minimal pain. The advantages of barbiturates include speed of action, minimal discomfort for the animals, and less expense than other agents. Intravenous injection is preferred and requires animals be restrained. Personnel must be well-trained and registered with the U.S. Drug Enforcement Administration (DEA). It is possible that a terminal gasp will occur in unconscious animals or animals may experience an excitatory phase. Both reactions may be objectionable to human observers. In addition, the drugs will remain in the carcass and could cause sedation or death to any animal that consumes part of the carcass (AVMA, 2001; AVMA, 2013a).

Pentobarbital combinations

Pentobarbital metabolizes from a combination of a barbituric acid derivative, such as sodium pentobarbital and a local anesthetic agent, such as lidocaine or phenytoin. These drugs are listed on a different schedule by the DEA than barbituric acid derivatives and are simpler to obtain and administer. It is not acceptable to combine pentobarbital with a neuromuscular blocking agent (AVMA, 2001; AVMA, 2013a).

Chloral hydrate

Chloral hydrate causes death by hypoxemia. Its use requires animal restraint because chloral hydrate depresses the cerebrum slowly and death may be preceded by gasping, muscle spasms, and vocalizations. It is only considered acceptable for large animals when administered intravenously to sedated animals. Chloral hydrate is not acceptable for small animals because the aforementioned side effects may be severe and objectionable to observers. Chloral hydrate in combination with magnesium sulfate and sodium pentobarbital was a common, economical, and inexpensive agent for large animals, but is now rarely used. It must be compounded from bulk drugs as it is not available as an FDA-approved drug (AVMA, 2001; AVMA, 2013a).

T-61

This three-drug combination is an injectable, no-barbiturate, non-narcotic mixture that provides general anesthetic, coraciiform, and local anesthetic actions. T-61 is no longer available in the US, but it is available in Canada and other countries. It should only be administered intravenously (AVMA, 2001). The agent must be administered slowly because fast administration is shown to cause pain. With agents such as T-61 that include neuromuscular blocking agents, the animal must be fully anesthetized to prevent animal distress (SVC, 1997).

Tributame

This is a combination of embutramide, chloroquine phosphate, and lidocaine. The addition of lidocaine eliminated stressful responses to injections and the combination leads to a speedier death than embutramide alone. Death is caused by a combination of severe CNS depression, hypoxia, and circulatory collapse. The result is rapid onset of activity with minimal discomfort. While approved for dogs in 2005, it is not currently manufactured (AVMA, 2013a).

Potassium chloride

Potassium chloride is only acceptable when used in a supersaturated solution that is injected intravenously or intracardially into an animal already under general anesthesia. All use in unanesthetized animals is condemned. The potassium ion is cardiotoxic, and when injected rapidly, results in cardiac arrest and death. Muscle spasms or ripples may occur shortly after injection. Potassium chloride is easily obtained, transported, mixed, and not a controlled substance. The resulting carcass is potentially less toxic to scavengers and predators if carcass disposal location is a concern (AVMA, 2001; AVMA, 2013a).

Other acceptable methods

AVMA also lists tricaine methane sulfonate (MS 222, TMS), ultrapotent opoids, dissociative agents, α_2-adrenergic receptor agents, magnesium salts, chloral hydrate, alcohols, benzocaine, hydrochloride, clove oil, isoeugenol, eugenol, phenoxyethanol, quinaldine, metomidate, sodium hypochorite, and formaldehyde as acceptable methods (AVMA, 20013a).

Unacceptable injectable agents

The following injectable agents are considered unacceptable when used alone for euthanasia purposes: strychnine, nicotine, caffeine, magnesium sulfate, potassium chloride, cleaning agents, solvents, disinfectants, other toxins, salts, and all neuromuscular blocking agents (AVMA, 2001). There are some agents, such as xylazine, ketamine, succinycholine, and phencyclidine that are not appropriate for euthanasia, but may be used for chemical restraint (NAHEMS, 2004).

General considerations

The NAHEMS guidelines list two specific examples of brand-name injectable agents: Fatal-Plus® by VorTech Pharmaceuticals and Somlethol by J.A. Webster Inc. The costs of these two agents for euthanizing a 1,100-lb cow was $23.36 and $17.57, respectively (NAHEMS, 2004). Animals euthanized with chemical methods must be closely monitored to ensure that death rather than a deep anesthesia has occurred. Chemical adjunct measures, such as potassium chloride, may be appropriate (NAHEMS, 2004).

If animals are to be used for human or animal consumption, the chemical agent used must be approved by the FDA. Only carbon dioxide can be used as a chemical agent without leaving chemical residue in the tissue. If other chemical means are used, carcasses must be disposed of in such a way that prevents them from being consumed by other animals. Proper carcass disposal techniques must be selected in conjunction with the selection of the method of euthanasia (AVMA, 2001).

Each of these methods offers various advantages and disadvantages. In the case of mass euthanasia due to natural disasters or disease outbreak, euthanasia options may be limited to those methods that minimize human and animal health concerns. Primary methods may include carbon dioxide, gunshot, penetrating captive bolt, and cervical dislocation (AVMA, 2001).

Species specific considerations

The NAHEMS guidelines discuss specific considerations for different species in the case of mass euthanasia.

Cattle

The Humane Slaughter of Livestock Act in Part 313 of 9 Code of Federal Regulations (CFR) specifies captive bolt, gunshot, and electrical stunning as humane methods of cattle euthanasia (NAHEMS, 2004; NAHEMS, 2011b). In the 2013 guidelines, AVMA specifically mentions barbiturates as acceptable, and it lists gunshot and penetrating captive bolt with adjunctive methods as acceptable with conditions. Penetrating and non-penetrating captive bolt are acceptable for calves (Shearer et al., 2013). AVMA also lists injectable agents (Styles, 2012). All of these methods could be practical in mass euthanasia operations. Injectable agents may be impractical in large numbers, but should be considered when euthanizing hand-raised animals, such as 4-H or FFA projects especially if owners are present (NAHEMS, 2011b). In a survey of feedlot managers, McReynolds (2013) found toxins in the feed supply to be an option for cattle euthanasia in large feedlots. While administration may be very feasible, concerns over animal welfare and the environmental impact of carcass disposal need to be considered.

Cattle should not be moved at faster than a normal walk and the use of electrical prods or slappers should be minimized. Animals should be restrained in a way that does not cause pain, injury, or unnecessary stress. Downed or disabled animals should be euthanized in their current location. If gunshot is used at long distances, experts should be used to guarantee death by single shot. Electrocution would be difficult to use in the field, but could be done if appropriate equipment is available (NAHEMS, 2004; NAHEMS, 2011b). In general, there is significant shortage of peer-reviewed research on euthanasia in all livestock (Styles, 2012).

Sheep and goats

The Humane Slaughter of Livestock Act identifies captive bolt, gunshot, and electrical stunning for both sheep and goats as humane methods of euthanasia. For sheep, euthanasia by CO_2 is also considered a humane method (NAHEMS, 2011b). AVMA specifically mentions barbiturates as acceptable, and it lists gunshot and penetrating captive bolt with adjunctive methods as acceptable with conditions. Electrocution is also an acceptable option, but is unlikely to be practical in a mass depopulation effort (AVMA, 2103a). All of these methods could, with proper planning and preparation, be used in the field for mass euthanasia. Injectable anesthetics could also be practical and should be used with hand-raised animals, as discussed with cattle. The same humane handling expectations also apply to sheep and goats (NAHEMS, 2004; NAHEMS, 2011b).

Swine

The Humane Slaughter of Livestock Act specifies CO_2, captive bolt, gunshot, and electrical stunning as humane euthanasia techniques (NAHEMS, 2004; NAHEMS, 2011b). AVMA also lists Ar, N, gas mixtures, injectable agents, and electrocution. Blunt force trauma may be considered an option with piglets (Styles, 2012; AVMA, 2013a). All methods could be adapted in a mass euthanasia incident. Injectable agents can be used more easily with hand-raised pigs. Humane handling considerations should apply. CO_2 will be difficult to use in the field unless animals could be safely transported to a central location (NAHEMS, 2004; NAHEMS, 2011b). The estimated cost of CO_2 for swine euthanasia is 15 to 20 cents per pound (Morrow & Meyer, 2003).

Equine

The Humane Slaughter of Livestock Act defines captive bolt and gunshot as humane methods of euthanasia for horses and mules. Electrical stunning is also acceptable in U.S. Code. AVMA guidelines limit acceptable use to penetrating captive bolt and barbiturates, and list gunshot and captive bolts as acceptable with conditions. Gunshot is conditional only due to the human safety hazards. Injectable agents could be used, but would be very slow. All equine should be sedated, if possible, before being euthanized. Again, humane handling expectations apply. With horses, many owners consider them as pets, and their loss may be particularly difficult (NAHEMS, 2004; NAHEMS, 2011b).

Poultry

The Humane Slaughter of Livestock Act and U.S. Code provide no guidance on the humane euthanasia of poultry (NAHEMS, 2004; NAHEMS, 2011b). AVMA lists cervical dislocation, decapitation, gas inhalation, injectable agents, blunt force trauma, electrocution, gunshot, and captive bolt as acceptable or acceptable with conditions methods (Styles, 2012; AVMA, 2013a). Identifying the best method for the depopulation of large numbers of birds is challenging. Methods need to be rapid, safe for personnel, humane, available, easy to implement, and applicable to a number of housing options (Turner et al., 2012). It is not acceptable to use a method resulting in death by suffocation or heat stress. Because poultry are easily bruised or fractured and see humans as predators, handling of birds should be minimized and personnel must be trained in handling techniques (Kingston et al., 2005; Raj, 2008). For example, the bones of laying hens are fragile and they must be handled humanely (Kingston et al., 2005).

CO_2 has been used in previous mass euthanasia situations and can be done in covered containers or dumpsters. Water-based foam is a recently developed method of euthanasia, has been used for mass depopulation of poultry, and has proven to be effective and faster-acting than other methods. N or Ar gas can also be used if completely airtight structures are available. Electrocution may be a humane and feasible choice, but only if the proper equipment is available and birds are consistently killed. Chemical injection may be appropriate if a limited number of birds require euthanasia. Cervical dislocation can be used if trained personnel are available, but may be impractical with large numbers of birds. Percussive stunning through the use of the Cash Poultry Killer renders birds immediately unconscious and can be used on chickens, turkeys, ducks, and geese. Decapitation is not recommended because of the mess, brutal appearance to observers, and inefficiency. Ventilation shutdown, while approved in the UK, creates significant welfare concerns and is not a recommended method in the US. Gunshot could be used in extreme circumstances, but is not suitable with large populations (NAHEMS, 2004; NAHEMS, 2011b).

Wild and exotic animals

The American Association of Zoo Veterinarians (AAZV) has developed guidelines for euthanasia of nondomestic animals. For captive ruminants in a zoo or game park, expert handlers should be consulted to determine appropriate methods. When the animals closely resemble domestic species, the identified methods for those species should be used. If animals cannot be captured or restrained, gunshot is likely the only humane option for mass euthanasia. Projectile equipment with powerful injectable agents can also be utilized, but should be done so by veterinarians with expertise or training with exotic animals (NAHEMS, 2004; NAHEMS, 2011b). The stamping out of susceptible wildlife in the case of an FAD is difficult and will require a number of partnerships and solutions to eradicate the disease and protect wildlife populations (Tickle, 2003).

Aquatic species

Traditionally, electrical or percussive stunning followed by exsanguination is used when fish are harvested. They may also be euthanized by tricaine methane sulfonate solution or overdoses of immersion or injectable euthanasia agents. Again, the AAZV guidelines should be considered and experts should be consulted (NAHEMS, 2011b).

Overall Welfare and Depopulation Considerations

Blancou and Pearson (2003) note many times in history, dating back as far as 1499, that leaders called for notification and destruction of diseased or exposed livestock for the purposes of keeping the disease from spreading, even if it appeared cruel (Rubira, 2007). Over time, animal welfare has improved due to eradication and treatment of disease and improved husbandry practices. Yet, the primary drivers behind controlling major FAD are market access, public health, and the increasing public expectations for quality animal welfare (Rubira, 2007). While previous cost-benefit analysis have indicated stamping-out policies to be more advantageous, the “value that society now attaches to animal welfare and the environment have each altered the balance of the equation” (Yeh et al., 2013, p. 295).

Comparative study

Researchers at Kansas State University studied the possibility of humanely depopulating cattle in a large feedlot in a timely and efficient manner while minimizing human and animal health concerns in response to an FMD outbreak. An online Delphi survey and a roundtable discussion were used to gather expert opinions on mass depopulation from food animal pharmacologists, toxicologists, animal welfare specialists, feedlot veterinarians, and feedlot managers. Depopulation methods, including toxicological agents, pharmacological agents, and physical methods, were identified and evaluated based on time requirements, effectiveness of euthanasia, human health risk, animal welfare concerns, carcass disposal concerns, and supply availability (McReynolds, 2013).

The only pharmacological agent considered highly effective for euthanasia was pentobarbital sodium IV. Concerns did exist over cost, access to adequate supplies, and methods of carcass disposal. Animal welfare concerns were minimal. Veterinary consultants and feedlot managers saw captive bolt as minimally effective for mass depopulation. However, captive bolt did offer minimal animal welfare concerns. Gunshot was identified as moderately effective by veterinary consultants but feedlot managers considered this method as non-effective. The use of sharpshooters to depopulate unrestrained and unsedated cattle resulted in high animal welfare, human safety, and public perception concerns. Animal welfare concerns would also be extended to cattle within the vicinity of those being depopulated. Overall, the panel did not find captive bolt and gunshot as effective means of mass depopulation in a large feedlot (McReynolds, 2013).

Application of depopulation methods such as injection or captive bolt was a concern. Any method that required animals to move through a chute would limit the average feedlot to euthanizing about 1,000 animals per day. In addition, removal of euthanized animals from chutes would slow down the process considerably. Sedation was considered an option that allowed animals to be treated in a chute and then released for gunshot or captive bolt depopulation after sedation. The only agent considered as an option for sedation was xylazine combined with ketamine. Concerns do exist over the residue remains in dealing with carcass disposal (McReynolds, 2013).

The only method considered highly effective by veterinary consultants and feedlot managers and considered most effective by all panelists was feeding a toxic agent, such as organophosphates, to cattle in feed bunks. Depending on the compound used only a small amount of organophosphates would be necessary to cause acute death with minimal clinical signs. The challenge would be to achieve consistent and adequate dosages through feed consumption. The panel toxicologist estimated that 95% of cattle would die acutely from feed toxin and a secondary depopulation method would be needed for other 5%. High or moderate welfare concerns were identified. This method would be seen as mass depopulation, but not considered acceptable as a euthanasia method. Questions do exist over the ability to dispose of carcasses and the impact disposal may have on the environment and the risks created for wildlife, scavengers, and other animals. These concerns kept this method from being considered acceptable (McReynolds, 2013).

No consensus was reached on a clearly acceptable method that was considered safe, humane, and able to rapidly depopulate large numbers of cattle. Panelists did agree that the most convenient and least costly method of depopulation would be sedation via intramuscular injection followed by euthanasia by captive bolt or gunshot after released from the working alley. General consensus was reached that it would be difficult to depopulate a large feedlot quickly and humanely and further research is needed on alternatives for FMD control. In addition, even though challenges exist with depopulation, it was also noted that timely and appropriate carcass disposal may actually be a more significant challenge (McReynolds, 2013).

Specific welfare issues

Any method selected must be able to withstand professional and public scrutiny. “It is imperative that animal welfare is the utmost concern and the process is humane” (Kingston et al., 2005, p. 738). Mass depopulation can best be minimized and animal welfare can best be protected by high levels of biosecurity, well-designed surveillance, and rapid alert systems. While killing a large number of animals may be the best option for disease control, it must be done quickly, without risking human safety, and without unduly compromising animal welfare (Berg, 2012). The public is more likely to accept the depopulation of non-diseased animals when the disease is zoonotic, as proven by the reaction to mass destruction of the cattle population due to FMD in the UK, versus the depopulation of the entire poultry population in Hong Kong for HPAI (Rubira, 2007).

Animal welfare in the case of an emergency will be optimized if proven principles of emergency preparedness and response are utilized. While the optimal animal welfare solution is to prevent an animal disease outbreak, response strategies need to be developed that protect animal welfare in the case of an outbreak (Heath, 2012). EU Regulation 1099/2009 states that in any depopulation operation an action plan must be created to ensure compliance with animal welfare regulations and to safeguard animal welfare in compliance with the OIE. This applies to all countries in the EU and any country wanting to export to the EU (Berg, 2012).

The Federal Emergency Management Agency (FEMA) identified Animal Emergency Responder credentials based on five states of animals: susceptible and infected, susceptible with unknown exposure/disease status, susceptible but not infected or exposed, susceptible and dead, and not susceptible (Heath, 2012). The incident commander should assign a safety officer with a focus on animal welfare concerns (Brown et al., 2005).

There are a number of issues that complicate the welfare status of livestock impacted in a mass depopulation effort. A delay in the euthanasia operation can create a number of welfare concerns. Any method that causes delay is inhumane, because it may lead to increased spread of disease and ultimately increase unnecessary animal death (Lewis, 2003).

Stocking density becomes a problem as animals nearing or passing their slaughter time are not allowed to be transported. Welfare issues may also arise because feed may not be able to be delivered (Berg, 2012). These issues could be compounded if vaccination-to-live or vaccination-to-die policies are implemented and animals are allowed to live longer but cannot be transported. It is possible the vaccination may result in a slight increase in welfare depopulation, as animals live beyond their normal sale age and weight, or feed is not available (McLeod & Rushton, 2007). The number of animals culled will increase with delays in disease diagnosis and if a vaccination-to-kill policy is implemented (Hagerman et al., 2012). In addition, the destruction of animals without the intent to use the meat when it is safe for consumption leads to ethical debates and greater societal concerns (Berg, 2012).

Audit systems or animal welfare assurance schemes do not exist for mass on-farm depopulation, and these events are unpredictable and not typically standardized. Government contingency planning and emergency management must incorporate animal welfare considerations. If the decision is made to depopulate, unnecessary animal suffering and stress should be avoided. The entire process should be monitored from an animal welfare perspective to create a level of trust with the public. Monitoring efforts should focus on animal handling prior to killing, the stun quality, and confirmation of death prior to disposal. All personnel should be monitoring for these concerns and corrective actions must be taken if problems are identified. In addition, a veterinarian with training in animal behavior, physiology, and identification of animal pain and suffering must be present with overall monitoring responsibility. If handled correctly, there does not have be a contradiction between disease control through depopulation and acceptable animal welfare (Berg, 2012).

As noted by Sebastian Heath, a division chief in the Department of Homeland Security, a delay in response due to uncertainty about the approach to take in an emergency (cull, treat, vaccinate, or leave to recover) is the most likely situation to result in animal welfare concerns. Often the inability to decide is based on conflicting values over trade and animals lives. In most cases, welfare can be managed if prioritized appropriately (Heath, 2012).

Differing ethical theoretical approaches will influence perspectives on the welfare impacts of disease control policy alternatives. The utilitarian theory is based on the idea that the most ethical choice maximizes good and minimizes bad. A mass depopulation policy likely follows a utilitarian approach because the death of a prescribed number of animals reduces economic losses and protects the remainder of the animal population. Rights-based theory (prescribed to by most animal rights groups) considers actions as either right or wrong based on moral rules. Followers are likely to oppose mass depopulation because they see animals as having the right to live and do not believe decision makers have the moral authority to engage in mass depopulation. Reactions from stakeholders will also be influenced by the stress and pressure created in an emergency and conflicts will occur internally and externally. Veterinarians will want to protect animal health, eliminate disease spread, and relieve animal suffering; farmers and ranchers will be concerned about the welfare of their animals and their own livelihoods; businesses will be focused on continuity and the long-term impacts; and the public will be concerned about their own health and the health of the animals and the environment (Hueston, 2007).

The traditional tools of zoning and movement controls add to the welfare implications, as does the lack of rapid detection tools (Breeze, 2004). The majority of animals in an outbreak has an unknown disease or exposure status and is most at risk for their welfare to be compromised (Heath, 2012). Limiting animal movement that disrupts natural animal flows between facilities at different life stages will also lead to welfare concerns (Knight-Jones & Rushton, 2013). In both cases, the creation of a geometric shape with a predefined radius and jurisdictional boundaries lead to the definition of the at-risk population of animals with unknown disease status. These delineations do not necessarily reflect industry realities, weather, geography, or other environmental factors. By considering more environmental and economic factors in defining the at-risk population, animal welfare situations can be more appropriately handled. In addition, standard slaughter methods that have been monitored for humaneness should be adapted and used for depopulation (Heath, 2012). Breeze (2004) noted that by utilizing computer modeling systems that consider weather and other factors, new zones can be created that allow animals in the 3-km area to be monitored, but not necessarily destroyed. In addition, on-site diagnosis could allow for animals to be slaughtered based on infection rather than proximity (GAO, 2005). “Every effort should be made to minimize animal destruction” (Rubira, 2007, p.333).

An example exercise

In 2007, USDA APHIS and the Texas Animal Health Commission conducted a table-top exercise, known as Operation Palo Duro, dealing with an FMD outbreak in the Texas Panhandle. Two of the exercise focus areas were euthanasia and disposal in a mass depopulation event and the use of mass vaccination as a response strategy. The high concentration of cattle in the region made exercise participants aware of the significant challenges to depopulation and disposal. Objectives developed during the exercise to depopulate within 72 hr and dispose of carcasses within 96 hr were not found to be feasible. The plan before the exercise began was to euthanize cattle by captive bolt followed by exsanguination and rumenal opening for gas release. Front-end loaders would then be used to move carcasses to on-site burial locations. When exercise participants realized they could not keep up with depopulation needs, they requested of the policy group that only cattle showing clinical signs would be depopulated and others would be vaccinated. Their request was denied. A few hours later, they requested gunshot be allowed as a depopulation method and were approved as long as sharpshooters were available and proper precautions were taken. No prior planning of gunshot protocols for mass depopulation had occurred. Participants concluded resource limitations, lack of trained professionals, realistic time assumptions, prioritization of resource use, detailed procedures for euthanasia methods, and resource lists needed to be considered and addressed (Giovachino, Speers, Morgan, Catarious, & Myrus, 2007). There was general agreement that it was not feasible under any situation to complete depopulation and disposal on-site in 72 and 96 hr, respectively, due to the high livestock density (McReynolds, 2013). Six years later, Palo Duro is still frequently cited by USDA APHIS officials as the reason stamping-out is unlikely to work and that we may not even have enough ammunition. However, the same officials indicate stamping-out is still the first response that will be implemented (personal communication).

Resource shortages

Emergency depopulation will require significant resources (NAHEMS, 2011a). Axelsen (2012) simulated the disease spread of FMD in California with the intent of evaluating alternative policy choices. Two factors that were consistently significant in their analysis were the size and availability of depopulation resources and the amount of time necessary to ramp up to full implementation of depopulation protocols. Depopulation was only used on infected premises and was critical to limiting disease. If preemptive depopulation is used, the resources and personnel needed would be significant and, if they were not available in a timely fashion, would lead to increased disease spread (Axelsen, 2012). In tabletop exercises conducted in Texas, they found the shortage of resources and personnel made the depopulation of 55,000 and 70,000 head of cattle in two infected feedlots logistically impossible (NAHEMS, 2011a).

APHIS and industry officials have expressed concern over the lack of a sufficient workforce to depopulate animals in the case of a large-scale animal disease outbreak. As an example, APHIS officials indicated that it could take as long as 80 days to depopulate a 100,000 head feedlot. These concerns have also surfaced when discussing the shortage of large animal veterinarians in the workforce prepared to help protect animal and public health. APHIS and DHS, through the NSTC Committee on Homeland and National Security subcommittee on Foreign Animal Disease Threats (FADT) identified the need to outline research gaps related to depopulation, disposal, and decontamination of diseased animals during a disease outbreak (GAO, 2009; GAO, 2011).

Current U.S. policy would likely result in substantial stamping out, potentially leading to a shift in the national supply and restrictions on international trade (Hagerman et al., 2012). The complexity of the impact and related analysis will increase with the use of a vaccination policy.

Vaccination consideration

Depopulation as a disease response is well-founded in the veterinary field as the primary consideration for disease control. While stamping out is the standard response, logistical, economic, societal, environmental, and animal welfare factors drive decision makers to consider other alternatives (Willis, 2003). A paradigm shift will be required in the field of animal disease control that brings alternative response options to the table (Willis, 2003). Vaccination as a substitute for stamping out will help avoid the animal welfare issues caused by significant on-farm depopulation (Morton, 2007).

The policy of mass depopulation creates a number of factors for consideration including waste of animal protein, environmental impacts, economic impacts, and psychological effects in addition to animal welfare concerns. "There is a growing trend in society to reject the excessive waste of valuable animal products, the negative environmental and animal welfare outcomes, and the devastating economic impacts on agricultural industries as well as on national economies. This is creating pressure for alternatives to mass animal slaughter and carcass disposal, and ultimately for a philosophical change in the approach to animal disease control, depopulation, and animal carcass disposal" (Willis, 2003, p. 149).

If stamping out is not considered effective in regard to disease control, containment, and eradication, modified stamping out approaches will likely be considered. But, according to APHIS, "it is not possible to delineate *a priori* the specific factors that might signal the need to modify the response to an FAD outbreak…the response will use a science- and risk-based approach that protects public health and animal health, and stabilizes animal agriculture, the food supply, and the economy" (APHIS, 2012a, p. 22).

Horn and Breeze (2003) noted it was obvious in the 1980s that traditional measures of quarantine, depopulation, and disposal would not be adequate to deal with an FAD especially in light of changing public opinion on animal welfare and the environment. Alternatives to mass depopulation and disposal should be considered, and one alternative is vaccination.

Summary: Policy Implications

Animal welfare deserves greater consideration in FAD policy development in regard to mass depopulation policy choices, euthanasia method selection, a potentially significant fall in livestock value, and overstocking and other implications of movement restrictions and trade ban implementation (Whiting, 2003).

The decision to implement mass depopulation as a disease control strategy may be based on the protection of public health, elimination of animal suffering, prevention of suffering in susceptible animals, maintenance of a health national herd/flock and agricultural economy, and access to disease-free trading status and affiliated global economic advantages (Raj, 2008). "An ethical, socially integrated, and acceptable policy for the control of infectious disease in food-producing animals needs to be developed" (Crispin et al., 2002, p. 881).

Any contingency plan for dealing with animal emergencies must give serious consideration to animal welfare concerns, including the appropriate methods of euthanasia. Ontario Ministry of Agriculture and Food officials have indicated they believe human safety and animal welfare must outweigh economic considerations (Rietveld, 2003). AVMA indicates guidelines must represent solid science and not be influenced by political pressure (Lewis, 2003).

"Selection of the best method of emergency mass depopulation involves maximizing human health and safety while minimizing disease spread and animal welfare concerns" (Alphin et al., 2010, p. 1). Humane depopulation methods must be considered an expectation in any animal disaster (CDFA, 2003). Animal welfare concerns may be overridden, however, if human health and safety is at significant risk (Raj, 2008). Euthanizing an animal is never a welcomed task, but every attempt needs to be made to avoid adding stress and suffering to the animals experience (CDFA, 2003). "Treating animals in a humane manner is the right thing to do" (Grandin, 1996, p. 25). Other ethical and social issues also may be considered when considering policy alternatives, including cultural or religious issues, environmental impacts, and global food security (Barnett et al., 2013).

All current policies and regulations related to animal depopulation deserve further research, especially related to a large-scale animal disease outbreak or natural disaster. Our livestock industry is more at risk then it has ever been. Any emergency response plans that do not consider animal welfare are inadequate. All methods of euthanasia need further review to determine which technologies are most appropriate in animal disasters of all types and to determine their overall effect on animal welfare and behavior.

Related issues, such as transportation and movement restrictions, must be evaluated for their impact on animal welfare, and issues related to the euthanasia technologies, such as economics, environmental effects, public health, and public relations, need to be reviewed. In addition, the impact of large-scale depopulation methods and policies will create an impact on producers that deserves attention.

Vaccination policy alternatives in the case of an FAD outbreak are also worthy of additional discussion. As noted by DeOtte and DeOtte (2009), depopulation with disposal may simply not be feasible in regard to cost and logistics when dealing with a large number of animals.

Clearly, a large number of issues surround animal welfare and euthanasia in a large-scale animal depopulation. Any policies developed to deal with such disasters need to pay careful consideration to the issues discussed. As the National Research Council (NRC) noted, there is a "pressing need" to understand the social and psychological impact of an attack on our food system and policy prescriptions must consider these concerns (NRC, 2002; Moon, Ascher, et al., 2003; Moon, Kirk-Baer, et al., 2003). This type of policy development requires a multidisciplinary approach that brings all players to the table.

Chapter 3 - Carcass Disposal Considerations

The greatest logistical problem in any large-scale animal death loss is carcass disposal. While many technologies exist, the best method for carcass disposal remains an issue of uncertainty and matter of circumstance. A number of factors must be considered in evaluating disposal alternatives. Contingency plans must consider the economic costs and the availability of resources for the actual disposal, as well as the numerous related costs. To develop a decision-making framework, policymakers must balance the scientific, economic, and social ramifications of disposal technologies (Ekboir, 1999). The World Organization for Animal Health (OIE), in the Terrestrial Animal Health Code (2012b), notes that mass destruction and disposal typically result in "intense public and media scrutiny" (p. 1). Carcass disposal operations must be conducted within acceptable scientific considerations that ensure pathogen destruction while satisfying animal welfare, public, and environmental concerns (OIE, 2005; OIE, 2012b). For a response to be successful, disposal methods must be available, implementation must be feasible, resources accessible, sites pre-identified for development, appropriate interests engaged, biosecurity issues resolved, the public informed, and the response timely.

A complete analysis of alternative methods of disposal for various situations is a necessity to determine the optimal alternative (Ekboir, 1999). Balancing economic considerations with regulatory options to determine the best options for carcass disposal should be the policy goal (Adams, 1999).

Historical Background

Historical carcass disposal events indicate that a multitude of issues must be considered when determining the appropriate process for disposing of infected and exposed carcasses. The following summary of historical incidents justifies the need for effective and efficient carcass disposal policy in the US.

United Kingdom – Foot and mouth disease (FMD)

The 2001 U.K. FMD outbreak provides the best historical example of large-scale carcass disposal. The government faced the challenge of disposing of approximately 6 million carcasses with limited disposal resources in a short time. The large scale of the epidemic made carcass disposal a major problem.

The 2002 U.K. National Audit Office (NAO) report summarizes the governmental issues related to the disease outbreak, including carcass disposal. During the height of the outbreak, an average of 100,000 animals were slaughtered and disposed of each day in a large and complex operation. In total, more than 6 million animals were slaughtered during the outbreak for disease control and welfare reasons; these totals do not include new born lambs and calves (NAO, 2002; Thomas, 2002). In the areas where less infection occurred, authorities were able to keep up with the disposal needs. However, in the worst hit areas, there were long delays in the slaughter and disposal of infected and exposed animals. The existing contingency plan simply did not allow for sufficient handling of a situation of that scale (NAO, 2002; Hickman & Hughes, 2002).

The Department for Environment, Food and Rural Affairs (DEFRA; formerly the Ministry of Agriculture, Fisheries and Foods [MAFF]) maintained lead responsibility for the disposal of all animals (NAO, 2002; Thomas, 2002). DEFRA's veterinary officers initially directed the disposal operations. The military was not immediately involved but within a month was playing a key role in assisting with the organization and logistics for slaughter, transportation, and disposal (NAO, 2002).

Timely slaughter is critical to disease control, so disposal of infected and exposed carcasses is crucial in controlling the spread of some diseases if it holds up the slaughter process. Risk of disease transmission from carcasses is relatively low because the virus is not produced after death. Carcasses awaiting disposal are at risk of attack from scavengers, which theoretically may spread the disease (NAO, 2002).

The massive scale of disposal required by destroying livestock on infected and exposed farms led to problems in disease control, communication, and public perception (Thomas, 2002). By mid-April, a back log of 200,000 carcasses awaiting disposal existed. During the first seven weeks of the epidemic, it was commonplace for dead animals to remain on the ground awaiting disposal for four days or more. The scale of the epidemic combined with resource shortages in both animal health officers and leak-proof transport for off-farm disposal contributed to the problem. The risk of disease spread resulting from off-farm disposal and the need for robust biosecurity protocols to minimize virus spread during transport and subsequent disposal was of major concern. The shortage of environmentally suitable and safe disposal sites also led to the delay (NAO, 2002; Hickman & Hughes, 2002).

The legal and environmental framework for disposal of carcasses and animal byproducts had changed significantly since the UK's last outbreak in 1967-68. Disposal plans recognized that disposal methods needed to be acceptable to the Environment Agency and local authorities. Slaughter at a location close to the infected premises was critical to slowing the spread of the disease. At that time, on-farm burial was initially considered the preferred method followed by on-farm burning. However, on-farm disposal proved to be impractical because of environmental constraints and high water tables. In mid-March 2001, the Environment Agency began conducting a rapid (within 3 hr) groundwater site assessment and advised on appropriate disposal. The Environment Agency also approved a disposal hierarchy for different species and age of stock (see Table 3-1). In addition, the Department of Public Health issued guides on how the risks to public health could be minimized. The stakeholders then agreed on a disposal hierarchy that attempted to protect public health, safeguard the environment, and ensure FMD control. Cost was a material, but much less important factor. This new focus on environment and public health was substantially different from the initial approach based on animal health risks and logistics (NAO, 2002; Hickman & Hughes, 2002).

Table 3-1 *National Audit Office Report: Approved Disposal Routes for Different Species and Age of Stock*

Preferred Method of Disposal	Permitted Animals
Rendering	All
High-temperature incineration	All
Landfill, on approved sites	Sheep, pigs of any age & cattle younger than 5 years of age (due to BSE concerns)
Burning	All (with a limit of 1,000 cattle per pyre)
Mass burial or approved on-farm burial	Sheep, pigs of any age & cattle younger than 5 years of age (due to BSE concerns)

Note. Adapted from NAO (2002, p. 73).

Rendering and fixed plant incineration methods were preferred, but the necessary resources were not immediately available and the capacity would only cover a portion of the disposal needs. Disposal in commercial landfills was seen as the next best environmental solution, but legal, commercial, and local community problems limited landfill use. With these limitations in mind, pyre burning was the initial method used, but was eliminated as a preferred method following the increasing public, scientific, and political concerns. Mass burial and on-farm burial was last on the preferred method list due to the bovine spongiform encephalopathy (BSE) complications and the risk to the groundwater (Hickman & Hughes, 2002). The hierarchy and individual case characteristics determined the methods utilized. Decisions were impacted by the availability of nearby rendering capacity, the relative risks of transporting carcasses, and suitability of sites for burial and burning. Even with the new hierarchy in place, burial, and burning remained a common choice because of the need to slaughter expeditiously and limit transportation of carcasses. Overall, burning was the most common method of carcass disposal (29%), followed by rendering (28%), landfill (22%), and burial (18%) (NAO, 2002; Thomas, 2002).

The disposal of millions of slaughtered animals created huge logistical problems. DEFRA cited problems with all disposal methods. Rendering was unavailable until rendering plants complied with necessary biosecurity protocols and transportation vehicles were adequately sealed. In March 2001, protocols for biosecurity of rendering plants and vehicles were approved. However, until late in the epidemic when numbers of animals began to diminish, the rendering plants could not handle the volume. High-temperature incineration was also difficult to utilize because the facilities were committed to the disposal of BSE-affected cattle. Air-curtain incinerators were used on occasion. Landfill operators and local communities were resistant to the use of landfills for disposal because they were often located near large population centers. While 111 suitable facilities were identified, only 29 were utilized. More than 950 locations were used for burning, with most located on farms. However, the use of mass pyres generated a negative response from the media and profoundly affected the tourism industry. These mass burnings ended in two months because of the public opposition. Mass burial was the selected alternative when carcasses began to stack up. Public protests and technical problems such as carcass liquid seepage resulted when 1.3 million carcasses were disposed of in mass burial sites. Despite the public concerns about the disposal process, DEFRA, the Environment Agency, military and local organizations eventually improved disposal efficiency and eliminated the backlog of carcasses (NAO, 2002).

Carcass disposal was a highly controversial issue. Public backlash, especially in response to burning and mass burial, was significant and long-term economic impacts remain in question (NAO, 2002). Burning of carcasses on open pyres was an enormous task requiring substantial materials and generating significant amounts of ash for disposal. These pyres were viewed unfavorably by local residents and producers. The images of burning carcasses were broadcast via television around the world and likely contributed to the wider economic damage, especially to the tourism industry. Local residents disliked mass burial as well. The general public reacted most positively to the rendering alternative (Rossides, 2002). At the beginning of the outbreak, the priority was to eradicate the disease. While DEFRA realized cost control was important, it was also clear that all steps to stop the disease needed to be taken regardless of expense (Hickman & Hughes, 2002).

NAO offered multiple recommendations for future contingency plans. One example of their recommendations is to develop a clear chain of command with defined roles and responsibilities, reporting lines, and accountabilities. They also recommended researching the effectiveness and efficiency of disposal methods of slaughtered animals and continually inspecting and monitoring the environmental impact of disposal sites (NAO, 2002).

In response to the government-commissioned inquiries, the U.K. government noted the need for multiple strategies for different disease situations. They are committed to reviewing preventive culling and vaccination policies. The government also noted that the disposal hierarchy in its current contingency plan differs, due to lessons learned, from the hierarchy agreed upon during the actual FMD outbreak by the Environment Agency and Department of Health. The new hierarchy indicates the first preference will be commercial incineration followed by rendering and disposal in licensed landfills. The need for pre-determined agreements ensuring minimum rendering capacity and use of national landfill sites was also identified. Mass burn pyres are not advised and on-farm burial will only be used if demand exceeds capacity of the preferred options (Veterinary Record, 2002; NAO, 2002). The 2005 NAO report also states that on-farm burial and open pyres are environmentally undesirable and concludes that they should only be used when no other alternatives are available or in remote areas. In a small outbreak, disposal should occur through incineration or rendering. In larger outbreaks, commercial landfill sites may be used (NAO, 2005).

Further review of the environmental impact by the Environment Agency found 212 reported water pollution incidents, mostly minor. Forty-four percent were caused by slurry, 24% by carcass disposal during burial, 18% by disinfection, and 13% by runoff from culling and carcasses prior to disposal. None of the pollution problems were on-going problems in private or public water supplies. Additional monitoring has not shown any ongoing air quality deterioration, and concentrations of dioxins in soil samples near pyres are the same as before the outbreak (Harman, 2001).

One portion of disposal efforts was the Livestock Welfare Disposal Scheme (LWDS), a voluntary program for farmers to dispose of animals that were not directly affected by FMD, but could not be moved to alternative accommodations or markets. Because transportation of animals was restricted, it made it difficult and, in some cases, impossible to move market-ready animals to open markets. The Rural Payments Agency paid farmers £205 million (U.S. $295 million) for the slaughter of 2 million animals from 18,000 farms. The program cost £164 million (U.S. $236 million), including operating costs, disposal charges, slaughter fees, transportation of animals, and administration (NAO, 2002). The FMD Inquiry commissioned by the House of Commons lists specific costs expended by the government, as noted in Table 3-2. Direct and indirect costs are identified in many areas of disease control (farmer compensation, vaccination, cleaning and disinfecting, staff time, etc.), including costs resulting from the slaughter and disposal of livestock, either to control the disease or deal with animal welfare. Total expenditures by the government were estimated to be more than £2.8 billion (U.S. $4.32 billion), with more than £1 billion related to direct costs of control measures. This included £252 million (U.S. $317 million) for haulage and disposal (Anderson, 2002; NAO, 2002).

In addition to the LWDS, the cost of disposal of infected and exposed carcasses was significant. Goods and services were purchased from a range of private and public sector businesses, including transportation and construction services, materials required for burn pyres, and slaughter services. Landfill operators received substantial sums for receiving slaughtered animals and landowners were paid several million pounds for allowing their land to be used as mass burial sites. DEFRA was forced to pay premium fees to get the work done in the necessary time frame. For example, in order to build the burial pits, crews worked 24 hr a day, seven days a week and were paid substantial amounts of overtime, nighttime, and weekend wages. Similar construction would have taken two years if tight deadlines did not exist. Because many small local firms were fearful of becoming involved with the crisis, shortages of goods and services existed and, thus, increased costs. Work with infected carcasses was also considered hazardous duty, which caused contracting firms to charge premium rates. DEFRA purchased coal and old discarded wooden railway sleepers to be used for pyres at prices five to 10 times higher than normal (Anderson, 2002; NAO, 2002).

Substantial costs were also incurred in protecting the environment and public health from carcass disposal risks; this included costs related to preparing safe locations and transporting to these locations. Construction costs for burial pits, for example, were substantial with DEFRA acquiring land for seven mass burial pits. These pits had to be designed from scratch to be environmentally acceptable and required heavy investment to stop the release of leachate (animal body fluids) into watercourses, protect surface water, and allow for disposal of contaminants. The total cost of the pits was £79 million (U.S. $114 million) of the disposal costs, not including restoration, monitoring, and maintenance. In one case, after the site had been partially filled, it was found to be unacceptable. The 18,000 carcasses buried were exhumed and burnt at a cost of more than £2 million (U.S. $2.9 million) (NAO, 2002).

High temperature incineration was costly at more than £500 (U.S. $720) per ton. Dealing with the ash from incineration and mass pyres was expensive because of the difficulties in disposal. In dealing with all expenses, DEFRA often found itself in a weak position for negotiating contracts and fee rates. This position forced the department to pay higher prices for almost all goods and services. Purchase controls were also weak. Because purchases were often made quickly, DEFRA did not benefit from bulk or surplus purchase prices. Normal procedures for authorization of department expenses were bypassed and contracts were not awarded competitively. Many contracts, amounting to millions of pounds, were agreed to in a few hours instead of the normal period of several weeks. The rates charged by contractors for labor, materials, and services varied greatly from one to another. By April 2001, DEFRA began to impose some cost controls, but was still unable to be cost effective and efficient (NAO, 2002; de Klerk, 2002).

Table 3-2 *Expenditures by the Government During the 2001 Outbreak of FMD in the UK*

Activity	Actual Expenditures to 24 May 2002 (£ million/US$ million)
Payments to farmers	
Compensation paid to farmers for animals culled and items seized or destroyed	1,130 (1627)
Payments to farmers for animals slaughtered for welfare reasons (Livestock welfare disposal scheme - £205.4 million (US$295.8 million); Light lambs scheme - £5.3 million (US$7.6 million)	211 (304)
Total payments to farmers	1,341 (1931)
Direct costs of measures to deal with the epidemic	
Haulage, disposal, and additional building work	252 (363)
Cleansing and disinfection	295 (425)
Extra human resource costs	217 (313)
Administration of the Livestock Welfare Disposal Scheme including operating costs, disposal charges, and slaughter fees	164 (236)
Payments to other Government departments, local authorities, agencies and others	73 (105)
Miscellaneous, including serology, slaughterers, animal value appraisers, equipment and vaccine	68 (98)
Legal claims against the Department	5 (7)
Total direct costs of measures to deal with the epidemic	1,074 (1547)
Other Costs	
Cost of government departments' staff time	100 (144)
Support measures for businesses affected by the outbreak (includes EU funds)	282 (406)
Total other costs	382 (550)
TOTAL COSTS	2,797 (4028)

Note. Adapted from NAO (2002, p. 82), Anderson (2002).

At the time of the 2007 outbreak, incineration remained at the top of the disposal hierarchy. Apparently, however, no planning exercises had covered contingency planning down to the details of carcass disposal. The incineration company located near the outbreak and used for disposal, Wessex Incineration, is one of the most advanced in the country, but no pre-existing contract was in place and they had not been previously briefed regarding biosecurity measures or involved in any contingency planning (Anderson, 2008).

Taiwan – FMD

In 1997, Taiwan experienced an outbreak of FMD that resulted in slaughter and disposal of about 5 million animals. Carcass disposal methods included burying, rendering, and incineration/burning. With the disposal choice dependent on farm locations, burial in landfills was the most common method. Swine producers were allowed to send hogs to nearby rendering plants. High water tables and complex environmental regulations complicated disposal. In areas where water resources were endangered, incineration with portable incinerators and open burning were the only approved methods. Army personnel completed the majority of the disposal work. At the peak of the crisis, disposal capacity reached 200,000 pigs, which caused many farms to wait for one to four weeks before animals could be slaughtered. The delay was blamed on lack of manpower and equipment, and there were large-scale death losses during the waiting periods. The manpower shortage was alleviated with military assistance. The disposal method depended on the availability of landfill sites, level of the water table, proximity to residences, availability of equipment, and other environmental factors. Major issues related to carcass disposal included the number of animals involved, biosecurity concerns over movement of infected and exposed animals, people and equipment, environmental concerns, and extreme psychological distress and anxiety of emergency workers (Ekboir, 1999; Ellis, 2001; Yang, Chu, Chung, & Sung, 1999).

The costs borne by the government associated with the epidemic were estimated at $187.5 million, with expenses for carcass disposal comprising approximately $24.6 million of the total (Yang et al., 1999). A comparative cost analysis showed that burying was the least expensive and easiest form of disposal, with 32.5% of total disposal costs covering 80% of the carcasses. Rendering was more costly, with only 15% of the carcasses being rendered for 26.1% of the costs. The most expensive method was burning or incineration with 41.4% of disposal expenses being used to dispose of 5% of the carcasses. In addition to direct costs, the Taiwanese swine industry faced an estimated loss of $1.6 billion as a result of production and export loss.

Related agribusinesses such as feed mills, pharmaceutical companies, equipment manufacturers, meat packers, auction markets and the transportation industry all suffered economic losses (Yang et al., 1999).

The use of mass vaccination in Taiwan could have impacted disposal costs, by either delaying the urgency of large-scale disposal efforts or by reducing the number of animals in need of disposal. Additional analysis implies mass vaccination was the cheapest way to eliminate the spread of the disease and future consideration should be given to cost-benefit analysis of vaccination and limited depopulation versus total depopulation (Ekboir, 1999; Ellis, 2001).

South Korea – FMD

In South Korea, after the burial of about 3 million carcasses during the 2010 FMD outbreak, the environment ministry became concerned about the public health repercussions. Some cattle were buried alive because of limited euthanasia drugs. Limited precautions were taken in carcass burial because of the inability to keep up with the demand for disposal. Animals were buried in more than 4,000 locations and, in some cases, were buried no more than 5 m deep in pits lined only with one layer of plastic sheeting. Due to rainfall leaching through the pits, rivers and aquifers were subject to contamination, making drinking water potentially hazardous (Mesmer, 2011; Government Accountability Office [GAO], 2011). The outbreak and disposal response resulted in contamination of some underground water resources, leachate reaching residential homes, and the public was critical of government for their slow response because carcasses continued to threaten the water supply (Miller, 2011). In one case, water mixed with blood was seen in faucets in a village infected by FMD (Bryant, 2011). During the outbreak, leaders called for measures to prevent water pollution, including the possibility of installing blocking walls in disposal sites and removing waste with pumps. Local governments were encouraged to consider building incinerators to burn carcasses instead of burial as a method of disposal (Miller, 2012b). In several cases, water near public schools was determined unfit for use (GAO, 2011). Government officials responded by committing to expert site surveys of the 4,632 disposal sites and the installation of automatic sensors to monitor leakage (OLPC, 2012).

Virginia and Delmarva Peninsula – Avian influenza

Two major outbreaks of avian influenza (AI) have impacted Rockingham County, Virginia, over the last 20 years. In 1984, more than 5,700 t of poultry carcasses required disposal and another 16,900 t were disposed of in 2002. On-site burial accounted for 87.5% of the carcasses in 1984, with the remaining carcasses disposed of in landfills. On-site burial cost and landfill costs were $25/t for a total of $142,000. In that outbreak, 1.4 million birds were destroyed at a total economic cost of $40 million, and disposal costs accounted for less than .5% of total costs (Brglez, 2003).

While carcasses take 6 months to decompose when composted, they can take several years to totally decompose in landfills or on-site burial pits. An example of this occurred in Virginia when a school was built in the late 1990s on a 1984 AI burial site and people were shocked to find the carcasses in near complete condition with little decomposition. This caused a change in state law requiring landowners to agree to record carcass burial on their property deed if they are applying for an on-site burial permit (Brglez, 2003). Additional research and excavation of burial sites has shown carcasses can remain relatively intact for several years (Glanville, 2006; Flory, Bendfeldt, & Peer, 2006a; Blake et al., 2008).

In the 2002 Virginia outbreak, 4.7 million birds were destroyed and disposed. Landfills, slaughter, incineration, composting, and burial where used in the disposal process (Puffenbarger, 2003). Initially, on-site burial was the preferred method, but was stopped due to public concern over well contamination (Wilkinson, 2007). Two primary landfill sites were used and more than 64% of total tonnage was shipped over 160 mi to these landfill sites. The cost to dispose in the landfill was $45/t, but more than $1 million in transportation expenses was expended for specially prepared trucks. In one case, the waste management plant associated with a landfill could not handle the ammonia leachate produced (Brglez, 2003). The distance, expense, and shortage of trucks for transportation of carcasses made landfilling problematic (Wilkinson, 2007).

Four incinerators were used late in the process due to slow negotiations. For 29 days, 76 t/day were disposed through the incinerators. The total cost of disposing of 3,023 t was $317,616.16 at a rate of approximately $105/t, including transportation. Transporting the carcasses to the quarry where the incinerators were located cost $267,908 for truck rental and mileage. Other costs included the rental of incinerators and labor for $810,389, screener rental and screening of ashes for $75,283, removing ashes and delivering as fertilizer for $173,466, and wood fuel costs of $477/t. This was an expensive process, and the stench and related public perception resulted in a negative externality (Brglez, 2003).

In the case of controlled slaughter, diseased birds were quarantined until the virus ran its course. Once the birds tested negative, they were sent to slaughter. Slaughtering protocols were used for 943,000 birds from 40 AI-positive flocks. With the implementation of a new state disposal protocol requiring all flocks be depopulated within 24 hr of disease confirmation, this practice came to an end. Controlled slaughter is less expensive, creates less waste and environmental impact, and generates producer income from the sale of the birds. However, consumer response was not positive because of concerns of disease transmission. Concerns also exist over increased biosecurity needs in the processing plant, transportation of live birds, keeping live birds on the farm, and possible virus mutation into a highly pathogenic strain. There is also a potential negative in the export market. It will not likely be acceptable in future outbreaks (Flory et al., 2006a).

A small percentage of the birds, about 43,000, in the 2002 outbreak were composted using in-vessel composting and windrow composting inside the poultry houses. The in-house composting was considered more successful and less challenging (Wilkinson, 2007). Because on-farm methods are preferable, in-house composting has some advantages, but has greater logistical demands and longer-term management than some other options. It is highly biosecure, relatively inexpensive, requires minimal equipment and personnel, requires no government approval or permits, and has limited negative perceptions in the public (Flory, Bendfeldt, & Peer, 2006b).

In the 2004 outbreak of (low pathogenic avian influenza) LPAI in Delaware, Maryland, and Virginia, composting was used significantly. In the 2004 LPAI outbreak on the Delmarva Peninsula, in-house composting was used to dispose of poultry carcasses. The virus was contained to three farms and the disease was eradicated in 14 days. In the same year, composting was used to dispose of half of the 1.2 million birds impacted by HPAI in British Columbia, Canada. These disposal scenarios and the success of composting disposal efforts brought composting to the top of the preferred methods list by some researchers (Malone, Cloud, Alphin, Carr, & Tablante, 2004; Flory et al., 2006a; Bendfeldt, Flory, & Peer, 2006; Wilkinson, 2007; Vanier et al., 2008; EPA, 2006).

Wisconsin – Chronic Wasting Disease

In February of 2002, Chronic Wasting Disease (CWD) was identified in whitetail deer in southwest Wisconsin. CWD is a transmissible spongiform encephalopathy (TSE). In order to control the disease, a 360-sq m disease eradication zone and surrounding management zone was developed. All deer within the zone were designated for elimination and deer in the surrounding area were designated to be reduced. Many of the deer were destroyed by citizen hunters, but they could not be used for venison. Disposal methods were selected that did not endanger animal or human health or environmental quality. Selected methods had to be able to handle a large number of carcasses and be regulatory compliant. Cost was also a consideration, and disposal costs were considered one of the most significant expenses of the CWD control program. The four preferred methods identified were landfilling, rendering, incineration, and chemical digestion (Wisconsin Department of Natural Resources [WDNR], 2002).

The aggressive approach of WDNR was not effective. Hunters and the general public created significant backlash. Since 2002, the geographic region where CWD exists in Wisconsin has grown extensively, and in 2010 the WDNR changed their focus to limiting the geographic spread of the disease. The revised goals included continued support of the proper disposal of carcass parts, road kill, and butcher waste inside and outside of Wisconsin to reduce the risk of disease transmission. Further research confirms landfills as safe and reliable, and the Wisconsin legislature passed a bill protecting landfills from financial liability. Nonetheless, landfill operators, local government officials, and municipal wastewater treatment facility workers remain concerned about landfilling deer. The WDNR continues to work to increase available landfills by working with these officials to educate them on the safety and cost-effectiveness of landfill use and providing indemnification to landfills that accept carcasses and butcher waste (WDNR, 2010). In 2009, WDNR restricted the movement of carcasses and select carcass parts from wild-deer from the CWD management zone or other infected states to non-infected parts of the state. In the last 11 years the presence of CWD has increased dramatically in all sex and age classes of deer despite WDNR efforts. More than 20% of adult male deer are estimated to have CWD (an increase from 8-10% in 2002) and the prevalence in females has increased to 9% from about 3-4%. The disease is currently in 18 counties in Wisconsin, as well as Colorado, Illinois, Kansas, Maryland, Minnesota, Missouri, Nebraska, New York, North Dakota, New Mexico, Pennsylvania, South Dakota, Texas, Utah, Virginia, West Virginia, Wyoming, Alberta, and Saskatchewan (WDNR, 2013).

United States – Natural disasters

Three natural disasters – the Texas floods in 1998, Hurricane Floyd in North Carolina in 1999 and a blizzard in South Dakota in fall 2013 – have provided similar yet smaller scale carcass disposal experiences. Dee Ellis of the Texas Animal Health Commission (TXAHC) reviewed the Texas and North Carolina disasters, collected data, and performed numerous personal interviews. His findings are summarized as follows.

In October 1998, torrential downpours in south central Texas resulted in the flooding of the San Marcos, Guadalupe, San Antonio, and Colorado River Basins. More than 23,000 cattle were drowned or lost in addition to hundreds of swine, sheep, and horses. The TXAHC worked with state emergency personnel from the Governor's Division of Emergency Management, the Texas Department of Transportation, and the Texas Forest Service to manage the disposal of animal carcasses. Local emergency response personnel played integral roles in the actual disposal process. Most animal carcasses were buried (where found if possible) or burned in air-curtain incinerators. Two air-curtain incinerators were utilized. One difficulty that arose was finding a burn site that was not located on saturated ground. Carcasses must be disposed of in a timely manner before decomposition makes movement of the remains nearly impossible. Some carcasses were inaccessible and began to decompose before actual disposal could take place. According to Ellis, the main carcass disposal issues were the lack of prior delineation or responsibilities between agencies, no carcass disposal plans and pre-selected disposal sites, a short window of time to complete disposal, minimal pre-disaster involvement between animal health and local emergency officials, and inaccessibility of some carcasses (Ellis, 2001).

In September 1999, Hurricane Floyd devastated North Carolina. The hurricane, combined with earlier heavy rains, resulted in the worst floods in state history. Animal loss was estimated at 28,000 swine, 2,860,000 poultry, and 600 cattle. Disposal of dead animals was coordinated by the North Carolina Department of Agriculture. Costs were partially subsidized at a cost of $5 million by the United States Department of Agriculture's (USDA) Emergency Watershed Protection program (Ellis, 2001). Total disposal costs exceeded $10 million and total agricultural loss neared $813 million (Wilson, 2003b).

The North Carolina State Veterinarian coordinated disposal to ensure safety for human health and the environment. Major problems related to carcass disposal included contamination of drinking water sources, fly control, odor control, zoonotic disease introduction, and removal and transport of carcasses. These problems were compounded in the cases of highly concentrated swine and poultry losses on heavily flooded property. The order of preference for disposal in North Carolina is rendering, burial, composting, and incineration. However, rendering capacity was so limited that it was not a viable option. Burial was the most widely used option and was utilized for 80% of swine, 99% of poultry, and 35% of cattle. Incineration was used for the remainder of the carcasses. Most burial took place on the land of the livestock producers. They were offered a financial incentive to bury on their own land in order to minimize transport of carcasses. However, this process led to additional environmental concerns because producers often buried carcasses in saturated ground that allowed carcass runoff to leach back into ground drinking water or local water resources. This threat caught the attention of environmental watch groups and the national media, resulting in a study group that created a multi-agency approach and animal burial guidelines for future use. Ellis summarized the major issues in North Carolina to be the high number of dead swine located near populated areas, environmental threats to groundwater and water resources, interagency jurisdictional conflicts, lack of well-developed carcass disposal plans, and minimal involvement of animal health officials with the state emergency management system (Ellis, 2001).

On October 4, 2013, an early autumn blizzard hit South Dakota bringing over 4 feet of snow in some parts of the state and killing an estimated 15,000 to 30,000 cattle. It was expected the state lost 5% of its cattle population, and some ranchers lost more than half of their herd. Ranchers were told they could burn, bury, or render cattle carcasses and encouraged to dispose of them as rapidly as possible. In Pennington County, emergency management officials prepared two, 20-ft deep, 60-ft wide disposal pits in accordance with Animal Industry Board guidelines. The pits were opened for ranchers to use 10 days after the storm on October 14. For some ranchers, the pits were more than 100 mi away. Regulations require that carcasses be buried at least 4 ft deep or disposed of in a licensed rendering plant within 36 hr of death (although the governor waived the time requirement). Burial is restricted within 1,000 ft from surface water, floodplains, rivers, and public and private drinking wells. Limitations on burial also exist when the pit is primarily sand or gravel, or the aquifer is less than 20 ft from the bottom of the pit. It is anticipated many cattle would be disposed of where they were found. Saturated ground previous to the snowstorm combined with wet weather after the storm made it difficult for ranchers to even locate dead cattle because high winds and the storm itself moved cattle tens of miles from their original location. Carcass disposal was not an immediate priority because the focus of most ranchers was on the cattle that survived (Lammers, 2013; Brokaw, 2013).

Other examples

The need for mass carcass disposal can occur without a disease outbreak or natural disaster. For example, in Northern Ireland in 2009, 4,300 cattle, along with hundreds of tons of meat, had to be destroyed and disposed of because the animals were provided feed contaminated with dioxins. While relatively small compared to a disease outbreak, the costs were millions of dollars and the culling lasted three weeks. Rendering and disposal was highly controversial and, while initially told they would not receive reimbursement, policies were changed so producers earned 70% of the animals' and products' market value. Officials determined that existing agreements needed to be reviewed and revised (Hayes, 2009).

Current Policy

Homeland Security Presidential Directive 9 [HSPD-9] established a national policy to defend the nation's agriculture and food system against terrorist attacks, major disasters, and other emergencies (Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities [FFADDRR], 2005). The effective disposal of carcasses and related material is fundamental to a successful response. The goal of disposal operations is to "eliminate in a timely, safe, biosecure, aesthetically acceptable, and environmentally responsible manner all animal carcasses that result from an animal health incident" (NAHEMS, 2012, p. ii). All materials that cannot be cleaned or disinfected must also be disposed. Disposal sites must be evaluated and appropriate methods must be selected (NAHEMS, 2005b; EPA, 2006).

National Animal Health Management System

The USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) National Animal Health Management System (NAHEMS) Guidelines call for a coordinated effort between local, state, and federal governments and the private sector to assess the emergency, respond, control the situation, and ensure recovery. It also calls for the emergency management community and the agricultural community to work together (APHIS, 2002; NAHEMS, 2005a; NAHEMS, 2012).

The disposal response goal as noted in the NAHEMS Foreign Animal Disease Preparedness and Response Plan (FAD PReP) is to "properly dispose of contaminated and potentially contaminated materials, including animal carcasses, as quickly as possible while maximizing pathogen containment, environmental sustainability, stakeholder acceptance, and cost effectiveness" (NAHEMS, 2012, p. 1).

The 2005 NAHEMS guidelines list burial as the preferred method of disposal, and noted that other methods could be considered under certain circumstances (NAHEMS, 2005b). The revised NAHEMS guidelines on disposal that were made available to the public in March 2013 have an increased emphasis on environmental considerations in the decision process and no longer indicate burial as a preferred method. Instead, the guidelines indicate six methods that are most likely to be considered: composting, rendering, permitted landfill or burial, fixed-facility incineration, air-curtain incineration, and open-air or uncontrolled burning. The guidelines also note potential emerging technologies and mention the importance of engaging an experienced professional in waste management during the decision process (NAHEMS, 2012).

Pre-planning and preparation are critical to a successful response. History has proven, in the case of catastrophic disposal, when procedures are not pre-approved and preparation has not taken place, the consequences will include delayed responses, conflict, and increased costs (Blake et al., 2008). Therefore, policy approaches that address the appropriate methods of carcass disposal are necessary.

Government and agency roles

The Environmental Protection Agency (EPA) in coordination with the USDA, Department of Health and Human Service (HHS), Department of Homeland Security (DHS), and Department of Defense (DOD) was tasked with documenting Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities (FFADDRR) in animal, crop, and food incidents. The document is consistent with the National Response Framework (NRF). There are three levels of response: level 1 – local/limited response, level 2 – state/regional response, and level 3 – national response (FFADDRR, 2005).

HSPD-9 identifies the USDA and HHS as "responsible for recovery efforts that rapidly remove and effectively dispose of contaminated food and agriculture products or infected plants and animals" (GAO, 2011, p. 17). The Food and Agriculture Incident Annex charges USDA, HHS, and EPA to "provide technical assistance and guidance to State, tribal, and local authorities who are coordinating the disposal of contaminated food, animal carcasses, or plants" (DHS, 2008a, p. 7).

Local and state roles

Most decontamination and disposal responsibilities are at the state level. Most disposal actions will occur at the local level with guidance from federal agencies when appropriate (FFADDRR, 2005). USDA APHIS provides guidance for carcass disposal to local and state government though NAHEMS, and the EPA Office of Solid Waste provides guidance to assist local decision makers as well (Marburger, 2007).

State solid waste agencies, in cooperation with USDA, are responsible for management of carcass disposal in the case of a foreign animal disease (FAD). Local and state emergency management disposal plans should be predetermined and federal documents specifically recommend landfills be identified for disposal. Local and state plans will be supported by federal resources. Disposal efforts will be focused on stopping disease spread, protecting human health and the environment, and conserving meat and animal protein if appropriate. Specific disposal decisions will be finalized by individual states based on pathogen/agent and site-specific conditions (FFADDRR, 2005).

In the ICS, there will be disposal unit leader and multiple disposal team managers and members. The disposal group is in the disease management branch in the operations section of ICS (FFADDRR, 2005). APHIS identifies the importance of defining a disposal unit leader and team to be responsible for the safe and efficient disposal of carcasses before an animal health emergency occurs. The disposal unit leader is responsible for maintaining up-to-date contact information, determining disposal needs, staying current with disposal technologies, determining necessary supplies and equipment, negotiating contracts for disposal services, working with environmental officers, training personnel, keeping records and reporting, and developing a disposal plan. The disposal unit leader and disposal team must observe strict biosecurity, cleaning, and disinfection measures (APHIS, 2002). The disposal group and the euthanasia group must work together to make sure timing and efforts are coordinated (NAHEMS, 2012).

Regulations vary between states and local regions. Proper permits and approvals must be obtained before disposal begins. Communication with the appropriate state and other officials is necessary to determine regulatory compliance. Animal health officials, experts in waste disposal and remediation, licensed professional environmental, civil, or agricultural engineers, and environmental officials need to be consulted as well (NAHEMS, 2012).

Carcass disposal laws differ from state to state and are often not based on science (King, McDonald, Seekins, & Hutchinson, 2009). As an example, in California, deficiencies in carcass disposal regulations became markedly apparent during a heat and humidity wave in 2006, resulting in 20,000 livestock mortalities. These large numbers, combined with a breakdown at a rendering plant, led to an extreme shortage in disposal capacity. Local regulatory officials allowed composting, burial, and landfilling even though it went against state regulations and little technical guidance was provided. This crisis resulted in the development of an Emergency Animal Disposal Workgroup (EADW) by the California Department of Agriculture and the California Integrated Waste Management Board with the purpose of addressing short and long-term livestock disposal needs. The workgroup consists of more than 100 members from more than 50 academic, industry and regulatory groups. The group developed a rendering database, a landfill database, landfill re-permitting template language, a secure web portal, clarification of emergency proclamation authority, and composting research plans. However, a number of laws and regulations would need to be changed for burial, landfilling, and composting to be legally allowed (Payne et al., 2009).

In some states and localities, certain disposal methods are approved for routine use while others are prohibited. In emergency situations, those restrictions may be relaxed to allow other methods to be used. However, as noted in the California, timely response to allow for the use of restricted methods was “hampered by a morass of ambiguous regulatory jurisdictions” (Collar et al., 2009, p. 3). Each state has the authority to establish carcass disposal-related regulations. In some states, that power lies with the state’s environmental agency, and in others it is with the animal health commissioner. In some cases, multiagency agreement is necessary. In Texas, the Texas Commission on Environmental Quality cannot establish carcass disposal rules and regulations without the agreement and consent of the TXAHC. There is still ambiguity, as well as the fact that the DHS would have authority over a state in the case of a nationally significant incident (Boadu, 2010).

It is critical to understand which level of government has responsibility for carcass disposal-related regulations. If an FAD response based on local regulations is in conflict with EPA regulations, as an example, there will be significant disconnect in execution of the response plan (Crnic, 2010).

Incident management will begin at the lowest organizational level, but the dynamic nature of the industry will likely demand a greater level of response. The response may require only limited federal personnel and equipment, but the potential risk level will warrant federal management. Thresholds for federal response and support must remain flexible (FFADDRR, 2005).

Federal roles

The federal government serves in a technical assistance and advice role, not one of implementation. If state or local resources are overwhelmed, federal officials may take on operational responsibilities. Appropriate disposal decisions will involve multidisciplinary expertise and teamwork (FFADDRR, 2005).

Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities

The FFADDRR recognizes seven phases of emergency response: preparedness/surveillance, detection/notification/initial response, control/containment, characterization, decontamination, disposal, and clearance. The response phases may not always be linear. The USDA serves as the primary coordinator of incident response in the control and eradication of a highly contagious animal disease outbreak. The procedures for response were developed based on an FMD scenario. Additional scenarios related to crop and food contamination were also considered (FFADDRR, 2005).

In the case of FMD or another FAD, USDA APHIS may assume a primary role and will serve as the lead federal agency in the coordination of disposal and decontamination efforts. In a presumptive positive case, APHIS, under the power of the USDA Secretary, will quarantine premises. Movement of susceptible animals will stop. Surveillance and infected zones will be determined, as will the depopulation and disposal of infected herds. APHIS will work in conjunction with local and state government environmental and health agencies. Vaccination may be considered for strategic use to create barriers between infected and disease-free zones (FFADDRR, 2005). In the case of an FAD, federal responsibilities include:

- USDA APHIS has lead federal oversight on carcass disposal,
- Activation of NRF will provide full federal authority and resources in the case of a catastrophe,
- EPA will provide technical assistance for food and animal incidents,
- Wildlife carcass disposal is under the authority of the Department of the Interior (DOI),
- FDA is responsible for animal feeds and should be involved with rendered material decisions; and
- U.S. Army Corps of Engineers and NRCS will be involved with handling of mortalities if needed (Marburger, 2007).

In the optimal situation, all animal carcasses should be disposed within 24 hr of depopulation for disease control, aesthetics, and public relations (FFADDRR, 2005; NAHEMS, 2005a). This goal creates extraordinary challenges. In addition, disposal must occur in a manner that does not create a negative environmental impact and stops the spread of pathogens (GAO, 2011).

Human health and the environment should be protected in all disposal efforts. The FFADDRR document identifies incineration, on-site burial, off-site burial in a municipal solid waste or hazardous waste landfill, alkaline digestion, composting, and rendering as potential disposal options. Acceptable options will be developed by the USDA and state solid/hazardous waste officials depending on the disease, number of carcasses, transportation, and availability of disposal capacity (FFADDRR, 2005).

Table 3-3 *Response Phase 6 – Disposal of Carcasses and Related Materials*

Carcass Disposal Process
Level 1 – Local Limited Response
• Incident Command is at the state emergency management level • Primary resources are local, state resources may be used, and federal resources are limited • USDA APHIS support efforts to assess disposal needs
Assess volume of animals for disposal
Determine methods of euthanasia and disposal, evaluate risks of options, and develop a site specific disposal plan
If rendering, determine fate of byproducts
If burial, determine whether euthanasia and disposal will occur on-site, off-site, or in combination
If on-site disposal, obtain appropriate permits
If off-site disposal, arrange transportation and approval
Appraise value of animals for indemnification purposes
Follow pre-approved plan for predetermined sites
Procure equipment and prepare site, including perimeter control
Carry out disposal plan following USDA Disposal Operations Guidelines
Close disposal site per requirements by state authorities
Arrange for disposal of all appropriate equipment and related waste
Level 2 – State/Regional Response
• Local resources used fully, state resources required to greater degree, and need for federal resources may increase but remain moderate • USDA APHIS support used to a greater degree • USDA AERO teams may be used
Same steps, but the scale increases
Level 3 – National Response
• Unified command (local, state, and federal) at the incident level with area command at the state level and national coordination through the NRF • USDA may coordinate interagency support through DHS and FEMA, but roles may vary depending on nature of emergency • All available assets from multiple agencies will be used, NRF will be fully engaged, and ESF#11 will guide efforts • EPA fully involved • DOD, U.S. Army Corps of Engineers (USACE), Department of Interior (DOI), and U.S. Geological Survey (USGS) may all provide contract support in disposal efforts • Additional resources made available through emergency declarations from Governor and the President
Same steps, but the scale is much larger

Note. Adapted from FFADDRR (2005).

Food Safety and Modernization Act (FSMA)

In 2012, Congress passed the Food Safety and Modernization Act (FSMA) that includes Section 208: Decontamination and Disposal Standard Plans. It codifies many of the directives under HSPD-9 and reemphasizes the need for a coordinated federal approach to disposal and decontamination planning and preparedness. The intent is to enhance federal support and assistance to local and state governments in dealing with waste management. It does not amend any of the roles and responsibilities delineated in the NRF, Emergency Support Function (ESF) ESF#11, HSPDs or other documents, but it does designate EPA as the lead in interagency disposal and decontamination efforts in food and agricultural emergencies including an FAD outbreak. It provides for no additional authorities or resources. It calls for the development of standards and model plans as well as exercises and plan modification reviews. An interagency working group consisting of EPA, USDA, HHS, and DHS has been assigned to review and identify gaps in existing standards, protocols, model plans, information needs, tools, and national/regional exercises. Efforts will be made to adapt new and existing guidance for food and agriculture scenarios. Enhanced collaboration with state and local governments, as well as environmental and agricultural communities, is a priority. The working group intends to hold food and agriculture decontamination and disposal exercises to test decision making processes and technology choices (GAO, 2011; Reyes, 2012; WARRP, 2012).

Contradictions in federal responsibilities

The designation in the FSMA of the EPA as the lead agency has created an additional challenge. This designation differs from the authority granted USDA APHIS in the Animal Health Protection Act for coordinating carcass disposal when FAD is a factor. USDA officials have expressed concern that this discrepancy could lead to confusion during an animal disease outbreak (GAO, 2011).

Previous to this legislative contradiction, a lack of clarity on carcass disposal responsibilities when ESFs are activated already existed and has resulted in inefficient execution of ESF#11. If ESFs are activated, the Federal Emergency Management Association (FEMA) has responsibility for determining the roles of federal agencies. FEMA officials consider carcass disposal as debris under ESF#3 on public works and engineering, and thus a responsibility of the U.S. Army Corps of Engineers (USACE). If, however, the carcasses were impacted by chemical, biological, nuclear, or radiological contamination, they would be covered by ESF#11 and be the responsibility of USDA. When FEMA has previously designated responsibility to USDA, responsibility has sometimes been designated to the USDA Natural Resources Conservation Service (NRCS) and other times to USDA APHIS VS. Further disagreement exists over whether or not carcasses needing disposal after a natural disaster create a public health threat. The ESF#11 coordinator says the responsibility will lie with the USACE unless HHS or a state declares the carcasses a public health threat. While the Center for Disease Control (CDC) indicates carcasses are not traditionally a risk to public health, other federal officials believe the rodents and insects attracted by decaying carcasses create a public health threat. This lack of clarity has caused slow and ineffective carcass disposal in some recent emergency responses, such as the disposal of cattle carcasses in Texas after Hurricane Ike (GAO, 2011).

The National Science and Technology Council (NSTC) Committee on Homeland and National Security subcommittee on Foreign Animal Disease Threats (FADT) identified a number of research needs for disposal and decontamination. Even if vaccination is used, euthanasia, and disposal will continue as significant elements of a national FAD response. Specifically, the FADT noted the need for research investment in disease agent persistence, fate, and transport related to methods and species; cost/benefit analysis of disposal methods; ecological and human health risk impact assessment; and identification of surrogate agents for research purposes (Marburger, 2007).

Research questions identified by the FADT focused on:

- Coordination between national, regional, and local disposal operations;
- Required state and federal approval of disposal decisions;
- Application of lessons learned from previous disposal operations; and
- Ability of local decision makers to weigh disposal options in site-specific situations based on public, animal, and environmental health protection in a timely manner (Marburger, 2007).

The inconsistency related to federal authority regarding carcass disposal in a national disposal operation was also identified as a concern by the subcommittee. They contend that no technologies should be used to meet mass disposal surge capacity needs that are not used as part of regular disposal operations system; instead, technologies used on a daily basis should be adapted to meet mass disposal needs. They noted that the development of a disposal operations system recognized by industry, farmers, ranchers, and all levels of government is the number one priority for effective and safe carcass disposal in future mass animal disposal situations. Such a system is necessary to address the lack of standardization between guidance coming from numerous agencies, including HHS, United States Geological Survey (USGS), EPA and USDA (Marburger, 2007).

The NSTC developed a Decontamination and Disposal Working Group. Disposal research priorities were identified by this group as risk-related projects designed to determine the ability of disposal methods to inactivate pathogens, development of regional disposal strategies and transportable disposable technologies, and economic feasibility cost-benefit analysis for disposal technologies with a focus on long-term impacts. As of late 2012, research projects on composting had been completed; projects on rendering, unlined burial, and permitted landfill were underway, and gaps had been identified related to fixed incineration and open burning. DHS also identified the need for a cost estimating tool (Miller, 2012a). As of October 2013, there is no new information on the NSTC website.

The multiagency involvement and the multidisciplinary nature of carcass disposal make it a challenging policy dilemma.

Disposal method selection

Selection of an appropriate disposal location and disposal technology is a critical concern. A single disposal site is preferred for the purpose of disease containment. On-site disposal as well as off-site disposal and temporary storage options should be considered. Historically, the most common and preferred method of disposal was burial on-site at the location of the death. Burial is seen as simpler, more expeditious, more economical, and depending on water tables and soil condition, less likely to cause damaging environmental effects. On-site burial minimizes biosecurity concerns in moving carcasses off-site (APHIS, 2002; CFSPH, 2012; NAHEMS, 2012).

Considerations for selection

Any decision-making system designed to determine optimal locations and methods should consider:

- public health,
- pathogen containment,
- environmental impact,

- environmental protection laws and regulations,
- availability of alternative sites (landfills),
- proximity of burial or incineration site to location of euthanasia (if necessary),
- scale and species of animal loss,
- types of additional materials that need disposed (milk, waste, feedstuffs, manure, bedding, wool, etc.),
- potential hazard the material may pose to humans or animals,
- type of soil and rock at disposal site,
- slope and permeability of site location,
- transportation needs,
- truck access to disposal site,
- water table at disposal site and local minimum permissible distance between water table and burial pit,
- proximity of proposed site to water resources,
- proximity to high population centers and public view,
- locations of underground and overhead utility structures,
- climate, weather, and seasonal conditions,
- scavenger access,
- air quality,
- biosecurity requirements,
- site security requirements,
- future intended use of site,
- physical and psychological health impacts,
- public perception,
- stakeholder acceptance,
- cost effectiveness.
- availability of necessary disposal equipment, and
- availability of the necessary supplies for method used (fuel, chemicals, etc.) (NAHEMS, 2005a; APHIS, 2002; CFSPH, 2012; NAHEMS, 2012).

Decision makers must be able to consider all alternatives and make safe, quick, and responsible decisions with limited environmental and biosecurity consequences. All critical factors must be considered in the decision process (NAHEMS, 2012).

Off-site disposal, transportation, or temporary storage may be necessary in some cases. Climate, environmental conditions, high animal population densities, and wild animal/scavenger presence that can spread disease may influence disposal site selection. Carcasses and materials may need to be temporarily stored until disposal conditions are amenable. If on-site burial or incineration options are eliminated, carcasses must be safely and efficiently transported to the off-site disposal locations. Insufficient space, unsuitable soil, high water table, seasonal conditions, or proximity to public areas may cause the need for off-site disposal. Carcasses may also be able to be landfilled or rendered more efficiently. If transported, special procedures and precautions must occur. Transportation to off-site premises offers multiple concerns, especially in the cases of contagious viruses and contaminated carcasses. Vehicles must be specifically prepared and all moving vehicles must be accompanied by government representatives and, potentially, law enforcement. Temporary storage may be necessary if prompt carcass disposal is impossible, which is highly possible in the case of a large-scale infection or death loss. In all cases, carcasses must be secured to prevent unauthorized access or potential disease spread (NAHEMS, 2005a; APHIS, 2002).

USDA NRCS serves as a resource to farmers and ranchers in identifying and preparing disposal sites. Technical assistance has long been available through the Animal Mortality Facility Conservation and Composting Facility Conservation Practice Standards. Due to recent emergency response efforts, NRCS was added as a member of the NSTC FADT Subcommittee. They have also developed a web soil survey tool for identifying suitable soils for disposal sites (Carpenter, 2009). The electronic code of federal regulations specifies in Title 9: Animals and Animal Products that in the case of a H5/H7 LPAI outbreak poultry carcasses must be disposed of using a method selected by the cooperating state agency in coordination with APHIS. Approved methods include burial, incineration, composting, and rendering. No other approved carcass disposal methods or technologies are identified for other species or diseases in the CFR (eCFR, 2012). On-site burial may be the most inexpensive, but off-site burial, composting, incineration, digestion, and rendering may be alternatives. The focus of disposal efforts should be to provide biosecurity related to disease spread and minimizing the impact on the environment (APHIS, 2012d).

Disposal hierarchies

Some states have developed disposal hierarchies to guide their decisions. USDA APHIS developed Online Emergency Management Tools to provide easy access, simple carcass disposal decision tools, and guidance. The objective of the tools is to share information about cost-effective disposal options, prioritize the options with a decision tree, provide web interface to make selections of options easier, provide training on options, and to summarize disposal options (Miller, 2009). In 2009, Lori Miller, at the time an employee of USDA APHIS, noted that APHIS tools are a "good starting point" but that primary information was limited to poultry and much additional information related to large animals was needed (Miller, 2009). As of fall 2013, the tools were still minimal and had not been recently updated, although referred to in published NAHEMS FAD PReP documents. The only decision tree provided on the USDA emergency response tools website is for in-house poultry composting and no large animal decision tools are included. The emergency response tools are located at: http://www.aphis.usda.gov/emergency_response/tools/aphis_role_emergency_tools_disposal.shtml (APHIS, 2013a).

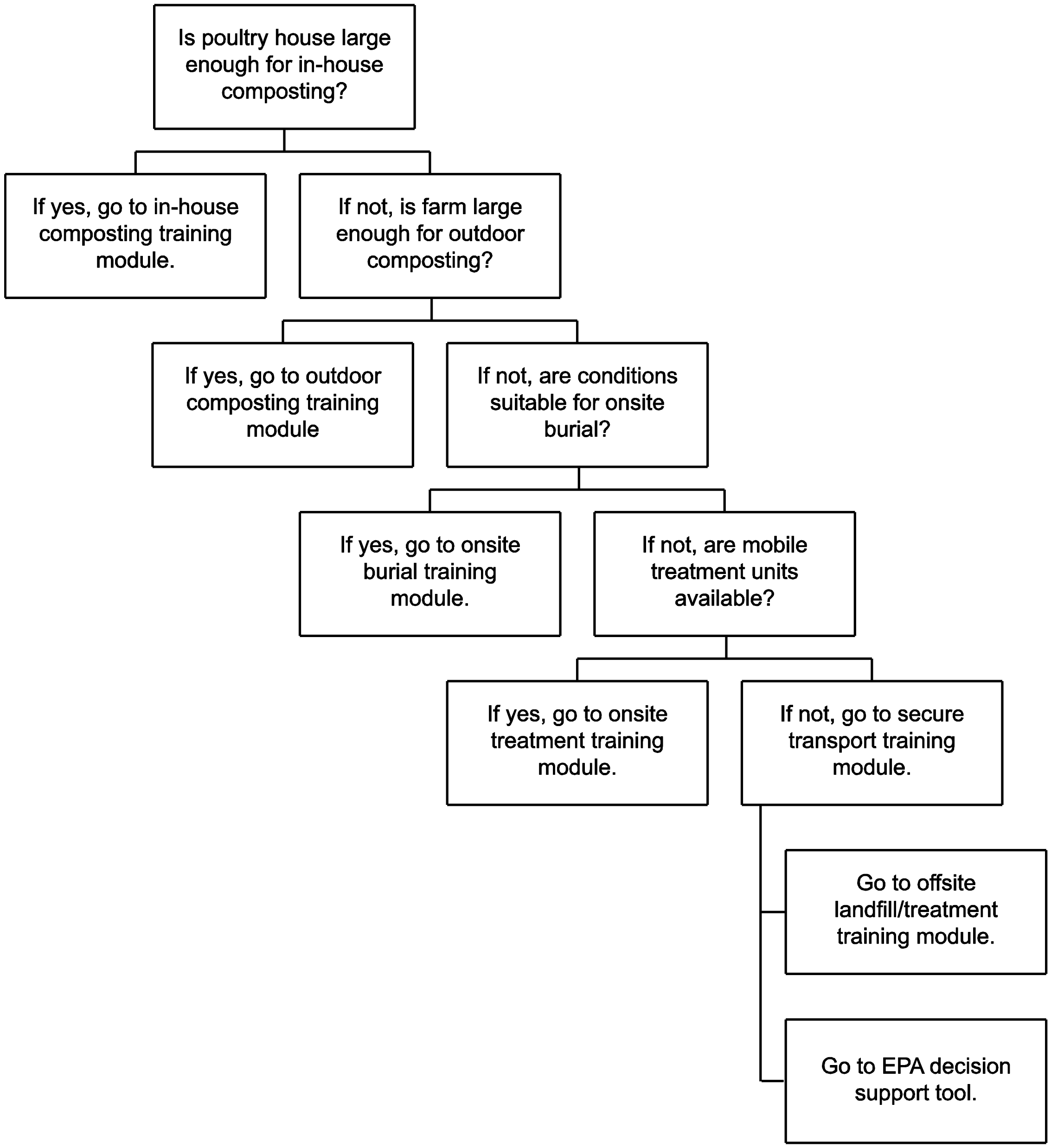

Figure 3-1 Emergency preparedness and response emergency management tools poultry disposal trees (APHIS, 2013a).

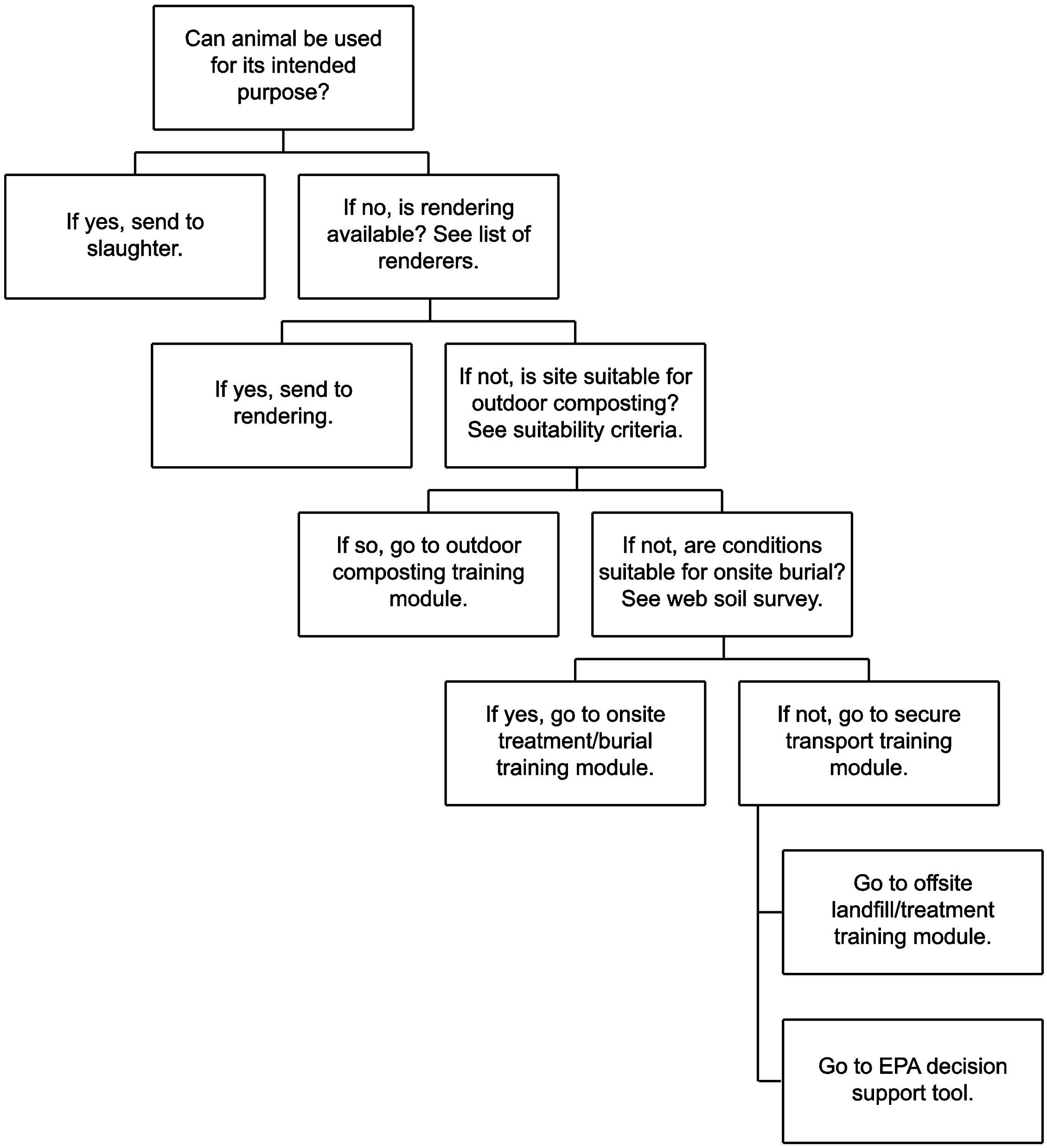

Figure 3-2 USDA APHIS disposal decision tree (Miller, 2012b).

However, in 2012, Miller shared a disposal options decision tree at the 4th International Symposium on Managing Animal Mortalities. Miller indicated current studies are being completed to determine and facilitate the use of the most sustainable disposal options and online decision tools and training modules would be updated. Focus will be on composting, rendering, and permitted landfills with EPA and DHS (Miller, 2012b). This decision tree indicates slaughter, rendering, composting, and onsite burial are the first choices for disposal, but the complexity of the decision process are not represented in the choices provided.

An agricultural waste disposal workshop was held in Weld County, Colorado, in summer 2012. Local, regional, state, and federal emergency management officials along with DHS, EPA, USDA, state animal health and environmental officials, private sector, and academic experts participated. The goal of the workshop was to work through a carcass disposal scenario based on an FMD outbreak in a 20,000-head feedlot. Specifically, the group tested APHIS carcass disposal decision-making tools (WARRP, 2012).

One of the APHIS developed tools shared at the summit was a matrix of disposal options. It is designed as a risk assessment matrix with numerical values assigned to each disposal method based on pre-determined criteria. Each disposal method was ranked as ideal, not ideal, or not suitable against a number of factors. Scores were then totaled and averaged to determine best technologies. The matrix indicated composting and rendering to be the best disposal choices. The matrix was then used to develop a disposal decision tree and checklist for each method. The decision tree provides for a linear progression of steps to be considered when making a carcass disposal decision. The checklist provides detailed considerations for each disposal option. The combination of these tools is referred to as MaTCh (matrix, tree, and checklist) (WARRP, 2012).

The tools are not currently available on the APHIS online emergency management tools, but were made available for the purposes of the workshop. This decision tree, also presented by Lori Miller, indicated a different disposal preference order than the one presented two months earlier (WARRP, 2012). These decision trees are shared in Figures 3-2 and 3-3.

Prior to exercising the scenario, the Colorado State Veterinarian, Dr. Nick Striegel, noted that depopulation and carcass disposal would begin immediately in the case of a confirmed case of FMD. The group was charged with applying the decision-making tools with the intent that all animals in the infected feedlot were depopulated within 24 hr and disposed of within 48 hr. In addition, they had to consider if the 90,000 cattle located at a neighboring feedlot 2 mi away should be depopulated as well (WARRP, 2012).

After the exercise, the process and tools were discussed. A number of the comments centered on the need for technical expertise and participants expressed a number of technical questions that were not covered by the available tools and information. A variety of opinions existed on the best disposal option, although some did consider composting to be the best option. There was some limited consensus that vaccination may be more viable than mass depopulation (WARRP, 2012).

There was a significant amount of concern with the decision making tools. Concerns were expressed that these options and tools would work for small farms, ranches, and disease outbreaks, but would not be effective for a large operation or incident. It was noted that a decision tree may not be the best option because all disposal methods should be considered simultaneously rather than sequentially. Questions were also raised over the values assessment in the decision matrix. While the checklist was lauded for providing some good information, it was seen as more of an educational tool and less likely to be useful during a disease outbreak. In fact, one participant commented that while it was a good informational tool, it actually led to the conclusion that these tools would not work (WARRP, 2012).

It was also noted that science is often trumped by public perception, and is, therefore, unlikely to drive decision making. Replacing the advice of experts and scientists with publicly determined approaches will lead to interference with the process and deter carcass disposal from occurring in the most logical manner (WARRP, 2012).

Table 3-4 *APHIS Disposal Options Matrix*

	Composting	Rendering	Off-site landfill	Off-site incineration	Open air burning	On-site burial	Mobile treatment technologies
Public health risk	3	3	3	3	2	1	?
Need to transport carcasses off-site	3	1	1	1	3	3	3
Byproducts	3	3	2	3	1	1	?
Pathogen inactivation	2	3	2	2	1	1	?
Cost effectiveness	3	2	3	1	1	3	?
Environmentally sustainable	3	3	2	2	1	1	?
Volume reduction	2	3	2	3	3	2	?
Capacity	2	2	3	1	2	3	1
Throughput	2	3	3	1	2	2	1
Availability	2	2	3	1	3	1	1
Speed to implement	2	2	3	2	1	1	?
Public acceptance	3	2	3	2	1	1	?
Efficiency	2	3	2	2	1	2	?
Operability	2	2	2	2	2	3	1
Total points	37	37	35	29	26	26	7
Average score	.5	.5	.3	.9	.7	1.7	1.4

Key: 3 – Ideal, 2 – Not Ideal, 1 – Not suitable
Note. Adapted from WARRP (2012).

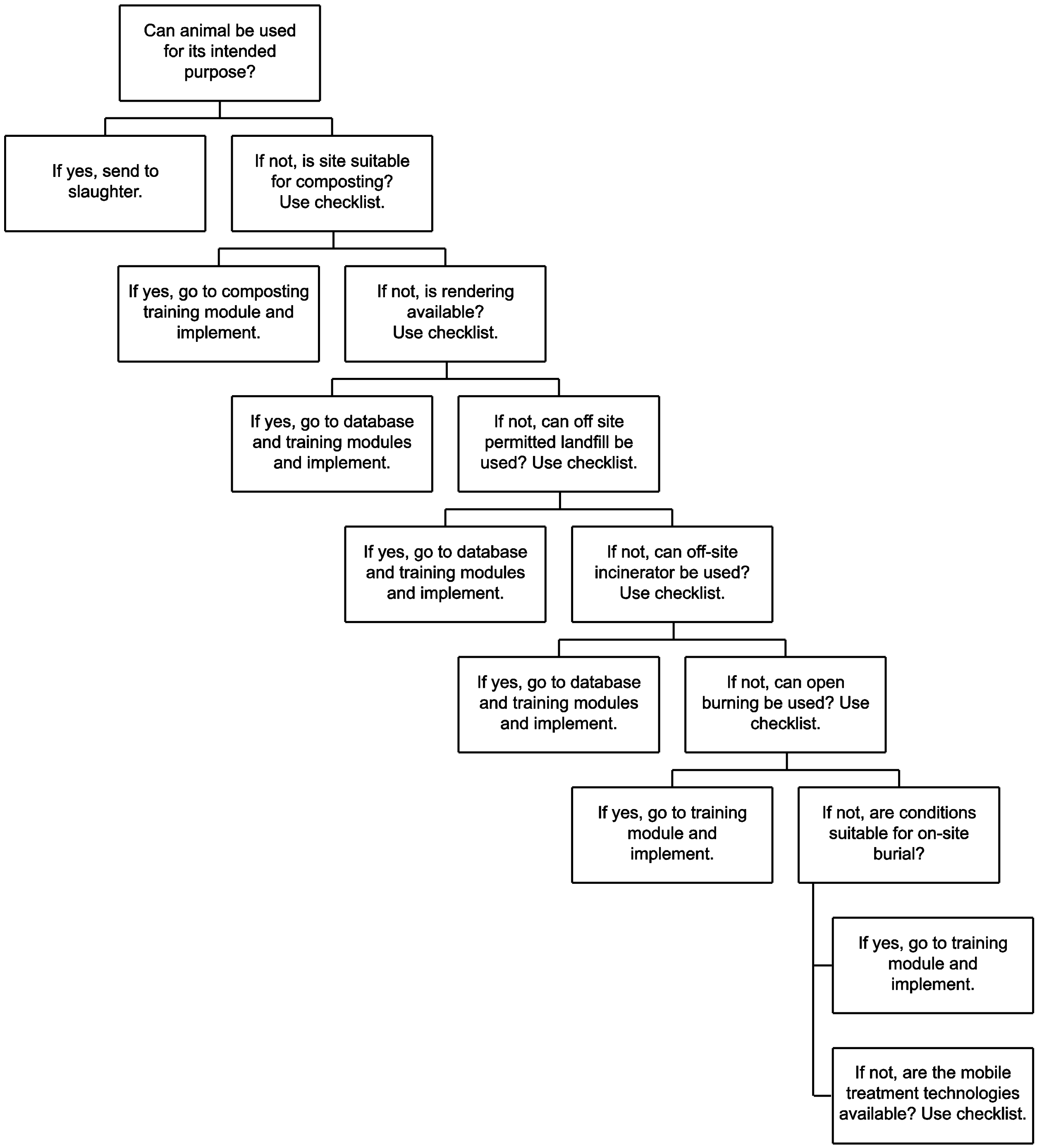

Figure 3-3 APHIS Carcass Disposal Decision Tree (WARRP, 2012).

Carcass disposal is multidimensional and typical disposal hierarchies may be limited in value, neglect relevant dimensions, and not fully capture all the issues. Preferred methods may not be possible, even if the hierarchy is based on a single priority such as direct cost or environmental impact. In a catastrophic mortality situation, any hierarchy may be set aside for the sake of emergency management. Decision makers should consider these possibilities in the planning process and have a strong understanding of all the alternative methods and their impacts. Any policy tool designed to provide decision making guidance needs to be multidisciplinary and address all related issues (Nutsch & Kastner, 2008).

Carcass Disposal Methods and Alternatives

The optimal disposal method will depend on the circumstances of the emergency. USDA APHIS (2002) defines the goal for disposal as "to control and contain the spread of disease." Prompt disposal is critical to disease control as well as public perception and other factors. Local, state, and federal environmental laws and regulations must be considered and environmental agencies must be consulted. If a transmissible spongiform encephalopathy (TSE), such as BSE or CWD, is present, specific regulations will apply.

It is unlikely that only one disposal method will be used in a large scale animal disease emergency. To be most effective, multiple disposal technologies may be integrated into the overall disposal strategy. The strategy must remain flexible to allow for necessary changes and improvements as the emergency progresses (NAHEMS, 2012).

The Center for Food Security and Public Health (CFSPH) (2012) identifies burial, subsurface disposal/landfills, incineration, composting, and rendering as the most common methods of carcass disposal. Other methods include air-curtain incineration, alkaline hydrolysis, and other novel technologies. The OIE also identifies a list of 11 recommended methods of disposal (OIE, 2007a; OIE 2012b). The common methods, as well as a few alternative methods, are described in the sections that follow.

Burial

Burial has often been considered the preferred disposal method by many government entities, except in the case of BSE-infected or exposed carcasses. Burial can take place on-farm or in mass burial sites. Trench burial can be utilized to bury large numbers of carcasses, while disposal pits are more appropriate for smaller losses. The environmental impact of burial should be a consideration when determining if burial is appropriate (Ellis, 2001; APHIS, 2002). The decision to bury will also be influenced by soil conditions, prevailing winds, topography, availability of digging equipment, and proximity to public areas (NAHEMS, 2005a). The specific burial site should be located near the site of euthanasia and the pace of depopulation and disposal should be synchronized (NAHEMS, 2012). Geographic information system (GIS) technology can be used in the planning process to identify sites suitable for burial. Databases can model topography, geologic, water, and soil characteristics and allow for the mapping of burial sites that are least likely to negatively impact the environment (Jacobs, 2006; Harper, et al., 2008).

In the US, each state has the responsibility for defining burial requirements, and disparity exists between state guidelines. Minimum burial depth in Wisconsin for a natural disaster death is 2 ft, while in Kansas it is 6 ft. The minimum distance from streams and wells in Arkansas is 600 ft, but in Texas there is no minimum standard. California regulations state that the minimum burial distance from residential dwellings is 100 ft, yet neither North Carolina nor Florida requires a minimum distance. It is unclear if these stated offsets are actually regulations or implied guidelines that can be set aside in the case of an emergency (APHIS, 2002; Morrow & Ferket, 1993; Scudamore, Trevelyan, Tas, Varley, & Hickman, 2002; Ellis, 2001). Some states will not permit burial, and it is anticipated that burial will become a less and less favored alternative due to regulatory considerations and fear of groundwater contamination. In 1994, Arkansas prohibited burial as a means of poultry carcass disposal, and Alabama prohibited burial starting in 2000 (Blake et al., 2008). As an example, Texas is approved for burial and incineration (Boadu, 2010). While many states may set aside regulations in an emergency situation, water quality concerns and public perception may eventually eliminate burial as an alternative (Blake et al., 2008).

Significant land area is required for burial efforts. Each bovine carcass requires about 3 ft of trench length and 14 sq ft (42 cu ft) of surface area. Five hogs or sheep are the equivalent to one bovine carcass. For poultry, 1 sq ft of surface area is required per bird. For every additional 3 ft in depth, the number of animals per 14 sq ft can be doubled (NAHEMS, 2005a). For example, to bury all the cattle in one 30,000-head feedlot would require a hole the size of a football field 31-ft deep. Other estimates indicate a 100,000-head feedlot would require 128 acres for burial (not including any buffer zone space) and create 4,000 gal leachate per day (Miller, 2011). Engineered mass burial sites that are designed for significant numbers of animals and incorporate containment measures and a more sophisticated approach may also be a possibility (Nutsch & Kastner, 2008). Mounding is the process of aboveground mass burial and has similar impacts as mass burial and composting (OIE, 2005; OIE, 2012b).

The transportation to off-site mass burial sites can also create a significant challenge. As an example, a 100,000-head feedlot with cattle weighing an average of 1,000 lbs each creates 100 million lbs (50,000 t) to transport. A large transport container can transport about 30 t, so nearly 1,700 containers would be required in this scenario (Miller, 2011). Some USDA officials have indicated burial is simply not feasible in a large scale outbreak especially due to intensive labor related needs. In at least one exercise, it was determined that the 70,000 cattle that needed to be disposed of could not be buried in four days (GAO, 2011).

Klassen and Malek (2009) indicate mass burial is a "safe, cost-effective, and environmentally acceptable method of disposal (p.1)" and seen by the public as the least controversial method (Klassen & Malek, 2009). However, some researchers have argued disposal by mass burial should be avoided because of the risk to groundwater pollution, unless engineered sanitary landfilling is used. If burial has to occur, only preplanned sites with lowest environmental impacts should be used (Harper et al., 2008). Liners should be used to minimize seepage; and groundwater, surface water sources, air quality, and odor should be monitored following a mass burial (CFSPH, 2012).

Because containment loads will occur at one time rather than over time, sites approved for routine burial may not be appropriate for mass burial. The potential long-term impacts and site characteristics deserve more careful evaluation. The environmental impact of mass burial is poorly understood and little knowledge exists on leachate movement from mass burial sites. The strength of the leachate is 5-10 times higher in a mass burial site than it is in manure storage and landfill sites (Pratt & Fonstad, 2009; Pratt & Fonstad, 2012). Researchers in Saskatchewan studied the impact of ion exchange and leachate movement beneath two preexisting burial sites, one 7 years post-burial of CWD elk and the other 60 years post-burial of FMD carcasses. At the CWD site, leachate movement was minimal and ions of concern remained in the burial pit. The same results were seen at the FMD site with no impact to surrounding soil cores. While hard water plumes resulting from the ion exchange reactions from ammonium will be the first to reach groundwater sources in the long term, this is less concerning than if there was movement of the attenuated ions from the burial pits. Further research is needed to determine the potential long-term hazards related to mass burial in different soils and locations (Pratt & Fonstad, 2012).

If mass burial is an intended disposal method, preapproved sites are a crucial emergency management practice. These sites can be selected to be more cost effective and reduce risk. Topography, geology, and hydrology should be considered when selecting sites in a transparent manner. A rapid response is more likely if sites are preidentified and preselection is a part of emergency plans (Klassen & Malek, 2009). A lack of preapproved burial sites was identified as a significant hindrance slowing the emergency response during the Japan FMD outbreak in 2010. Japanese officials originally decided to bury with the intent not to disturb the burial sites for three years, although post incident interviews indicated the selection of three years was arbitrary (Miller, 2011). The rainy season added an additional complication with burial because the lined pits accumulated rain water and required pumping out (OLPC, 2012). After reviewing the response efforts, Japanese officials have determined that a combination of alternative disposal methods, including incineration and rendering, must be considered in the future (Muroga et al., 2012).

The public has become more environmentally conscious and is likely to oppose burial for fear of groundwater contamination. Also, producers may not be supportive of on-farm burial because of impacts on land value and future land-use decisions (Flory et al., 2006a). Mass burial may also be a challenge in cold weather (CFSPH, 2012). Burial may not be the best option, although the "knee jerk reaction to any emergency, whether due to disease outbreak or natural disaster, is to bury" (Schwarz & Bonhotal, 2009).

Landfill

Public landfills are also an option for disposal. Carcasses are considered non-hazardous waste and can be disposed in landfills (FFADDRR, 2005). While landfills are often used for companion animal disposal, landfills are unlikely to be prepared to handle the additional needs that would be created with significant carcass disposal. They may serve as a reasonable alternative if burial is identified as the best method for the circumstance, yet timing and location do not make digging burial pits efficient or effective (Bagley, Kirk, & Farrell-Poe, 1999; Franco, 2002; Sander, Warbington, & Myers, 2002).

The greatest advantage of landfilling is that the infrastructure already exists. They pose little risk to the environment, because they have already taken necessary environmental precautions (Flory et al., 2006a; Harper et al., 2008). Landfills are highly regulated under the

Resources Conservation and Recovery Act and most have leachate and gas collection systems in place. It is possible that carcass degradation may take longer in a landfill site (CFSPH, 2012).

Timely disposal is critical and landfills already have preexisting sites, equipment, personnel, procedures, and containment systems. However, some landfills will simply refuse carcasses or increase landfill costs to an exorbitant level. Landfills may be owned by municipalities, private owners, or corporations and operators may choose not to cooperate. Use of landfills depends on preplanned agreements with landfill owners. For example, during an AI outbreak in British Columbia, landfill operators closed their gates on trucks carrying dead poultry. The need for transportation to a landfill site will also create challenges. Appropriate permits will need to be obtained as well (Flory et al., 2006a; Harper et al., 2008).

In the US, there are three types of landfills: subtitle C – hazardous waste, subtitle D – municipal solid waste, and subtitle C&D – construction and demolition debris. Subtitle C and D landfills are designed with leachate collection and gas recovery, and subtitle D landfills are generally clay or synthetically lined (NAHEMS, 2012). Research has indicated that subtitle C landfills are the only kind suitable for carcass disposal. If a national emergency required the use of subtitle D landfills, sites would need to be indemnified by the federal government (Vanier et al., 2008). However, recently published NAHEMS guidelines indicate subtitle D landfills are the optimal landfill type for carcass disposal. Some small local landfills may not meet the subtitle D landfill regulations (NAHEMS, 2012).

The public may oppose landfilling large numbers of carcasses. Public opinion has varied in previous carcass disposal emergencies. In the U.K. FMD outbreak, landfill capacity could have handled all the carcasses needing disposal, but only 16% of carcasses were landfilled due to strong public opposition. However, in the California END outbreak, a majority of carcasses were disposed in landfills with little public reaction (Nutsch & Kastner, 2008). Local public, city officials, farmers near the landfill, and interest groups could influence landfill availability if prior planning and communication has not occurred (Harper et al., 2008). The geographic locations of landfills may serve as either an advantage or disadvantage depending on the situation (Nutsch & Kastner, 2008).

Landfilling TSE-infected carcasses is not recommended. After the 2003 BSE case in Washington state, risk analysis was conducted by major disposal companies and landfilling for TSE-infected carcasses was deemed safe. However, concerns remain that prions could pass through wastewater treatment. National Carcass Disposal Symposium (2006) presenters agreed such disposal comes with some level of risk (Hater, Hoffman, & Pierce, 2006; Lin, 2006; Vanier et al., 2008).

Some landfills are likely to be unwilling or hesitant to accept animal carcasses. This concern may relate to a lack of understanding or influence of public opinion. It may also be the result of a lack of personnel, equipment, and soil. Precatastrophe agreements between government agencies and landfill operators will make their use in an animal disease emergency simpler and more likely (Ruman, 2012; NAHEMS, 2012). As a response to this concern and the concern that agreements should be prenegotiated with local landfills, a major landfill company, Waste Management, Inc., was approached by the USDA APHIS VS Area Emergency Coordinator for Illinois, Indiana, Minnesota, and Wisconsin regarding their willingness to accept FMD animals into their landfills. After providing the necessary information, completing the appropriate forms, and gathering relevant resources, the application was accepted, the company agreed to accept FMD animals into three sites in Illinois. Financial arrangements are still under discussion and signing authority was also being considered. This type of pre-planning and further expansion of these types of agreements with landfill companies is critical. Because each disease and species will be different, educational efforts must be complete and multiple agreements are necessary rather than a blanket approach. Also, due to variations in state regulations, it is likely that each state must be handled individually (Ruman, 2012).

Incineration/burning

Burning is likely only to be used if other options are not possible. It is often considered to be difficult and expensive when labor and materials are included in cost estimates.

There are three methods of incineration: open burning, stationary or fixed-facility (municipality/commercial) incineration, and air-curtain incineration. Burning on-site can occur if carcass numbers are limited, burning permits can be obtained (if necessary), and appropriate fuel is available. Pathology incineration, resulting in safe and complete disposal, is a possibility, but access is normally limited. This type of biological incineration is ideal for small numbers in close proximity to the location of the incinerator or when the disease agent is BSE or a similar prion (APHIS, 2002; Ellis, 2001; Ekboir, 1999; NAHEMS, 2005a). Species type will largely impact speed of burn because carcasses with higher fat percentage will burn more efficiently (NAHEMS, 2012).

Open burning is designed to use maximum fire temperatures and minimum burn time to dispose of carcasses through efficient combustion. Burn sites need to be in a flat area, out of public view, and accessible to large vehicles. Burning can be done above ground, in a burn pit, or on combustible burn pyres. Considerations need to be given to prevailing winds and the prevention of unnecessary smoke and objectionable odors in public areas. Burn permits and air pollution regulations must be considered. Obtaining sufficient fuel material will be challenging, and burn temperatures may vary. Local availability and weather conditions will influence material choice between straw, hay, heavy untreated timbers, kindling wood, coal, and liquid petroleum fuel. Controversy may exist over public reaction, environmental impact, and possible open-air disease transmission (Vanier et al., 2008; NAHEMS, 2005a). While there is no proof from previous disease incidents that pathogens have been transported after being expelled from animals' respiratory tracts during open burning, concerns remain that open burning may initially help spread the disease through possible particulate transmission as a result of incomplete combustion (Harper et al., 2008).

State burning regulations vary. Many states have strict requirements on burning, yet they will routinely waive those restrictions in the case of an emergency. Public reaction to burning was significantly negative in the UK and potential public relations problems exist with all burning options (APHIS, 2002; Ellis, 2001; Ekboir, 1999). Overall, open air burning is an unfavorable choice for catastrophic mortality disposal (Harper et al., 2008).

Municipal or commercial incinerators are fueled by natural gas, diesel fuel, or propane. They are designed to burn household or industrial wastes with moisture content of 20-25%, so burning carcasses with 70% moisture may be challenging. Burn temperatures can be controlled and effective inactivation of pathogens can be guaranteed. Rising cost of fuel combined with the high energy requirements to dehydrate high moisture carcasses may make fixed-facility incineration difficult (Vanier et al., 2008). Co-incineration can also be considered. It is a process where carcasses are burned with hazardous waste incineration, clinical waste incineration, and other industrial incineration such as power plants, cement kilns, blast furnaces, and coke ovens (OIE, 2005; Marburger, 2007).

Air-curtain incineration uses a burn pit or refractory box with fan-forced air to burn the materials. It is more fuel efficient, environmentally friendly, and has been proven effective in carcass disposal. It is also a faster acting burn technology, because 4,000 lbs of animal carcasses can be burned in an hour at higher temperatures than other burn methods. This method is an excellent choice when dealing with smaller numbers of carcasses. Air-curtain units are portable and can be moved from site to site. However, large quantities of fuel are still required (APHIS, 2002; Ellis, 2001; Ekboir, 1999). Air Burners, LLC, air-curtain manufacturers, contend that their method is the only publically acceptable method that lends itself to effective and safe disposal of carcasses infected with highly contagious disease (Air Burners, 2008).

More economical incineration units may become more viable disposal alternatives as their improvements are based on incineration technology that increase ease and efficiency of on-farm use. Ash disposal, overall costs of operation, and turnaround time remain challenging (Blake et al., 2008).

Composting

Composting is a fairly simple process if proper supplies and an appropriate site are available. But, while appearing simple, composting remains a complex process and good management techniques are critical to success. Composting is the controlled, biological decomposition of organic materials and consists of two stages, a high temperature active stage and a lower temperature curing stage. The process requires a variety of carbon sources, bulking agents, and biofilter layers. Nitrogen, oxygen, carbon, and moisture are required for composting to occur. Composting is an environmentally friendly technology, because it is basically recycling. The end result is a nutrient rich byproduct that can be applied to agriculture land to increase nutrients and productivity. While examples with animal disease are minimal, volume composting has been effective on mass death losses in poultry. It is commonly used in the poultry industry and is starting to be applied more frequently to larger animals. However, composting is not legal in some states for large animals. While composting is fairly inexpensive and the end product can be utilized for land application as a soil amendment, it is a slow process and is not appropriate in some situations. Bin or static windrow composting are both possible alternatives, and the required carbon nitrogen ration is between 25:1 and 40:1. In large-scale emergencies, passive low-tech composting techniques may be used. The focus would be on disposal, not creation of compost. Compost piles will need to be monitored and isolated until the disease agent is no longer present, especially when predators or scavengers are possible. (Ellis, 2001; APHIS, 2002; NAHEMS, 2005a; Wilkinson, 2007; Harper et al., 2008; OIE, 2005; CFSPH, 2012; NAHEMS, 2012). Bag composting or in-house composting are also options for carcass disposal. In-house composting has proven successful in poultry houses, especially in the Delmarva Peninsula AI outbreak. In some cases, compost windrows have been removed from poultry houses in 10 days with effective disease eradication (Bendfeldt et al., 2006; EPA, 2006; Flory, Peer, & Malone, 2009).

Composting can contain the disease and limit off-farm transmission while limiting the risk of groundwater and air pollution. Pathogens in the carcass and litter are deactivated and specialized equipment is not required. Typically, composting would not be impacted by severe weather or frozen ground and the general public is less likely to be concerned about disease exposure or environmental impact. To be most effective, carbon sources, euthanasia methods, worker decontamination plans, adaptation of housing designs, and identification of rapid response teams should be predetermined (Flory et al., 2009). If carcasses are composted properly, the compost piles should not contribute to surface and groundwater contamination through leachate and runoff (Bonhotal & Schwarz, 2009).

Catastrophic composting can be effective especially when a disease agent is involved. Pathogens are deactivated by high temperatures, so composting is believed to be a relatively biosecure process when performed properly. While burial may remain a more likely option for catastrophic mortality disposal, composting can be especially useful when limitations exist because of shallow water tables or frozen ground (DeRouchey, Harner & Murphy, 2005). It also appears that composting poses less environmental risk than burial or open burning, making it the most environmentally friendly on-site method that does not require special machinery (Harper et al., 2008). Mass mortality composting has been considered better suited for small to medium carcasses, such as swine and poultry (Wilkinson, 2007; Vanier et al., 2008).

The ability of composting to eliminate pathogens is one of the primary concerns, especially with large animals. There is uncertainty regarding the ability of composting to eradicate large animal pathogens, the amount of time pathogen elimination will take, and spatial uniformity when composting large animals. Researchers in Alberta, Canada performed tests on feedlot cattle that indicated the majority of bacteria and viruses were rapidly inactivated. The bacterial surrogates for anthrax and scrapie prions were reduced, but survived the composting period. Researchers also found duration of heating was more important than peak temperature. Reduction of the manure moisture content and elevation of carcasses led to improved pathogen elimination and carcass degradation. In addition, compost piles create less public scrutiny and minimize risk to groundwater and air (Standford et al., 2009).

In an Iowa State University study, 54 t of cattle carcasses were composted to assess effectiveness in disease control and environmental impact. Researchers found composting to be a successfully biosecure process for cattle and have published guidelines for composting cattle mortalities (NAHEMS, 2005a; Glanville et al., 2006; Glanville et al., 2008). Researchers agree that additional efforts are needed to determine the level of biosecurity risk associated with composting in the case of a disease outbreak (Harper et al., 2008). A study of stocker calf carcass composting showed that pine shavings and poultry litter were effective compost materials and reached temperatures required for pathogen inactivation and were more effective than hay (Payne & Pugh, 2009).

In 2004, the Canadian Food Inspection Agency used a "plastic-wrapped passively ventilated composting system" for emergency disposal of poultry during an AI outbreak (Glanville, Ahn, Crawford, Kozial, & Akdeniz, 2009, p. 1). Glanville et al. (2009) tested this system for emergency disposal of swine carcasses. Tests were completed in cool and warm weather with six potential envelope materials. The research focused on biosecurity. The research showed that average moisture content declined, leachate was minimal, and the carcasses became desiccated due to excessive airflow. While corn silage did not meet minimum O_2 levels due to excessive moisture, the envelope material met and maintained high enough internal temperatures for pathogen reduction. Excessive airflow resulted in loss of valuable moisture and heat. By controlling air flow, biosecurity and pathogen reduction may be more effective, which indicates that more research is needed (Glanville et al., 2009).

In the LPAI outbreaks in West Virginia and Virginia in 2007, composting was used as an effective method for disposal of poultry, including 40-lb turkeys. It is important that disposal and depopulation methods work together, and these incidents allowed composting to be tested in conjunction with firefighting foam as a method of depopulation. Composting was found effective when used with firefighting foam, and, in fact, quality foam was found to benefit the composting process. Large birds were effectively composted within 4-6 weeks, even without preprocessing. These findings, combined with the fact that composting inactivates the AI virus, make composting a disposal method that should be seriously considered (Flory & Peer, 2009).

Another concern regarding composting relates to its ability to be used with sodium pentobarbital as a method of euthanasia. Secondary poisonings of domestic animals and wildlife have occurred when improperly disposed euthanized carcasses were accessed. Increased risks to the environment, public health, and wildlife may exist if sodium pentobarbital is used for mass euthanasia prior to large-scale disposal. Research needs to determine how long and in what levels sodium pentobarbital might persist or enter the environment if euthanized animals are composted (Schwarz & Bonhotal, 2012; Wolfgang, Vadathala, & Murphy, 2009).

A study at Oklahoma State University on sodium pentobarbital residues in equine composting indicated that in the 129 days it took equine soft tissue to compost, there was no reduction trend in the concentration levels of sodium pentobarbital (Payne, Farris, Parker, Bonhotal & Schwarz, 2012). Further study has indicated the sodium pentobarbital may be detectable for up to 224 days at reduced levels, but properly built compost piles will keep scavengers away until levels are reduced. Comparisons to breakdown in the soil indicate the reduction is not due to the heat of composting but more likely to biological degradation. The final compost product did not contain concerning levels of the barbiturate. Research also showed that nonsteroidal anti-inflammatory drugs given to animals for relief of pain and inflammation do not persist in compost piles (Schwarz & Bonhotal, 2012).

A field exercise designed to test the state's FMD response plan was conducted by the Maine Department of Agriculture on an active dairy farm in 2008. The exercise focused on all aspects of the response with an emphasis on composting the carcasses. Based on previous trials, Maine's plan called for on-farm composting using active municipal compost as cover. A number of lessons were learned related to needs for personal protective equipment, worker safety supplies, lighting, outside water source, additional trucks, generators, higher quality radios, and other supplies. Overall, the use of composting as a disposal method was successful, primarily due to appropriate planning, input, and access to needed materials (Seekins, 2009).

In Vermont, the Department of Agriculture used a catastrophic dairy barn fire to test trench composting as a means of carcass disposal in an emergency situation. While the emergency management aspect of the project was successful, the composting component was not. Containment and disposal were completed within three days and the compost trench remained intact without disturbance by scavengers, odor emission, pathogen release, or leachate discharge. However, the project resulted in poor composting performance because temperatures within the compost did not reach optimal temperatures and poor surface drainage caused a lack of aeration. They also noted that limited availability of personnel and equipment was a challenge (Comstock & Weber, 2009).

The Montana Department of Livestock has added composting to its possible disposal methods for use in an emergency situation and is conducting research on feasibility of large carcass composting through the composting of road kill. Composting is considered a more viable alternative for AI or mass mortalities of small animals rather than for a number of large animal carcasses (Crowley, 2009).

Composting is not considered a legal method of carcass disposal in California. In 2008, the California Code of Regulations was amended to allow a research project on composting of bovine mortalities under real-world conditions to determine feasibility of composting as a disposal method and to investigate the potential environmental impacts of mass carcass composting. Initial field tests indicated composting may be a practical and effective disposal method (Collar et al., 2009). University of California Cooperative Extension completed a study in 2010 on carcass disposal in an emergency situation. This study was a result of the situation California dairy producers found themselves facing in 2006 when heat waves killed thousands of dairy cattle, resulting in rendering facilities being overwhelmed. At that time, Kings County approved emergency burial, but it was evident that other methods needed to be considered in the future. The California Department of Agriculture funded the study to determine if composting was a reasonable alternative that would be environmentally safe and protect human and animal health. California EPA provided approval for the study, although composting of mammalian carcasses is restricted. Results indicated that composting is a viable alternative for emergency carcass disposal, although the only legal means of disposal is rendering. Pathogen reduction, speed of decomposition, and heat levels attained all indicated effectiveness of composting. A limited number of states allow animal composting for mass mammalian carcass disposal, including Kansas, Maine, Iowa, New York, Nebraska, Virginia, Wisconsin, and Washington (Souza, 2010).

Rendering

Rendering is a process of separating animal fats and proteins by cooking. Carcasses are converted into protein-based solids. Rendered products are used for feedstuffs and industrial purposes. If rendering plants are available, it can be the most economical method of carcass disposal according to current guidelines. The advantages of routine rendering could be applied in the case of mass disposal, including existing environmental regulation, biosecure end products, and cost recovery through marketable end products (Ellis, 2001; Morley, Chen, & Rheault, 2003; Harper et al., 2008; NAHEMS, 2012).

The greatest concern comes with the transport of carcasses to the rendering facility. Managers of rendering facilities must be willing to cooperate and stop all other operations. Continuous, rather than batch, rendering should be used if diseased carcasses are rendered. Facilities must have strong security protocols. The receiving side of the facility must be completely separate from the finished side, and airflow must be directed from the finished to the receiving side. All rendered material must be tested to ensure it is safe and disease free. The product may then be buried, incinerated, or composted. While rendered material may be reused, public perception and disease transmission both must be considered. BSE, CWD, or other TSE infected materials should not be rendered (Ellis, 2001; Food and Drug Administration [FDA], 1997; Morley et al., 2003; NAHEMS, 2005a; CFSPH, 2012).

Rendering is a business and depends on the marketability of the end product. If end products from catastrophic mortality rendering cannot be used for animal feed, rendering companies will likely not find rendering to be economically justifiable without additional compensation (Vanier et al., 2008). Over time, renderers have changed their business model from one that pays for carcasses to one that charges to pick up carcasses, resulting in a reduction of animals being rendered. Renderers also have to pay landfills to take meat and bone meal (MBM) from specified risk material and then pass these costs on to farmers and ranchers. Research is taking place to determine if bovine MBM can be gasified to produce a useable syngas with the intent to regain value in the system (Fonstad et al., 2009). The enhanced feed ban issued by the FDA in 2008 eliminating the use of the highest risk cattle tissues of brain and spinal cord from all animal feed is likely to continue to negatively impact rendering profitability (Collar et al., 2009; FDA, 2012). There are cases where rendered fat has been used as fuel in rendering facilities and where other rendered products (MBM) have been used as fuel in power stations (Vanier et al., 2008).

Currently, there are approximately 300 rendering facilities in North America according to the National Renderers Association (NRA, 2012; Lemieux, 2012a). Due to the changes in feed rules, the rendering industry has consolidated. In the case of a catastrophic mortality disposal effort, rendering plants could easily become overwhelmed and haul distances to rendering plants may prove too burdensome (Glanville et al., 2008; Harper et al., 2008).

Rendering is a highly logical approach when facilities are available because it is more efficient that other recycling systems. In addition, removing animal carcasses from the waste stream via rendering would result in the emission of significantly less greenhouse gases than if those carcasses were disposed of in landfills, compost piles, or burial pits and the carbon released as CO_2 into the atmosphere (NRA, 2012). Current research is examining the challenges of returning a rendering facility back to normal operation following use for mass carcass disposal in a disease event (Lemieux, 2012a).

Alkaline hydrolysis

Alkaline hydrolysis is a form of tissue digestion created for the biomedical and pharmaceutical industries to dispose of radioactive animal carcasses. It was introduced in 1992 by Waste Reduction by Waste Reduction, Incorporated (WR^2). Recent advances in equipment and technology have made alkaline hydrolysis a more feasible option in carcass disposal. Heat and pressure combined with sodium hydroxide or potassium hydroxide digests the carcass and results in liquid effluent and the mineral portion of bones and teeth. The effluent can be discharged into the sewage system, or, if potassium hydroxide is used, it can be dehydrated and used as a fertilizer. The bone and teeth can be crushed and sent to a landfill (Ellis, 2001; APHIS, 2002; Taylor & Woodgate, 2003; NAHEMS, 2005a; Vanier et al., 2008; Waste Reduction by Waste Reduction Inc. [WR^2], 2008). Alkaline hydrolysis is effective in destroying numerous infectious pathogens, and there are few emissions and minimal odor associated with the process. However, its role in catastrophic disposal efforts would be limited by the lack of available units (Kaye, Weber, Evans, & Venezia, 1998; Harper et al., 2008; CFSPH, 2012).

Permanently installed alkaline hydrolysis units currently in operation require transportation to the site, but portable units are being developed. Fixed systems can handle

10,000 lbs/cycle and portable units take 4,000 lbs/cycle. Other methods are under development that will significantly increase the efficiency of digestion capacity. The use of alkaline hydrolysis tissue digesters is a preferred method for disposal of TSE contaminated carcasses because it ensures a biosecure end product. It has been utilized for the disposal of elk and deer that are infected or exposed to CWD. It is also a preferred method for disposing of poultry infected with AI H5N1. It has also been found to compare well economically for disposal and animal byproducts especially in large-scale, intensive livestock production systems. In theory, large-volume portable units in routine use around the country could be pulled together to deal with a mass animal disease disposal effort (Ellis, 2001; APHIS, 2002; Taylor & Woodgate, 2003; NAHEMS, 2005a; Vanier et al., 2008; Gwyther, Williams, Golyshin, Edward-Jones, & Jones, 2011; Williams, Gwyther, Golyshin, Edward-Jones, & Jones, 2012).

Lactic acid fermentation

Fermentation is a closed system of anaerobic microbiological decomposition. Lactic acid fermentation is an anaerobic process that produces an end product that may be pathogen-free and nutrient-rich. *Lactobacillus acidophilus,* bacteria that produces lactic acid from fermented sugars, is the most common form of inoculant. To be most effective, carcasses should be ground before fermentation. Carcasses are mixed with a fermentable carbohydrate source such as lactose, glucose, molasses, ground corn, or whey. During this process, carcasses can be decontaminated and there is a possibility of recycling the final products into feedstuff. Fermentation should be viewed as a means to preserve carcasses for up to 25 weeks until they can be rendered. The resulting product is biologically safe, a valuable feed ingredient, and can be stored until transport to an appropriate facility is viable (Crews, Donald, & Blake, 1995; Harper et al., 2008).

Anaerobic digestion

Anaerobic digestion, also known as biodigestion, is an alternative disposal method and has been mostly evaluated for poultry mortality disposal. Its use is increasing. It involves the transformation of inorganic matter by a mixed-culture ecosystem with no oxygen into the generation of heat, carbon dioxide, and methane, which can be used as fuel. It also results in end products of liquid and solid fertilizers. Anaerobic digestion couples methane production with waste treatment and effectively inactivates pathogens. It is a highly complex process and can require intensive equipment investment. It is traditionally used for processing animal waste, but could be adapted to carcass disposal (Chen, 2000; Harper et al., 2008; Gwyther et al., 2011; Williams et al., 2012).

Variances occur in size and technology, depending on location and needs. An on-farm system can be a plastic-covered trench with attached storage tank or large commercial plants. The combination of time and temperature reached impacts the survival of pathogenic agents, and biodigestion can be highly efficient when carcasses are co-digested with livestock waste. Previous studies show various impacts on pathogen removal, and the combination of biodigestion with a secondary heat treatment and minimum storage period aids in inactivation of pathogenic organisms. TSEs are not destroyed at normal operational temperatures and additional heat treatment would be required following digestion. Biodigestion is an optimal environmental option, but the need for further treatment to address biosecurity may increase the environmental footprint. While the initial capital costs make this a challenging alternative to implement for on-farm disposal, the production of bioenergy makes this option, if existing digesters could be used for carcass disposal, economically and environmentally appealing (Gwyther et al., 2011; Williams et al., 2012).

In Sweden, anaerobic digesters are used to convert animal carcasses, seized alcohol, and human waste into alternative biofuel. Biogas is used to fuel more than one-quarter of the city buses in Stockholm. Overall, anaerobic digesters produce more than 250 million cu ft of biogas (Sen, 2007). Biogas production from carcasses thorough a closed system of anaerobic fermentation is included on the OIE recommended methods list (OIE, 2012b).

Other methods and technologies

A few examples of other forms of disposal that have been discussed include: fermentation, acid preservation, plasma vitrification, refeeding to non-affected species such as fur or alligator farms, refrigeration or freezing, isolation, pet food processors, scavengers, ocean deposit, biofuels, and mounding (top of ground) (Ellis, 2001; Sander et al., 2002; EPA, 2006). The NAHEMS guidelines specifically mention plasma vitrification, and gasification (NAHEMS, 2012). These novel technologies and others are described in limited detail.

Fermentation, acid preservation, and refrigeration or freezing will not decompose mortalities but they can serve as a means for storage, stabilization, and potential pathogen reduction (Crews et al., 1995; Harper et al., 2008). Yeast fermentation is similar to lactic acid fermentation and requires the grinding of the carcasses, the addition of a fermentation carbohydrate, and a yeast starter culture. This process has limitations for inactivation of pathogens (Blake et al., 2008).

Another potential storage technology is acid preservation. This method uses mineral acids or organic acids to preserve carcasses until transported for rendering (Blake et al., 2008). Ground, split, or punctured poultry carcasses have been preserved for more than a month in a 3.4% sulfuric acid solution (Morrow & Ferket, 1993). Because of the risks associated with sulfuric acid, phosphoric acid can be used as well and may be more practical (Harper et al., 2008).

Refrigeration or freezing could serve as storage before transportation to a rendering facility or other disposal location. It is a fairly expensive option, but does allow for carcasses to be stored and held for disposal or later conversion into valuable feed ingredients (if feasible). In the Netherlands outbreak of classical swine fever in 1997, 200,000 t of carcasses were kept in cold storage prior to being rendered. Again, with FMD in 2001, cold storage plants were used as temporary storage and eliminated the bottleneck created from limited rendering capacity (Crews et al., 1995; de Klerk, 2002).

Bioreduction is a potential method for storing and simultaneously reducing the volume of carcasses in need of disposal. A water-tight vessel is used to heat the material while being aerated with a pump. The vessels are filled with two-thirds water before the carcasses are added. The carcass material liquefies and volume is reduced through vented evaporation. Anaerobic reduction, with no air input, has been used on pig and rabbit farms, while aerobic bioreduction has been tested on sheep. The rate of carcass breakdown shows this method is highly effective. The impact on TSEs continues to be investigated, but it is possible they are degraded if they do not adhere to the solid components of waste material and vessel. This method could provide an on-farm disposal alternative (Gwyther et al., 2011; Williams et al., 2012).

Isolation, especially in warm weather, may be a viable option for poultry in cases of rapid virus deactivation. To ensure safe handling, carcasses should be covered and contained. Isolation can be used as an interim method and used in combination with composting, incineration, or burial. Or, if the virus is deactivated due to isolation alone, material may be disposed of in another manner at a later time (EPA, 2006).

Plasma vitrification is the use of a plasma arc generated from electricity to produce an extremely hot flame in an efficient and cost-effective manner. In theory, carcasses could be placed in a burial pit and then the plasma torch used to pyrolize the carcasses in the soil generating a gaseous effluent (Brglez, 2003). Solids remaining after vitrification can be used as gravel, made into concrete aggregate, or landfilled. Methane gas can also be captured for energy use (Gwyther et al., 2011; Williams et al., 2012).

Hydrolysis uses indirect steam applied to a bioreactor where that material is treated at 180^{o}C. It produces a biofuel, but is not seen as suitable for TSE-infected materials (Gwyther et al., 2011; Williams et al., 2012).

High-pressure, high-temperature thermal hydrolysis in a sealed chamber, also known as biorefining, is on the OIE-approved list and is considered effective against microbial agents and TSEs (OIE, 2012b).

Fast-burning napalm can be used to burn carcasses. Air emissions, as well as ash and potential contamination of soil and groundwater, are all environmental concerns. In addition, human health hazards exist when handling napalm (Gwyther et al., 2011; Williams et al., 2012).

Pyrolysis is the use of electromagnetic waves to heat organic material. Thermal depolymerization utilizes high heat and pressure to produce a biofuel from organic matter. The resulting waste minerals can be used as a fertilizer. This method is expected to eliminate prions and pathogens as organic matter is destroyed at the molecular level. Low amounts of waste are produced, energy requirements are low, and emissions and hydrocarbons are reduced (Gwyther et al., 2011; Williams et al., 2012). Co-combustion systems that have been built in the EU since the BSE crisis can be used for carcass disposal while creating heat and electricity (Blake et al., 2008).

Gasification technology heats the biological material inside a confined high-temperature burn container and generates carbon monoxide and hydrogen, known as synthesis gas, which serves as a fuel to create further combustion. The gasifier converts the biomass into an inert ash and the combustible synthesis gas, which is burned in a secondary chamber. The process is similar to incineration, but is more fuel efficient and produces less air emissions. While it has applicability in carcass disposal, commercial adoption has been slow and few commercial gasification units are available (Harper et al., 2008; Lemieux, 2009a; Lemieux, 2012b).

Single-chamber systems were used in the U.K. BSE outbreak, but newer dual-chamber units are a significant improvement, more efficient, effective at eliminating disease risk, and environmentally safe. Research has focused on development of transportable dual units. The initial research goal is to develop a unit with six gasifiers linked to one macerator that allows for throughput of 150 t per day (Brookes, 2009). In North Carolina, the DOD, in coordination with the EPA and USDA APHIS, built a transportable gasifier to be tested for disposing of large numbers of animal carcasses during an emergency event. Tests indicated it was transportable over primary and secondary roads, could be ready to operate within 24 hr, and the burner and material feed systems operated sufficiently. However, deficiencies included that it was not able to handle equine or bovine carcasses, the ash removal system was inadequate, material feed distribution needed adjustment, the oil-fired burners were difficult to ignite and could not be replaced while hot, the electrical system was not sufficiently shielded from heat, and operation required a significant amount of manual labor. The project working group has planned initial modifications and will perform another round of tests in maximum throughput capacity and long-term operation (Lemieux, 2009a; Lemieux, 2012b). Gasification is not considered a viable alternative for elimination of TSEs, but is a preferred method in disposing of poultry infected with AI H5N1 (Gwyther et al., 2011; Williams et al., 2012).

Homogenization can be used by producers in disposing of small carcasses. Carcasses can be ground or homogenized and disposed of in the existing manure system (Harper et al., 2008). The potential also exists to use carcasses for feeding exotics. In Minnesota, the fur industry utilizes dead animal carcasses as feed for minks. A farmer in Pasco County, Florida feeds dead hog and poultry to alligators slaughtered for hides and meat, and a hog farm in Singapore fed all its dead animals to crocodiles slaughtered for the leather industry (Morrow & Ferket, 1993). In California, dead livestock carcasses are used to feed condors as part of a condor reintroduction project (Brandt & Massey, 2009).

Extrusion processing could also be used for carcass disposal. Extrusion uses high temperature over a short time to cook, sterilize, dehydrate, and stabilize byproducts into highly digestible feed ingredients (Blake et al., 2008). It has been used to convert whole chicken carcasses into high-protein feeds and is being investigated for swine disposal. Fluidized bed drying using a centrifugal fan over a natural gas or propane burner is being tested for waste disposal including poultry and swine carcasses. Flash dehydration is a similar process also being tested (Morrow & Ferket, 1993). Another disposal option is ocean dumping. Ocean disposal is an approved OIE option. It requires an EPA permit and is clearly only an option in coastal areas (OIE, 2012b; Wilson, 2003b). It does require biosecure transport and carcasses must be treated so that they will sink (Wilson, 2003b). Some researchers have argued that ocean disposal should not be an approved option in an intentional bioterrorism disease incident because the Marine Protection, Research, and Sanctuaries Act restricts any materials produced or used for radiological, chemical, or biological warfare from being disposed of in the ocean (Boadu, 2010).

While most contaminated carcasses or animal products will be disposed of using methods already described, some materials require special considerations. Milk, eggs, wool, mohair, wastewater, hatchery waste, and manure, as well as contaminated feed, grain, hay, straw, and silage all require special considerations in the disposal process (APHIS, 2002).

It is also possible to consider sending uninfected animals to slaughter through normal methods. This reduces the number of animals that need disposed and eliminates the need for welfare slaughter. However, the public and trading partners must be willing to accept the product (Rubira, 2007).

Special considerations must be given to prion disease outbreaks. No method (except closed furnace burning) has proven to deactivate prions with 100% effectiveness, but rendering, incineration, and alkaline hydrolysis are the most reliable technologies for prion deactivation (OIE, 2005).

Direct and Indirect Costs of Disposal Alternatives

In order to analyze the economic implications of disposal options, various costs need to be identified, including those related to direct disposal, transportation, facilities, equipment, energy requirements, environmental impact, and social costs. Major economic factors and implications also need to be identified and disposal options need to be compared and contrasted.

An effective control strategy will not only limit disease spread but will keep costs low and economic impact minimized. There is relatively little data on the costs of carcass disposal, and consistency regarding direct and indirect costs is lacking. The available data are primarily related to routine disposal and not disposal in an emergency situation. Costs can be divided into the following categories: direct costs – including fixed costs and variable (operating) costs – and indirect costs.

In the following section, examples of direct costs are identified and potential indirect costs are discussed relative to each technology. However, most existing data applies only to small-scale disposals and does not attempt to quantify indirect costs.

Burial

The two most common forms of burial are disposal pits and trench burial. Both can be used for daily mortality needs, but trench burial is the most likely process used when there is large-scale death loss (Wineland, Carter, & Anderson, 1997). Decision makers usually assume burial is a low-cost option. Most direct-cost estimates available are relative to the use of disposal pits for normal mortality use, and the costs in a large-scale disaster situation would differ significantly.

Burial requires significant labor and equipment, and actual costs depend on the availability and accessibility of these two factors. A number of studies have identified costs related to routine disposal efforts. These studies may provide insight into the cost factors in large-scale disposal estimates.

In a study by University of Nebraska researchers to be discussed repeatedly in this section, costs were estimated for the disposal of normal death loss on a hog farm. Nebraska regulations state that burial must occur within 36 hr of death and carcasses must be buried at least 4-ft deep. They also recommend that trenches should be immediately closed, making it a difficult option for routine disposal purposes. Therefore, they paid relatively less attention to burial costs in their research. They did estimate a basic budget that included building one trench to hold one year's death loss of 40,000 lbs. Digging the pit and fencing the area would cost approximately $600. Additional labor costs based on 135 hr for transporting animals to the burial site and covering the carcasses appropriately were included. Estimated costs totaled $3,878 per year, resulting in estimates of $0.097/ lb of mortality and $193.90/t (Henry, Wills, & Bitney, 2001).

Researchers at the University of Alabama investigated routine poultry carcass disposal. The poultry industry produces 18 million broilers each week, but also generates 800 t of carcasses weekly that require disposal, thus economically efficient and environmentally friendly disposal methods are important in daily routines. Disposal pits designed for everyday use are a potential solution for both large and small producers. The cost of the pits varies depending on materials used and size of pit. Routine mortality disposal costs were estimated for a flock size of 100,000. Estimates included initial investment costs ($4,500), annual variable costs ($1,378) and annual fixed costs ($829) totaling $2,207, resulting in a cost per hundredweight of $3.68 or cost per ton of $73.60. For a flock of 200,000 birds, the cost per ton would be reduced to $62.40 (Crews et al., 1995).

Sparks Companies, Inc. (2002) estimated costs of on-farm burial of daily livestock mortalities. They assumed each mortality was buried individually, all environmental safeguard procedures were followed, on-farm burial was feasible, and the only direct costs associated with burial are labor (estimated at $10/hr) and machinery (rental or depreciation estimated at $35/hr). These costs resulted in per mortality costs of $15/head for cattle over 500 lbs and $7.50/head for calves and hogs. These estimates are likely not representative of the costs that may be incurred during a catastrophic mortality loss, because multiple mortalities would be buried together, rather than individually as estimated here. Furthermore, actual hourly rates for labor and equipment may be significantly different during an emergency.

A survey of Iowa Pork Producers Association members was conducted in March 2001 to determine the disposal methods used for daily mortalities, as well as associated costs (Schwager, Baas, Glanville, Lorimor, & Lawrence, 2001). The authors defined the total estimated cost for disposal by burial (including labor, machinery, contractors, and land) as a function of operation size, rather than as a function of the number of mortalities disposed. They estimated that the total cost for burial was approximately $198 per 100-head marketed. A report on various carcass disposal options available in Colorado identified the cost of renting excavation equipment as $50-75/hr (Talley, 2001).

The New South Wales Department of Agriculture Resources states that on-site burial may be the only economic choice because the costs of transport may be expensive relative to the value of the stock. They estimate on-farm disposal can cost A$1-2/ head if machinery is hired (Burton, 1999).

Little information exists regarding the costs associated with carcass burial during emergency situations. During the 1984 AI outbreak in Virginia, a total of 5,700 t of poultry carcasses (about 1.4 million birds) were disposed. Approximately 85% of this total (about 4,845 t) was disposed by trench burial at an estimated cost of approximately $25/t (Brglez, 2003).

The 2001 U.K. FMD outbreak provides emergency disposal cost examples for mass burial sites. The costs of mass burial sites includes purchase or rental; construction, operation, and maintenance; and long-term restoration and maintenance. Based on the estimated number of carcasses buried at each site, the approximate cost per carcass has been estimated. The approximated cost per ton ranged from £20.41(US $29.38) at the Birkshaw Forest mass burial site to £337.77 (US $486.39) at the Tow Law site, with an average cost of £90.26 (US $129.97) for the 1,262,000 carcasses buried in five mass burial sites. Although cost per ton would be a more preferred basis for comparison, for all sites except Throckmorton, it was not possible to determine this value because few reports provided either the total weight of carcasses buried at each site, or the number of carcasses by species at each site (although reportedly the majority of carcasses were sheep). For the Throckmorton site, based on an estimated total weight buried in the site of 13,572 t, the cost of using this site on a per ton basis is estimated to be £1,665 (US $2398) per ton (NAO, 2002).

Burial as a method of carcass disposal can result in a variety of indirect costs, including environmental costs. The major environmental impact is ground- and surface-water contamination, particularly in areas with light soil and a high water table. Body fluids and high-concentrate ammonium leachate could pollute the groundwater. Most degradation would occur within 5-10 years, but leachate could be released for 20 years or more. Calculating values aligned with indirect costs is challenging because individual producers may not have knowledge of or may choose to ignore approved procedures, leading to additional environmental costs. Predators could also be a problem by spreading the disease or causing an unsightly disturbance if they are uncovering the carcasses. Such disturbances or other unpleasing circumstances may also create negative public reactions. In addition, if anaerobic digestion occurs, the hydrogen sulfide created can exceed safe human levels. It is also possible that acid-forming bacteria may exist and decomposition-inhibiting fermentation may occur. Burial on private land can also impact future land use and land values, especially if legislation requires that carcass burial be listed on the property deed. Mass burial offers similar environmental risks at a higher level of significance (Harman, 2001; Morrow & Ferket, 1993; Sparks Companies, Inc., 2002; Wineland et al., 1997).

Landfills

The use of public landfills is another potential disposal alternative requiring the cooperation of operators, transportation to the disposal location, and regulatory compliance.

The fee charged by a landfill for accepting waste is typically based on either weight or volume, and may vary with the type of waste deposited. Even though many state regulations allow landfill use for carcass disposal, many municipal authorities refuse carcasses. Many can charge $10-30/t, making them cost prohibitive (Morrow & Ferket, 1993).

For landfill disposal of small numbers of animal carcasses – such as companion animal remains, carcasses resulting from hunting activities (such as deer or elk), or small numbers of daily mortalities from livestock production facilities – fees may be based either on weight or on the number of carcasses (Talley, 2001). Landfill disposal fees vary, but average around $70/t (Blake et al., 2008). Fees at three landfills in Colorado were reportedly $10/animal, $160/t, and $7.80/cu yd, respectively (Talley, 2001). As of 2003, fees for carcass disposal in Riverside County, California consist of a $20 flat fee for quantities less than 1,000 lbs and $40/t for quantities greater than 1,000 lbs. These fees are slightly higher than those charged at the same facility for general municipal solid waste because animal carcasses are classified as "hard-to-handle" waste because they require immediate burial (immediate cover) (Riverside County Waste Management Department [RCWMD], 2002). Landfill costs for disposing of animal byproducts in European countries range from 30- 80 Euros/t of material (Commission of the European Communities [CEC], 2001). During the 2002 outbreak of END in southern California, disposal fees were approximately $40/t of poultry waste, plus additional transportation costs (Hickman, 2003).

Following confirmation of two cases of CWD in South Dakota, the City Council of Sioux Falls established disposal fees for deer and elk carcasses at the city landfill. A mono-fill area (waste of only one type) designed to accommodate up to 10,000 deer carcasses was developed in an unused expansion of the landfill at a reported cost of about $50,000. Fees of $50/t were established for deer or elk carcasses originating within the state, and $500/t for carcasses originating outside the state. However, private individuals are exempt from the ordinance and may dispose of up to 10 carcasses without charge (Tucker, 2002).

In situations involving significant volumes of carcass material (e.g., an animal disease outbreak), fees would most likely be based on weight (i.e., per ton of carcass material). Costs associated with transportation of carcass material from the site of the outbreak to the landfill must also be considered. In instances where this distance is great, transportation costs can be significant. During the 2002 outbreak of AI in Virginia, disposal fees were approximately $40-45/t of poultry carcasses. However, significant additional cost was incurred due to transportation distance. More than 64% of the carcasses were shipped over 160 mi to available landfills. Each truck could only make two trips a day and an average of 10 trucks were on the road each day, hauling 20 t of carcasses. In addition, the trucks had to be specially prepared to transport the carcasses (Brglez, 2003). When costs of all equipment and transportation were included, costs increased to approximately $122/t (Flory et al., 2006a). Another example cited landfill disposal fees, known as tipping fees, ranging from $46-90/t, with costs increasing to $149/t when killing, transport, and tipping fees were all included (Wilkinson, 2007).

Disposal in landfills requires additional daily management, which leads to increased management costs. The use of a landfill for carcass disposal is likely to impact the location's ability to handle other waste disposal needs, which creates opportunity cost. In addition, if landfills are used, the county may be financially impacted if the life expectancy of the landfill is reduced prematurely. Environmental costs also exist with landfill usage. Disposal of carcasses in landfills can generate very high organic loads and other pollutants for up to 20 years. The odors are also considered a public nuisance. Landfills offer similar concerns as burial regarding groundwater contamination and predators. If landfill usage is mandated at a higher level of government, the cost of public perception and poor cooperation could be large as well (Morrow & Ferket, 1993).

Incineration/burning

There are three common forms of incineration: open burning (e.g., pyre burning), air-curtain incineration, and fixed-facility incineration. Intervals of approximation have been used to describe the costs for each incineration technology. These intervals are listed as $196-723/t for open burning, $98-2,000/t for fixed-facility incineration, and $143-506/t for air-curtain incineration.

An open-air pyre requires fuel, which may include coal, timber, pallets, straw, or diesel fuel. While this may seem clear, specific cost data is limited. Cooper, Hart, Kimball, and Scoby (2003) estimate open-air pyre burning of cattle carcasses to cost $196/t (Cooper et al., 2003).

During the U.K. 2001 FMD outbreak, there were concerns about the on-farm burial of pyre ash. Therefore, pyre ash was disposed of at landfills at a cost of approximately £317 ($457) per ton (Anderson, 2002).

The most significant costs related to fixed-facility incineration are the fixed costs associated with construction of the incineration facility and purchase of incineration equipment. These are the most extensive costs for individual producers and governments preparing for large-scale mortality capability (Harman, 2001). A 500-lb capacity incinerator costs $3,000 and will last for approximately four years (Sander et al., 2002).

Researchers at the University of Nebraska have estimated disposal costs on an annual basis for a pork production system with average annual mortality loss of 40,000 lbs per year. The costs do not include labor or loader use for removing dead animals from the farm, because they assumed no change between alternatives. They calculated fixed costs to include depreciation, interest on the undepreciated balance, repairs, property taxes, and insurance. The incinerator used had a 500-lb capacity and along with a fuel tank and fuel lines, costs $3,642. The rate of incineration was estimated to be 78 lbs per hour with diesel fuel consumption of 1 gal per hour priced at $1.10/gal (compared to over $3/gal at the time this dissertation was completed). The incinerator was calculated to last 10 years or 5,000 hr. Interest rates were calculated at 10% and annual repairs were calculated as 3% of original cost. This study assumed the incinerator would be taken to the production unit, so transportation costs were not relevant. An incinerator with an afterburner may be necessary to reduce emissions and would increase investment costs by $1,000 and increase fuel consumption to 1.35 gal/hr. The study estimated costs for both types of incineration as depicted in Table 3-5 (Henry et al., 2001).

In Alabama, poultry producers utilize incineration when burial is ruled out due to environmental concerns. An incineration unit with gas or oil burners is required, and producers need a concrete slab and shelter to house the unit. Additional cost considerations are fuel costs and burn rate. Initial investment costs are $2,000 at a minimum with annual variable costs of $4,833 and annual fixed costs of $522. These equate to total net costs of $5,355 and a cost per hundredweight of $8.92, resulting in a per ton cost of $178.40 (Crews et al., 1995). In a similar study in Alabama, costs are estimated at approximately $3.50 per 100 lbs or $70/t of carcasses assuming fuel costs at $0.61/lb (Crews et al., 1995).

Table 3-5 *Cost Estimates for On-Farm Incineration of Daily Mortalities*

	Incineration without afterburner	Incineration with afterburner
Disposal equipment	Incinerator and fuel tank	Incinerator and fuel tank
Capital investment	$3,642.00	$4,642.00
Labor hours per year	60.7	60.7
Budgeted annual costs	$710.19	$905.19
Fixed costs –		
Disposal equipment		
Machinery operation	$572.00	$1,341.44
Labor	$667.33	$667.33
Annual cost per year	$1,949.52	$2,913.96
Annual cost per pound	$0.049	$0.073
Annual cost per ton	$97.48	$145.70

Note. Adapted from Henry et al., (2001).

In a study at the University of Tennessee, the use of incineration for poultry mortality management was studied. Variability in fuel prices will impact the cost of incinerator operation. If propane costs are estimated at $.75/gal, the cost to burn 100 lbs of poultry broiler carcasses will average at $4 per 100 lbs or $80/t. The amount of fuel needed is impacted by the size of birds and their body fat percentage. The researchers also noted that while incineration is an effective technique, producers should have an alternative plan for handling catastrophic bird loss (Burns, 2002).

The Georgia Department of Agriculture reports that the cost of incinerating 450 t of dead chickens after 2001 tornadoes struck Mitchell County was $300/t or outsourced for $1,600/t.

Larger, fixed-facility incineration has been approximated by WR^2 at $460-$2,000/t of carcass material in the US. This interval captures a forecasted during-emergency price of $1,531/t (Western Australia Department of Agriculture, 2002).

Cost information for air-curtain incineration depends on species type, fuel costs, and ash disposal. The model described below is completely self-contained and powered by a diesel engine with a 15,000 CFM centrifugal caged fan. Air speed can be adjusted up to 165 mph, and air is forced across the top and angled down into the trench. Combustion efficiency and burning rate increase as oxygen is fed into the fire with a burning rate 4-6 times faster than an open fire and less fuel requirements. Once the fire is started and the air-curtain is operating, no auxiliary fuel source is needed. The largest single expense related to air-curtain incineration is the expense of the air-curtain incinerator, either by purchase or rental. In a test operation in Texas held by the USDA and Texas Animal Health, a trench burner was leased from Air Burners, LLC for 3 days for $7,500 including transportation to the site and operators. The test operation disposed of 504 head of swine carcasses weighing 91,600 lbs. In this same case, fire wood was used as the fuel and with delivery cost nearly $4,000. Another large expense was the transportation of swine to the location costing more than $4,500. All costs noted for the operation of the air-curtain incinerator are listed in Table 3-6. The project investigators did not include the time of any animal health or emergency professionals nor did they attempt to account for any indirect costs (Ford, 1994). Jordan (2003) and Brglez (2003) estimated per ton incineration costs for poultry to be $143 and $477, respectively.

Table 3-6 *Air-Curtain Incineration Project Cost Based on 91,600 lbs of Swine Carcasses*

USDA/Texas Animal Health Incineration Project Cost	
Site and equipment preparation	$1,700
Site rental (by contract)	$650
Air-curtain incinerator	$7,500
Diesel fuel	$300
Protective wear	$2,400
Lumber and plywood	$135
Firewood and delivery	$3,960
Truck rental	$250
Animal transportation	$4,640
Modification of chute/knock box	$1,285
Miscellaneous supplies	$225
TOTAL	$23,045
Cost Per Ton	$503

Note. Adapted from Ford (1994).

The negative impacts of burning include pollution of the environment and release of noxious gases and compounds, including dioxins, which affect the health of the population. Dioxins have been identified as a possible carcinogen and the opportunity exists for uptake by plants or animals, and thus for the contamination of the food chain. Public perception of pyres, combined with emissions of dioxins and the health effects from smoke inhalation, are additional negative externalities. Mass slaughter of animals and the large "funeral" pyres in the UK horrified the public, and these televised images contributed to greater economic damage, specifically tourist activity (Franco, 2002; Hickman & Hughes, 2002; Hutton, 2002; National Farmers Union [NFU], 2002; Serecon, 2002). The Canadian Animal Health Coalition concurs that scenes of piles of dead animals burning in farmers' fields would not help the values in Canada's brand in the international market place (Serecon, 2002).

While incineration is biologically safe, produces little waste, and does not create water pollution concerns, the primary concern is emission of particulates generated during burning. Indirect environmental costs include the impact of emit particles and other products of combustion on air, liquid leakage on soil and water, and the remaining ash that needs disposed. The concern of disease spread through the air is also a concern. The air quality risk will be higher if the process is not properly managed. Smoke and odor are both a concern to neighbors and the general public. Other issues for cost consideration include worker safety precautions, management expenses, and burn permits. The cost of maintaining on-farm incineration permits has escalated, as has the inspection and regulatory costs for large incinerators for medical or hazardous waste disposal (Harman, 2001; Morrow & Ferket, 1993; Sparks Companies, Inc., 2002; Winchell, 2001; Wineland et al., 1997). Available estimates do not take into account regulatory-compliance costs as well as public-perception problems, which in 2001 in the UK, were tremendous for the tourism industry.

Composting

Composting has captured the attention of producers as a means of disposal because they are already familiar with the practice in manure management. It has moved from a novel, experimental idea to a viable, common practice in more industries than just that of poultry (Rynk, 2003). Three types of composting deserve consideration: bin, windrow, and enclosed composting. For individual livestock producers, decisions regarding an appropriate carcass composting system will depend not only on the recurring expenses associated with the method, but also on the initial investment required for construction of the system (bin or windrow) and required agricultural machinery and equipment.

The most important factors involved in cost analysis of carcass composting processes have been described by Mescher (2000) and are ordered in importance: volume and weight of mortality, frequency of mortality occurrence, labor requirements, accessibility and timeliness, impact on the environment, required facilities and equipment (new and existing), and their useful life expectancy. The major rendering costs are construction, equipment, and labor needs. Plentiful carbon sources must also be readily available. Carcass composting has some economic advantages, such as long life of the facility or pad, minimal cost of depreciation after startup, similar labor requirements, inexpensive and readily accessible carbon sources in most livestock production areas, and, finally, no need for new equipment (Mescher, 2000).

In the University of Nebraska study, two types of composting units were used for average annual cost estimates. Both structures included concrete floors and bin walls, and the higher investment option also included a roof, higher sidewalls, a storage bin for carbon source, and a concrete apron in front of the facility. The estimated construction cost of high-investment version was $15,200, and the low-investment version was $7,850. The lifetime of both was estimated to be 15 years. Researchers estimated that 80 cu yd of sawdust would be needed at a cost of $4/cu yd. A skid steer loader would be utilized at $10/hr for transporting dead animals, moving sawdust, and loading materials on the manure spreader. Labor was measured for daily loading of sawdust and animals, moving materials from primary to secondary bins, and moving materials to a recycling bin and spreading the remainder. Labor costs for the low-investment option are slightly higher, because the carbon source materials are not stored in the compost bins and must be moved into the bin (Henry et al., 2001). Estimates do not include indirect costs, nor do they show the economic benefit of the final product (see Table 3-7).

In the Alabama poultry study, researchers estimated costs for large-bin and small-bin composting. Poultry producers have readily accepted composting as a means of disposal and more than 800 have purchased freestanding composters. The large-bin composting method requires two covered bins with concrete foundations. The initial investment cost is $7,500 with annual variable costs of $3,281 and annual fixed costs of $1,658. The total cost is $4,939, but the value of the byproduct for fertilizer use is $2,010, which results in an annual net cost of $2,929 and cost per hundredweight of $4.88 or $97.60/t (Crews et al., 1995).

Table 3-7 *Estimated Costs for Bin Composting of 20 t Annual Routine Daily Mortalities*

	Composting High Investment	Composting Low Investment
Disposal equipment	Compost bins and buildings	Compost bins
Capital investment	$15,200.00	$7,850.00
Other equipment needed	Skid steer loader, tractor, manure spreader	Skid steer loader, tractor, manure spreader
Labor hours per year	115	125.9
Budgeted annual costs	$2,305.33	$1,190.58
Fixed costs – Disposal equipment		
Machinery costs	$382.19	$447.39
Fixed	$254.79	$298.26
Operating	$320.00	$320.00
Other operating costs		
Labor	$1,265.15	$1,384.68
Annual cost	$4,527.47	$3,640.92
Annual cost per pound	$0.113	$0.091
Annual cost per ton	~$226	~$182

Note. Adapted from Henry et al. (2001).

Sparks Companies, Inc. (2002) estimated the overall cost of small-bin composting carcasses of different species. Their report indicated the total annual costs of composting incurred by the livestock sector to be $30.34/head for cattle and calves, $8.54/head for weaned hogs, $0.38/head for pre-weaned hogs, and $4.88/head for other carcasses.

Kube (2002) used a windrow system and composted cattle carcasses with the three different methods, each with 1,000-lb carcasses. The first method was conventional composting (no grinding), the second was grinding carcasses after composting, and the last was grinding carcasses before composting. The cost analysis of this experiment indicated that, depending on the option selected for carcass composting, the total estimated cost ranged from $50-104/t of carcasses. While carcass grinding before composting increased the operation cost by about $6/head, it reduced time, surface area, and management costs needed for composting in comparison with conventional windrow system. Furthermore, the value of finished compost was estimated at a rate of $10-30/carcass or $5-15/t, and the estimated net cost per carcass was found to be approximately $5-42. In this estimate, no value was assigned to the organic matter of the compost (Kube, 2002).

An enclosed or in-vessel system of composting organics using aerated synthetic tubes called Ag-Bags has been available commercially for the past 10 years. The system consists of a plastic tube 10 ft in diameter and up to 200 ft long. These tubes are equipped with an air distribution system connected to a blower. Raw materials are loaded into the tube with a feed hopper. Tubes used for medium or large intact carcasses are opened at the seam prior to loading raw materials and then sealed for forced-air distribution during composting. In the 2002 AI outbreak in Virginia, 200 t of turkey carcasses and 25 t of layer pens were composted in Ag-Bags (Flory et al., 2006a; Mickel, 2003). APHIS used Ag-Bags to compost more than 100,000 birds infected with AI depopulated from poultry houses in West Virginia. The structural equipment costs are estimated at $130,000 with additional equipment operating costs of $6-10/t (Mickel, 2003). These costs do not include the necessary carbon source expense or labor expense estimates. Virginia AI Ag-Bag composting costs were reported by Brglez at $60/t with service from an outside agency (Brglez, 2003).

The value of the byproduct would offset a portion of the estimated costs. No permits would be necessary for composting and it could serve as a temporary step because the virus is destroyed quickly and could be moved and disposed of elsewhere permanently (Brglez, 2003). Odors can be a concern if improperly managed. Risks to water sources occur if composting is poorly located or managed. Opportunity costs could exist if land use is impacted while composting is taking place. Keeping the carcasses in public view could also be a public relations problem. In a large-scale outbreak, more compost may be created than can be used, and, therefore, another disposal problem will exist in the long-term. A problem also exists with the attraction of disease vectors such as flies, mosquitoes, rats, and wildlife. Additional record keeping and management time is also necessary (Franco, 2002; Sparks Companies, Inc., 2002).

Rendering

Renderers have historically played a critical role in disposal of animal carcasses, accounting for approximately 50% of all routine livestock mortalities and representing the preferred method of disposal. Renderers typically charge modest fees to collect mortalities, but they are able to keep the costs low because they profit from the sale of meat and bone meal. However, the role of the rendering industry is changing significantly. The risk of BSE has prompted the US and other countries to create safeguards to protect the livestock industry, resulting in tight restrictions and bans on rendering livestock carcasses. Changes in regulations are likely to result in large increases in renderer fees to make up for the profit loss associated with the reduction of the MBM market (Sparks Companies, Inc., 2002).

Therefore, the rendering industry has experienced general consolidation in recent years, resulting in higher fees and discontinued service in some areas. There are fewer rendering plants, and those plants are located at a greater distance from the livestock farms that depend on them to process mortalities. Farms used to be paid by the rendering plants for the mortalities, but renderers no longer find it profitable to pay for the carcasses. Instead, producers are required to pay for the same service. Depressed world market prices for fats, protein, and hides, combined with the elimination of use of animal proteins in ruminant feeds, are forcing many renderers to leave the industry or significantly increase their fees. Additional regulations that limit the use of rendering will have an increasingly significant impact. Therefore, use of rendering for even daily carcass disposal has become a more significant problem (Rynk, 2003; Doyle & Groves, 1993; Henry et al., 2001; Morrow & Ferket, 1993; Peck, 2002).

The most important factors involved in cost analysis of massive carcass rendering include collection, transportation, temporary storage fees, extra labor requirements, impact on the environment (sanitation for plant outdoor and indoor activities, odor control, and wastewater treatment), and potential needs for additional facilities and equipment. These expenses primarily make the renderers’ costs much higher than the cost of usual rendering.

In a University of Nebraska study, cost estimates for routine rendering to accommodate annual mortality of 40,000 lbs were budgeted at four pickup loads a week at a cost of $25/load. The cost of creating a holding pen away from the production facility and public view is estimated to be $300. Labor costs include transporting to and from the holding pen at an average of 70 min/week. The values included in Table 3-8 refer to the four pickup loads per week and results in a cost per pound of mortality of $0.163. The estimates for one, two, three, five or six load would be $0.066, $0.098, $0.131, $0.196, and $0.228 per pound of animal mortality, respectively. When calculated per ton, costs range from $132-456/t (Henry et al., 2001).

Table 3-8 *Estimated Rendering Costs to Dispose of 20 t Annual Mortality*

	Rendering (4 pickups per week)
Disposal equipment	Screen storage area
Capital investment	$300.00
Other equipment needed	Skid steer loader
Labor hours per year	60.7
Budgeted annual costs	$51.00
Fixed Costs – Disposal equipment	
Machinery costs	$364.00
Fixed	$242.67
Operating	$5,200.00
Labor	$667.33
Total annual cost	$6,525.00
Annual cost per pound	$0.163
Annual cost per ton	~$326

Note. Adapted from Henry et al., (2001).

Sparks Company, Inc (2002) estimated the labor and equipment (rental or depreciation) costs, at $10 and $35/hr, respectively. As long as the rendering industry can market valuable products from livestock mortalities (including protein-based feed ingredients and various fats and greases), collection fees will likely remain relatively low. However, collection and disposal fees will be much higher if the final products can no longer be marketed. Having a commercial value for end products is key to the economic feasibility of carcass disposal by rendering. The national average for renderers to pick up a bovine carcass is $25/head. If there is no use for end products, the charge would likely near $100/head (Vanier et al., 2008).

For rendering, theoretical estimates were based on a plant owner agreeing to a fee of $80/t with one cooker solely dedicated to diseased carcasses as a biosecurity measure. If all tonnage were taken to this plant in a 2002 scenario, the total government cost would have been $2,820,206, including the disposal of the rendered product at a landfill, which would result in a per ton cost of approximately $167. If the rendered product could be used as a fuel source, the total cost would be $1,565,006 or $93/t, and, if the product could be used in feed to local trout farms, the final cost would be $662,606 or $39/t (Brglez, 2003).

Currently in the US, rendering cannot be used for any carcasses that could be infected with a TSE. Therefore, rendering creates an indirect cost related to lack of biosecurity, the risk of disease spread when carcasses are moved to the rendering plant, and in the impact on the future use of the rendering plant (Winchell, 2001; Wineland et al., 1997). The environmental costs are minimal if the plants are well managed and control measures are followed (Harman, 2001).

Rendering animal mortalities is advantageous to the environment and helps stabilize the animal feed price in the market. Selling carcass meal on the open commodity market will generate a competition with other sources of animal feed, which allows animal operation units and customers to benefit by not paying higher prices for animal feed and meat products.

Exporting the carcass rendering end products promotes U.S. export income and international activities. For example, the US exported 3,650 million lbs of fats and proteins to other countries during 1994, which yielded a favorable trade balance of payments of $639 million returned to the US (Prokop, 1996). This export figure is particularly important in view of the shared rendering industry for future marketing of U.S. fats and protein materials and their impacts on the country’s economy.

Lactic acid fermentation

Fermentation was studied in the Alabama poultry study, which was based on 30-t annual death loss. To practice this method, the producer must purchase a grinder and multiple fiberglass holding tanks. All equipment should be housed in an open shed of approximately 150 sq ft. The initial investment cost is fairly expensive at $8,200. Annual total costs of $4,052 include variable costs of $2,862 and fixed costs of $1,190 (Crews et al., 1995).

The value from byproducts totals $1,320, resulting in annual net costs of $2,732 and per hundredweight costs of $4.55 or $91/t. Other estimates range from $68-171/t. On-farm fermentation results in reduced transportation costs and safer transport with the fermented product (Crews et al., 1995). Fermentation can hold carcasses for more than 25 weeks and the resulting product could be used as fur animal or aquaculture feeds. Acid preservation costs are estimated at $0.10/lb and could be a fairly low cost alternative (Morrow & Ferket, 1993).

The costs in an emergency are estimated to be about $650/t. Their example was based on the disposal of 1,000 head of cattle weighing approximately 1,100 lbs. This price does not include the sale of byproducts to rendering companies or resale of used equipment (Crews et al., 1995).

Alkaline hydrolysis

A mobile tissue digester, supplied by WR^2, is a specially designed mobile unit for carcass disposal. The units have a 4,000-lb capacity and can dispose of that amount in less than 3 hr. For the 2002 Virginia AI outbreak, Brglez (2003) estimated 12 digesters would have needed to operate for 24 hr with one operator per location, regardless of the number of units. Each unit is priced at $1 million. The digesters handle 15 t per day and would have required operation for the full 90 days at a cost of $97/t or $1,636,567. Disposal of effluent may also have been necessary if it is not possible to use it as fertilizer (Brglez, 2003). Current estimates indicate fixed-based systems cost between $500,000 and $1.2 million, and the large mobile prototypes being tested will each cost approximately $2 million (Vanier et al., 2008).

The cost of operation of these units is low compared to some other means of carcass disposal. Estimated cost of disposal of animal carcasses with the unit operating at maximum capacity and efficiency is $0.02-0.03/lb or $40-60/t. Estimated cost of the mobile trailer unit with vessel, boiler, and containment tank included is approximately $1.2 million. This unit would have capacity of digesting 4,000 lbs of carcasses every 8 hr or approximately 12,000 lbs in 24 hr (Wilson, 2003b). Researchers experienced with alkaline hydrolysis have estimated $0.16/lb ($320/t) including costs for power, chemical inputs, personnel, sanitary sewer expenses, maintenance, and repair (Powers, 2003). Manufacturer estimates indicate a cost of $0.04-0.07/lb for fixed-base systems, with mobile units being higher to cover generators, supply trucks, and transportation (Vanier et al., 2008).

Anaerobic digestion

Anaerobic digestion costs were estimated by Chen (2000) on a system with one upflow anaerobic sludge blanket and five leachbeds. He estimated the costs for a poultry farm with 10,000 birds at $105-118 per 10,000 kg live-weight production. Capital costs made up 41% of the costs and economies of scale existed with decreasing costs as farm size increased. With 100,000 bird operations, costs were estimated at $28 per 10,000 kg live-weight production. Based on Chen's assumption of an 8% mortality rate, the costs per ton of mortality range from $109-123/t for a 10,000-bird operation to $29/t for a 100,000-bird operation. Calculating the potential benefits available from the sale of methane could improve the economic impact (Chen, 2000). Scale-up consideration and a costing analysis showed that thermal inactivation was likely to be more suitable and considerably less expensive (Turner, Williams, & Cumby, 2000).

The various alternatives for construction materials and installation methods will impact the cost of the chosen system. If digester use is temporary, the construction materials will be less expensive, estimated at less than $50/kg of daily capacity ($22.73/lb of daily capacity) and the construction could be done in less than a month. For a permanent installation, concrete construction of the digester takes about six months and would cost between $70-90/kg of fresh carcass daily capacity ($31.82-40.91/lb of fresh carcass daily capacity). Consequently, this type of installation requires construction well in advance of an emergency situation. It would be logical to use the digester for other substances like manure or municipal waste to help alleviate the expense (White & Van Horn, 1998; Boehnke, Eidam, & Pierson, 2003).

Novel Technologies

Refrigeration/freezing

Refrigeration/freezing can be used for the purpose of storage and allowing disposal efforts to catch up with depopulation efforts. The initial purchase cost of a large-capacity freezer combined with ongoing electrical costs makes this a very expensive option. Initial costs are estimated at $14,500 with annual variable costs of $5,378 and annual fixed costs of $2,670. The value of the byproducts is $1,200 and if combined with total costs of $8,048, results in an annual net cost of $6,848 or $11.41 per hundredweight or $228/t (Crews et al., 1995). Freezing has been utilized in the poultry industry. Freezers that hold one ton of carcasses are available for around $2,000 and require electricity at approximately $1.20/day or $0.01/lb ($20/t) (Morrow &

Ferket, 1993). A broiler company in Florida developed special weatherproof units that could be moved with a forklift. The freezer unit that cooled the containers never leaves the farm. The loaded containers are hauled away or emptied at the farm to transport the contents to a processing facility (Damron, 2002).

Grinding

Grinding of carcasses is a mechanical process that can be used as a pre-process to make mortality processing more rapid and effective and is required before fermentation. Typically, carcasses would be ground to an inch or less in diameter and would result in a paste-like material. A large portable grinder would be taken to the site and processed material can be preserved with heat or chemicals and contained for off-site transport. Smaller grinders can be used for poultry or swine and larger grinders for cattle. The largest portable grinders available could handle about 15 t per day. Power and water will be required, and a bulking agent such as straw, sawdust, cornstalks, or a similar material is needed to absorb liquid. If the final product is used for alligator or pet food, the bulking agent needs to be digestible (Jones, Hawking, & Ess, 2004). The installation costs for a grinder appropriate for pigs would be approximately $11,000 for a cutter, grinder, and associated costs. Shelter for the grinder and bulking agents are not included in the cost estimate. A portable unit would be more expensive because of the associated transport costs and portable power plant required. The size of carcass and the throughput needed will greatly affect cost and type of grinding equipment (Foster, 1999).

Grinding/sterilization by STI Chem-Clav®

WR^2, also known as Biosafe Engineering, headquartered in Indianapolis, Indiana, patented nonincineration technology for processing biological and biohazard waste materials called the STI Chem-Clav®. Equipment can be stationary or portable and has traditionally been used to process medical wastes. Waste is shredded to maximize surface area for permeation of steam from a steam auger into the materials. The end result is a dry, sterilized material. This system would not neutralize prions. Depending on the disease agent and ability to deactivate pathogens, the resulting materials can be composted, deposited in a landfill, cold stored, or utilized in an energy recovery system such as thermal depolymerization or a plasma arc furnace (Jones et al., 2004).

The cost of a mobile STI Chem-Clav® as is approximately $150,000. This does not include a semi-tractor or fuel supply trucks for transport. A fuel source such as propane and electricity are also required and would add to the expense of operation. The addition of a disinfectant into the screw-processing mechanism would add to the cost. If the system were used on a daily basis for processing other wastes (food scraps, medical, etc.), the cost of processing would be decreased; however, the normal flow of feedstock would need to be diverted or stored in the event of a large mortality event (WR^2, 2008).

Ocean disposal

Ocean disposal can be a low-cost option where geographically available, estimated at approximately $1/t. Costs are primarily due to biosecure transportation to the location by truck and then barge rates of $2,000/day and tug rates of $2,500/day. There would also be a minimal cost for weighting the carcasses to sink. Indirect costs of ocean disposal are minimal. The most significant environmental risk is that of transportation risk. The actual disposal itself is environmentally friendly and is beneficial to marine life. However, appropriate public relations efforts would be necessary in order to avoid significant public disapproval (Wilson, 2003b). Before ocean disposal is considered, sufficient information about the disease and the potential risk to marine life should be understood and evaluated.

Plasma arc

Plasma vitrification generates heat in an efficient and cost-effective method. Brglez (2003) estimated that four plasma arc torches would have been needed to assist with the Virginia AI outbreak. The units cost $2 million each and the gas collection hoods cost $500,000. Five people would be needed to operate and maintain the torches. The operation costs were estimated to be $120/t and the cost of digging the pit was $30/t. The total cost for 240 t of carcasses was $36,000/day and the total cost for the 2002 AI outbreak disposing of 16,500 tons was $2,475,000 resulting in a per ton cost of $150. There is no odor, little to no environmental risk; it is considered very biosecure (Brglez, 2003). At the North Carolina Disposal Conference, costs were estimated costs to be $60/t to treat *in situ* (i.e., buried) carcasses (Wilson, 2003b).

Thermal depolymerization/pyrolysis

Pyrolysis is an approach used by Renewable Oil International LLC (ROI) similar to thermal depolymerization. Pyrolysis is done at a higher temperature than thermal depolymerization, uses a considerably dryer feedstock, and does not take place in the presence of water. ROI estimates a capital cost of $3 million for a 120 t/day and a 2.5-MW gas turbine to generate electricity, including the cost of feedstock (Renewable Oil International LLC [ROI], 2004).

Refeeding (primarily to alligators)

Startup costs for an alligator farm can be substantial at approximately $250,000. Some operations in the Southeast raise alligators indoors in temperature-regulated facilities. Alligator waste must be filtered from the water in which they are kept, secure fencing must be provided (Sewell, 1999), and permits acquired (where necessary). Some poultry farms in southeastern states use alligator farms as a routine disposal method, and research has been done on the potential use for swine disposal. Alligator farms in Georgia and Florida of 6,500 alligators can devour more than a ton of dead chickens per day (Clayton, 2002). Disease impacts on alligators should also be considered.

Napalm

Estimated costs of using napalm for carcass disposal are $25-30 per animal but will depend on the cost and temperature of available fuel and the size of animal. The price of aluminum soap powder varies from $4.60-5.30/lb. The disposal of a large number of carcasses may be more efficient than dealing with small disposal situation (Wilson, 2003b).

Non-traditional rendering

While the operational costs of using flash dehydration followed by extrusion to recycle mortality carcasses or spent laying fowl appear to be economically sustainable, the process is unlikely to attract outside investors because the time to recover capital expenditures ranged from 11.41 to 48 years. The addition of the expeller press technology could be expected to increase the capital costs and reduce the annual profits for the plant. Extrusion has been used in the food industry for some time. The cost to dehydrate turkey mortalities to 20% moisture is about $27/t of final product and $40/t if followed by extrusion (Nesbitt, 2002). The use of extrusion methods has high capital costs, but it is possible that farmers could use the extruders for other purposes in creating feeds (Morrow & Ferket, 1993).

Agreements and contracts

For efficient and immediate action during an outbreak of an FAD and reduce the uncertainties, agreements with all parties must already be in place and as many decisions as possible should be made prior to the outbreak. Agreements should be in contracts. Contracts should be in place to allow for the increase of expert staff and resources so situations will be controllable. It is easier to negotiate prices with service providers during a disease-free time. Contracts should be negotiated with providers responsible for laboratories, rendering plants, slaughterhouses, cold-storage plants, incinerators, disinfection companies, equipment suppliers, employment agencies, large machinery owners and operators, shower trucks, livestock haulers, communication systems, accommodation suppliers, and others. Any required licenses should be confirmed at this time as well. To ensure proper use of public funds when commercial operators are involved, sound management with consistent and sound financial control is necessary. Government agencies should utilize and delegate to specialists available in the private sector to deal with a large animal death loss (de Klerk, 2002; NFU, 2002).

During the 2001 outbreak of FMD in the UK, organization and management of contracts and the increasing number of contractors created serious challenges in disposal operations. Material for pyres became difficult to obtain, and rapid price inflation existed on fuel sources. Poor quality coal made achieving combustion difficult and a lack of available manual labor caused efforts to be less efficient than in the 1967 outbreak (Scudamore, Trevelyan, et al., 2002).

The disposal of thousands of animal carcasses in North Carolina in the wake of Hurricane Floyd resulted in additional provisions regarding carcass handling. In the County Plan recommended by the North Carolina State Animal Response Team, the Mortality Management Section coordinators, Drs. Jim Kittrell and Dan Wilson, identified the need to prearrange contracts for resources to handle dead animal removal, burial, and disposal. Under the State Plan, it is recommended to work out financing so counties can arrange local contracts with understanding of reimbursement. An important consideration in any contract is how the contracted work is measured and compensated. In developing such contracts, consideration should be given to how the animal will be handled and the condition of the carcass. Both parties of the designated contract, the payee and payer, must be able to accurately and consistently measure and count the unit (Ellis, 2001; Kittrell & Wilson, 2002).

Previous Carcass Disposal Comparisons

FADs and the efforts to control them are costly. Disposal methods and other means of disease eradication will have high short-term costs. However, failure to employ an effective strategy will lead to enormous long-term costs. Selection of appropriate strategies should consider both the short and long-term costs (Nelson, 1999).

Cost comparisons

A 2002 study commissioned by the National Renderer's Association and conducted by the Sparks Company investigated methods of disposal for livestock and their potential costs. The evaluation was completed to examine the economic impact of regulations on rendering as an alternative for daily mortality disposal because of the related risks to BSE. Their estimates were based on 2000 annual mortality rates in the US of 3 billion lbs of livestock and 346 million lbs of poultry (Sparks Companies, Inc., 2002). These estimates are calculated at a per ton rate that do not include capital costs for specialized facilities (Table 3-9).

Renderers typically charge modest fees, but rendering is still highly cost effective because of the operating and fixed costs of other methods. However, if regulations keep renderers from selling their byproduct, their fees will likely increase significantly. The viability of disposal options for producers will depend on logistics, mortality quantity, facility locations, soil type, topography, labor availability, and equipment accessibility. Estimated costs will be driven by producers' attitudes toward the environment, management preferences, and government regulations. Results indicated rendering is a top preference assuming current rendering rates. If rendering prices increase, producers will likely choose other methods and, depending on method choice, could increase costs on society through environmental degradation, groundwater pollution, or spreading of disease. Furthermore, if the costs of "approved" methods increase, the use of "unapproved" methods may increase and lead to greater environmental risks. Methods with high capital investment costs will be especially challenging for small producers. Therefore, any regulations impacting disposal methods need to carefully analyze the benefits and costs of any proposed change (Sparks Companies, Inc., 2002).

Table 3-9 *Cost Estimates for Methods of Mortality Disposal*

	Rendering				
Species	MBM sold for feed	MBM not sold	Burial	Incineration	Composting
		Total (Sector-Wide) Operating Costs ($1,000)			
Cattle and calves	34,088	99,619	43,902	38,561	125,351
Weaned hogs	48,020	79,061	51,450	16,906	58,018
Pre-weaned hogs	5,533	7,786	8,300	1,226	4,209
Other	5,828	8,003	6,245	1,184	4,063
Total operating costs	$93,470	$194,470	$109,898	$57,879	$191,643
Cost per ton ($)	$55	$116	$66	$35	$115
		Operating Costs, Dollars per Mortality ($/head)			
Cattle and calves	$8.25	$24.11	$10.63	$9.33	$30.34
Weaned hogs	$7.00	$11.53	$12.45	$4.09	$14.04
Pre-weaned hogs	$0.50	$0.70	$2.01	$0.30	$1.02
Other	$7.00	$9.61	$1.51	$0.29	$0.98
		Total (sector-wide) Fixed Costs for Specialized Facilities ($1,000)			
Beef cattle				797,985	1,241,310
Dairy cattle				333,630	518,980
Hogs				158,031	245,826
Other				90,000	140,000
Total fixed costs				$1,379,646	$2,146,116

Note. Adapted from Sparks Companies, Inc. (2002).

Dan Wilson of the North Carolina Department of Agriculture gathered data from a variety of vendors and presented a simple cost comparison at the Midwest Regional Carcass Disposal Conference held in Kansas City, Missouri on August 18-19, 2003. His data appears in Table 3-10 (Wilson, 2003b).

Table 3-10 *Estimated Cost Per Ton and Technology Capacity for Various Carcass Disposal Methods*

	Cost	Capacity
Rendering	$86	35-40 t/hr
Burial	$30-60	10 t/hr
Composting	$40-60	Equipment limit
Air-curtain incineration	$30-200	5-6 t/hr
Landfill	$40-100	Transport limit
Alkaline hydrolysis	$45-260	4 hr/cycle
Plasma	$60	.25-7.5 t/hr
Ocean disposal	$1	Transport limit

Note. Adapted from Wilson (2003b).

In a study completed at Iowa State University, data was analyzed from pork producers on disposal methods used, satisfaction with method, and costs associated with each method, including capital investment, labor, and operating costs. Incineration requires the highest capital investment, while burial requires the lowest investment. However, this investment level changes if feasible burial land is not available. Composting does require an initial capital investment, but often an existing facility was converted to a composting bin. Burial had the highest labor costs, and rendering required the least labor because renderers picked up the dead stock. Depending on the labor available to the producer, it became a critical factor in method selection. Since composting is a fairly new method for these producers, labor costs are high but are likely to decline over time. Due to equipment costs, total operating costs were the highest for burial, followed by composting. If the producer already owns the necessary equipment, these costs would be relatively lower. When calculated for 100 head, rendering was the least costly. When satisfaction is considered, rendering and burial are the least satisfactory; while composting, a more expensive alternative, had the highest satisfaction level (Schwager et al., 2001).

While rendering is a common option, regulatory changes in the ability of renderers to use dead animal byproducts may increase the cost to producers for rendering services. This will in turn deter rendering and result in an increase of on-farm disposal. Small producers are more likely to change activities than large producers, yet small producers may spend just as much in appropriately disposing of their death loss on their own property (FDA, 1997).

In the University of Nebraska study that estimates cost for routine disposal, incineration at $0.049/lb ($98/t) is the lowest cost alternative, followed by the incinerator with afterburner at $0.073/lb ($146/t). Low-investment composting comes next at $0.091/lb ($182/t), followed by burial at $0.097/lb ($194/t). (Researchers do not consider burial as a viable option). High-investment composting is next at $0.113/lb ($226/t) and rendering is the most expensive at $0.163/lb ($326/t) (with four loads per week) (Henry et al., 2001).

Alabama researchers found small-bin composting to be the most efficient method at a cost of $3.50 per hundredweight ($70/t). The size of the production unit has an impact on the identification of the most economic method. Three size operations were compared: operations with 40,000, 100,000, and 200,000 chickens. Large-bin composting showed economies of scale when comparing a farm of 40,000 to 200,000 with a reduction in net costs of 53%. Increasing flock size reduced net costs of fermentation by 60%. Burial pits were the least responsive with the operation size increase showing a reduction of only 26% while small-bin composting costs were reduced by 26% and incineration costs declined 30%. Refrigeration costs decreased by 11% (Crews et al., 1995).

Incineration and composting of poultry (broilers, broiler breeders, and commercial layers) were compared by researchers at North Carolina State University. Cost analysis is based on fuel consumption, composter capacity needs, and labor requirements. Analysis was based on 100,000 head of broilers, layers, and broiler breeders. The capital investment for incineration of layers and broiler breeders was $2,500 and $1,400 for their composting. The additional cost to incinerate layers was $1,730 and to compost was $2,237. For broiler breeders, the cost to incinerate was $1,612 and to compost was $1,976.50. Broilers are more expensive to dispose because they are larger. The capital investment for incineration was $3,500 and $3,750 for composting. The fixed and variable costs of incineration were $4,003.50 and $4,093 for composting (Wineland et al., 1997).

The Canadian Plan Service compared methods of disposal of poultry mortalities. They considered regulation compliance, reliability, biosecurity level, and economic factors, such as amount of carcasses, capital costs, equipment availability, and labor costs. They considered four methods: incineration, rendering, composting, and farm burial. Catastrophic losses would require alternative plans be in place because no single method could likely handle the disposal needs. Incineration costs will vary depending on the types of poultry to be destroyed and the most significant cost is capital expense, followed by fuel costs. Delivery to a rendering plant for the producer is the easiest, lowest cost method, but depends on a rendering plant being nearby. Composting costs include the building of the compost bin, material, labor, and the positive value of the fertilizer. Burial on-farm was the most common, but the least recommended. However, it may be necessary in the case of a catastrophic death loss (Winchell, 2001).

In Australia, a commission estimated the economic, social, and environmental costs of an FMD outbreak. They specifically looked at control and disposal costs and found significant social costs exist related to disposal and other strategies. Also, environmental costs from carcass disposal can be minimized with good preparation and site selection. The Australian Veterinary Plan (AUSVET Plan) identifies a "stamping out" policy to control FMD. The steps of the plan include establishing a quarantine around the outbreak, slaughtering infected and exposed herds, disposing of animals, disinfecting properties, compensating stock owners for livestock slaughter, and inspection and surveillance. The added pressure on producers, communities, and emergency workers due to the large-scale slaughter and disposal can lead to depression, psychological impacts, substance abuse, physical health problems, family and relationship difficulties, and disrupted communities. It is noted that these costs should be estimated in further studies (Productivity Commission, 2002).

The Productivity Commission also found the environmental effects due to the disposal of carcasses and livestock products need further review. Groundwater pollution caused by leachate from disposal pits and visual and emission pollution from burning are examples. This study did not attempt to evaluate the cost of the environmental impact, but noted that the key to minimizing risk is good preparation. The costs of minimizing risk would not be small, but, in relation to overall economic and social costs, the magnitude or risk minimization would be modest. The disposal methods for carcasses and livestock products were burial, pyre burning, rendering, and incineration. Burial was the endorsed method. The control costs calculated included slaughter, disposal, disinfection, movement restrictions, etc. They were calculated together because component costs were not available. The estimated control costs were $20-25 million for a 3-month outbreak, $130-150 million for a 6-month outbreak, and $360-420 million for a 12-month outbreak. Moreover, the export loss was expected to be up to $12.8 billion and the loss to tourism to exceed $300 million (Productivity Commission, 2002; Baker, 2005).

In a study by the University of California Agricultural Issues Center, the total estimated cost of an FMD outbreak (direct, indirect, and induced costs) is estimated in a two-component model: an epidemiologic module that simulates an FMD outbreak in the South Valley and an economic module that estimates the economic impact. The economic model has three parts: (a) calculating the direct cost of depopulation, cleaning and disinfection, and quarantine enforcement; (b) using an input-output model of the California economy to estimate direct, indirect, and induced losses; and (c) estimating the losses caused by trade reduction. The first component includes only cattle and swine. Carcass disposal costs are included in a summed depopulation cost with compensation payments and euthanasia costs. Depopulation cost per individual animal is estimated and multiplied by the expected loss from the first module. The model assumes all disposal occurs through burning and burial. Recommendations from the study state that depopulation costs would exceed the financial resources available and includes the following statement: “Depopulation and carcass disposal would face serious difficulties – timely availability of sufficient human, physical and financial resources, availability of burning materials, lack of knowledge of the cost imposed on different social groups by alternative carcass disposal methods, environmental and legal issues, etc” (Ekboir, 1999, p. 68).

Previous comparative studies

Norman Willis (2003), past president of the OIE: International Committee, reported on a survey of 15 OIE members to identify available technologies for carcass disposal and develop a hierarchy. Parameters considered for evaluation were environmental impact, production intensity, trade and economic impact, animal welfare, pathogenic characteristics, disease control, producer impact, financial and logistical impact, and public reaction. A well-balanced choice must be able to be made and implemented in a short time, because speed of decision making is paramount (Willis, 2003).

The resulting hierarchy was rendering, incineration (fixed, mobile air curtain, municipal, and co-incineration), pyre burning, composting, mass/open farm burial, licensed commercial landfill, mounding, fermentation, and new technologies such as alkaline hydrolysis and biosphere process. If a prion disease is involved, the selected technology must be effective at inactivating prions, including rendering, incineration, and alkaline hydrolysis. Survey results indicated each disposal technology has advantages and disadvantages, but that overall capacity is critical. Further consideration should be given to technical and financial preparedness, simulation exercises, risk communication tools, mobile and environmentally responsible disposal technologies, and the need to avoid slaughter if possible (Willis, 2003).

In a CAST study in 2008, researchers noted the unpredictability of mass disposal events and the lack of practical methods to reproduce such events have limited the ability of researchers to perform scientific studies comparing disposal technologies. They identified questions that need to be considered when determining the appropriate disposal choice specifically in the case of poultry:

- Cause of the event;
- Number and size of birds involved;
- Spread of loss – partial, whole-house, entire farm, regional;
- On-farm or company resources and disposal options available;
- State of carcass decomposition;
- Proximity of infected farms to other farms;
- Local, state, and federal regulations;
- Site conditions and weather;
- Public perception;
- Anticipated disposal costs and who is responsible for costs;
- Compatibility of depopulation methods with disposal options; and
- Farm accessibility during or immediately after event (Blake et al., 2008).

Researchers recognized burial, incineration, composting, and rendering as the most common methods for poultry disposal. They noted continuing problems with burial, improvements in incineration technology, increasing acceptance of composting, logical advantages of rendering when appropriate facilities and innovative storage are available, usefulness of alkaline hydrolysis in limited quantity cases, and the potential of emerging technologies such as pyrolysis and co-combustion. Final recommendations included the importance of having a response plan in place and using multiple disposal methods because no one method will be satisfactory (Blake et al., 2008).

Based on AI outbreaks in Virginia, Brglez (2003) compared methods of disposal in the case of a catastrophic avian influenza outbreak. Each method was evaluated on its capacity to dispose of 188 t of diseased poultry carcasses per day for 90 days. Actual costs of the disposal methods used were compared with hypothetical cost estimates.

Brglez found rendering as the method of choice. The other methods considered included on-site burial, landfill burial, composting, incineration, alkaline hydrolysis, and *in situ* plasma vitrification. The variables of disposal cost estimated were transportation, labor, materials, land-use fees, and equipment usage. The value of potentially saleable products was also considered. All methods were considered to meet the needs of stopping the spread of pathogens. It was important for the method to be cost effective and quickly accessible. Environmental concerns can be managed with burial, landfill, and incineration management techniques. The objective of the study was to determine the cost, environmental impacts, public perception impact, and complexity of each method.

Brglez examined each method by weighing the four factors on a point scale with good=1, average=2, and poor=3. Any decision-making tool needs to consider all factors. The recommended choice in his final analysis was rendering (Brglez, 2003).

Table 3-11 *Summary of Comparative Analysis*

Method	Cost	Environment	Perception	Complexity	Total Score
On-site burial	2	2	3	1	8
Landfills	3	2	2	1	8
Incineration	3	2	3	3	11
Composting	1	1	1	3	6
Rendering	1	1	2	1	5
Alkaline hydrolysis	3	2	2	2	9
In situ plasma vitrification	3	1	2	1	7

Note. Adapted from Brglez (2003).

Flory et al. (2006) compared methods of disposal for poultry carcass disposal. After a qualitative comparison of advantages and disadvantages of several methods, they determined the preferred methods to be:

1. In-house composting;
2. Out-of-house on-site composting;
3. Other on-site methods as availability allows (i.e. alkaline hydrolysis, anaerobic digestion);
4. Landfill off-site;
5. Rendering, incineration, or comporting off-site; and
6. Burial on-site under emergency permit (Flory et al., 2006b).

Based on the 2002 Virginia AI outbreak, they found incineration to be the most costly at approximately $500/t and the least publically accepted (Flory et al., 2006a).

The EPA issued a report comparing bird carcass disposal options in an AI outbreak. They compare methods but do not offer a set hierarchy, instead noting that each disease situation will be unique. The EPA offers three critical factors for selecting a method:

- Limiting transportation to ensure virus containment,
- Expedience in the response to reduce potential for genetic mutations or human transmission, and

- Disease containment and virus inactivation.

On-site management is identified as a priority when feasible (EPA, 2006).

The OIE, in the Terrestrial Animal Health Code, compares multiple disposal methods (OIE, 2005; OIE, 2012b). Listed below are the risk factors and practical considerations identified that may influence the choice of disposal technology. The list has expanded as additional research has occurred. Factors include:

- Speed and timeliness – Early disease detection, immediate depopulation, and rapid carcass removal and disposal are critical to disease control.
- Occupational health safety – Workers should be adequately protected from potential zoonotic disease spread and the other health risks associated with handling decomposing animal carcasses.
- Pathogen inactivation – The method must rapidly inactivate the pathogen, or at a minimum, block the spread of the pathogen.
- Environmental concerns – All methods may have negative impacts in the environment.
- Availability of capacity – All disposal methods may have capacity limitations, but it is important that the method(s) of choice will not create a bottleneck in the disposal efforts.
- Cost and funding adequacy– Each technology will come with associated costs, and those methods requiring sophisticated equipment may be costly.
- Public reaction and societal acceptance – Carcass disposal may lead to adverse public reactions for multiple reasons.
- Acceptance by farmers – Owners on infected farms will want disposal to occur off-site; famers outside an infected zone will want disposal to stay inside the zone.
- Transportation and necessary equipment– On-site and off-site transport vehicles must be available and properly prepared and equipped. Off-site transportation creates the need for additional biosecurity precautions. Selection and availability of transport contractors must also be considered.
- Logistical preparedness – Availability of materials, qualified personnel, manual labor, facilities, electricity, cell phone coverage, and other logistical requirements are critical to successful disposal efforts.

- Wildlife, scavengers, and vectors – Diseases can be transmitted between domestic stock and wildlife, so disposal decisions must consider the potential of disease spread to wildlife (OIE, 2005; OIE, 2012b).
- Economic impact – The method selected will have an impact on the economic impact of the outbreak (OIE, 2012b).

The OIE report identifies the following hierarchy:

1. Rendering,
2. Incineration (fixed, mobile air curtain, municipal, and co-incineration; open air/pyre burning is not recommended),
3. Composting,
4. Trench burial and mass burial,
5. Licensed commercial landfill,
6. Mounding (aboveground mass burial),
7. Fermentation,
8. Alkaline hydrolysis,
9. Lactic acid fermentation,
10. Anaerobic digestion, and
11. Non-traditional and novel technologies, such as pre-processing, ocean disposal, and biorefining (OIE, 2005).

In order for carcass disposal efforts to be effective, a number of major issues must be considered. Disposal efforts will be expensive, accumulating fixed and variable costs as well as direct and indirect expenditures. A disposal hierarchy may not be fully capable of capturing and systemizing all dimensions of carcass disposal. When all options are considered, a less preferred technology may be required. Decision makers must have a comprehensive understanding of all methods of disposal and be able to balance the scientific, economic, and social issues. The primary considerations for policymakers should be timely slaughter and disposal along with security and prevention of disease spread (OIE, 2005).

The OIE defined the process for decision making as a five-step process:

1. Define all relevant factors to be considered in the decision process. Flexibility should exist to account for situational modifications. Factors may include operator safety,

community concerns, international acceptance, transport availability, industry standards, cost effectiveness, and speed of resolution.

2. Determine the relative importance of the factors by weighting each on their importance. The value of the Factor weighting (F) must total to 100.
3. Identify all disposal technologies. Rate each option against each factor and assign a Utility rating (U) of between 1 and 10 to each comparison. The U assigned should reflect how well the disposal option achieves the ideal in respect to each factor (1 is the worst possible fit and 10 is the best fit).
4. Multiply the F by the U to yield a numeric Balanced Value (V), (V = F x U).
5. Sum the Vs for each disposal option. Compare the suitability of each technology by numerically ranking the sums. The largest sum should identify the best balanced choice (OIE, 2005; OIE, 2012b).

An example which is included on the OIE website and Terrestrial Animal Health Code is duplicated in the following table.

Table 3-12 *Carcass Disposal Decision Making Process Example*

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial	
Factor	Weight(F)		V		V			U		U	V	U	V
Operator safety	20	7	40	4	80	8	160	3	60	7	140	8	160
Speed of resolution	20	8	60	8	160	2	40	5	100	5	100	6	120
Pathogen inactivation	15	10	150	10	150	8	120	5	75	4	60	4	60
Impact on environment	10	10	100	8	80	3	30	10	100	3	30	3	30
Reaction of the public	10	10	100	7	70	1	10	9	90	3	30	4	40
Transport availability	5	1	5	1	5	8	40	5	25	3	15	8	40
Acceptable to industry	5	7	35	7	35	7	35	7	35	6	30	7	35
Cost	5	4	20	1	5	6	30	9	45	8	40	9	45
Risk to wildlife	5	10	50	10	50	5	25	4	20	5	25	5	25
Capacity to meet requirements	5	5	25	3	15	9	45	9	45	9	45	9	45
Total weight & balanced value	100		785		650		535		595		515		600

Note. F = Factor weighting, U = Utility Rating, V = Balanced Value
Adapted from OIE (2005); OIE (2012b).

In the EU, disposal requirements for all animal byproducts not intended for human consumption are detailed in *Regulation (EC) No 1774/2002*. Animal byproducts are categorized into three areas: Category 1 – TSE sensitive material, Category 2 – high risk material, and Category 3 – low risk material. Category 1 materials must be incinerated either in an incineration plant or processed by approved method and then incinerated. Non-risk materials must be heat processed and disposed in an approved landfill. Category 2 material must be incinerated or processed by approved method. Material use may include use as a fertilizer, fuel for a biogas plant, or compost. Category 3 can be used in a biogas plant, composted, or used in pet food. Ruminants may be incinerated and landfilled. No livestock carcasses in these categories may be used in animal feed or human food. EU scientific committees are considering alkaline hydrolysis, high pressure hydrolysis biogas production, and biodiesel production for Category 1 materials. For Category 2 and 3 materials, the three previously listed methods, as well as high pressure high temperature hydrolysis and Brookes gasification, are under consideration. In the Netherlands, regulations are even stricter (Hoeksma, Lourens & Bokma, 2009).

Studies have been completed to attempt to reduce veterinary risk and cost related to carcass disposal in the Netherlands. Previously, the Dutch government covered a high percentage of associated disposal costs, but over the last 10 years those costs have been shifted primarily to farmers. The economic feasibility of on-farm preservation and processing has been considered. Specifically, freezing, incineration, composting, and fermentation were considered. Conclusions included:

- On-farm carcass treatment is generally more costly than central rendering;
- Co-fermentation can be cost effective if a biogas plant is nearby;
- Composting large carcasses is too expensive, but small carcasses can be composted at costs similar to rendering;
- Temporary freezing can reduce cost and risk; and
- Reduction of veterinary risk, need for transportation, and odor nuisance may justify higher expenses (Hoeksma et al., 2009).

The U.K. Department of Health compared carcass disposal methods solely related to the potential significant risk to public health. Their analysis resulted in a hierarchy based on the lowest public health hazard:

1. Rendering,
2. Incineration,
3. Landfill,
4. Pyre, and
5. Burial (United Kingdom Department of Health, 2001).

In 2011, researchers at Bangor University in the UK assessed the potential environmental impacts and biosecurity risks associated with different disposal options and considered the socioeconomic and practical implications of existing EU policy. While traditionally burial and burning have been the most common disposal methods worldwide, EU Animal Byproduct Regulations forbid these practices and limit disposal options to incineration, rendering, alkaline hydrolysis, and licensed maggot farms. These prohibitions are based on concerns related to pathogens and infected agents entering the food supply and that carcass disposal is considered pollution. The differing perceptions "raise questions about the quality of evidence-base upon which legal decisions have been made" (Williams et al., 2012, p. 1) and create a need for a more critical analysis of disposal options (Gwyther et al., 2011).

Williams et al. (2012) compared the socioeconomic aspects, human health considerations, biosecurity risks, and environmental impacts of several carcass disposal methods using a five-star system to classify factors based on scientific evidence. They concluded that while there are numerous disposal methods available, the limitations created by the inability to destroy TSEs and other pathogens make many of them unacceptable in the UK and other regions. The preferred methods are those that allow for on-farm disposal, such as composting and anaerobic digestion, because they are considered to be more practical and economical as well as providing greater biosecurity benefits and fewer environmental repercussions. However, the EU does not consider these options safe, and the approved legal options are not acceptable to the agricultural community. This difference of opinion leads to extensive noncompliance and increases environmental and biosecurity risks due to illegal activity. Therefore, there is a need for alternative disposal methods to be developed and for policy changes to be implemented based on new evidence. The researchers identified bioreduction as a promising alternative. Williams et al. (2012) further noted that while proper analysis of mortality disposal systems is important, these systems have been scrutinized far more than other livestock industry activity such as waste disposal and livestock access to waterways that may pose even greater risk to human health and the environment. It is necessary that disposal policy be based on realistic and proportional risk levels rather than a zero-risk approach. They noted where further research was warranted and called for further research into the economic impacts of disposal alternatives and lifecycle assessments so policymakers can understand the cost implications and the long-term environmental impacts (Gwyther et al., 2011; Williams et al., 2012).

Table 3-13 *Grading of the socioeconomic and biosecurity aspects of methods used throughout the world for disposal of routine livestock mortalities; assuming best practice*

	Socioeconomic aspects			Human health	Biosecurity risks					
					Pathogen contamination of:					
Method	Process Speed	Relative cost	Practicality (for farmer)	Dioxins & furans	Air	Soil	Water	Land-spreading of waste produced	Transport of animals off-farm	Prion destruction
Burial	***	*****	****	*****	****	***	MRN	N/A	*****	*
Burning	****	****	***	**	MRN	MRN	MRN	MRN	*****	***
Incineration (on-farm)[a]	*****	**	***	****	*****[b]	*****[b]	*****[b]	MRN	*****	*****
Incineration (large central facility)	*****	**	*****	***	*****[b]	*****[b]	*****[b]	MRN	*	*****
Rendering	*****	***	*****	MRN	N/A	MRN	MRN	N/A	*	****
Composting[c]	**	****	***	MRN	***	MRN	MRN	MRN	*****	***
Anaerobic digestion	**	***[d]	***	MRN	***	***	***	MRN	*****	**
Alkaline hydrolysis	****	**[e]	***	MRN	*****	*****	*****	*****	*****	*****

*Very poor, **Poor, ***Moderate, ****Good, *****Very good; MRN More research needed; N/A Not applicable

[a] Assumes conformation to ABPR (1774/2002) specifications e.g. use of afterburners

[b] Omits handling and storing phase of carcasses pre-incineration which may constitute potential biosecurity risks (Section2.3)

[c] Assumes unlined static pile with no forced aeration

[d] Benefits from methane production (biogas for energy production) not considered

[e] Unlikely to be suitable for small farms; although increasingly cost-effective with increasing farm size

Note. Adapted from Gwyther et al. (2011, p. 771), Williams et al., (2012, p. 5).

Table 3-14 *Grading of the environmental impacts of methods used throughout the world for disposal of routine livestock mortalities; assuming best practice*

	Environmental impacts					
			Pathogen contamination of:			
Method	Odour	Greenhouse gas emission	Air	Soil	Water	Land-spreading of waste produced
Burial	***	****	*****	**	***	N/A
Burning	*	MRN	MRN	MRN	MRN	MRN
Incineration (on-farm)[a]	****	**	****[b]	****[b]	****[b]	MRN
Incineration (large central facility)	****	**	***[b]	***[b]	****[b]	MRN
Rendering	***	****	MRN	*****	***	MRN
Composting (unlined)	****	****	MRN	***	MRN	****
Anaerobic digestion	****	*****	*****	MRN	MRN	****
Alkaline hydrolysis	***	MRN	MRN	****	***	***

*Very poor, **Poor, ***Moderate, ****Good, *****Very good; MRN More research needed; N/A Not applicable

[a] Assumes conformation to ABPR (1774/2002) specifications e.g. use of afterburners

[b] Omits handling and storing phase of carcasses pre-incineration which may constitute potential biosecurity risks (Section 2.3)

Note. Adapted from Gwyther et al. (2011, p. 772), Williams et al. (2012, p. 13).

A study was completed from 2003-2006 in New Zealand by the Ministry of Primary Industries (formerly Ministry of Agriculture and Forestry) on carcass disposal alternatives and policy approaches with a focus on burial, rendering and portable incineration units. Specifications for on-farm and mass burial sites were developed that complied with national biosecurity, environmental, and legal regulations. Research showed that burial sites needed to be preidentified. Air-curtain incineration was found only to be feasible at the beginning of an outbreak or in limited disease scenarios. Rendering capacity was limited as was geographic distribution. In addition, existing systems could not handle whole or hide-covered carcasses. Neither rendering nor air-curtain incineration were viable alternatives in the case of a large disease outbreak, such as FMD. Landfills were then considered as was composting and small-scale pyre burning in isolated areas. A disposal hierarchy was created based on: rendering → incineration → landfill → pyre burning → mass burial or on-farm burial. A gap analysis of these alternatives was completed leading to the identification of the need for further research and planning (Pollard, 2012).

Researchers at Texas A&M University noted that the best method for carcass disposal depends on the situation and must be determined on an individual basis. Selecting the optimal disposal method requires considering the availability and capacity of disposal technologies and facilities, and the regulatory environment (Jin, Gao, McCarl, Ward, & Highfield, 2006; Jin & McCarl, 2008). Previous carcass disposal cases have been relatively small and lessons learned from them are minimized due to the uncertainty related to the impact of a larger disease outbreak. Factors to be considered include: disease control, daily carcass disposal load, event size, cost, environmental impact, public reaction, and availability of disposal facilities. Researchers compared methods based on biosecurity and safety, environmental, regulatory and legal, logistical and infrastructure, and economic and cost factors (Jin & McCarl, 2008).

Direct costs of operations, transportation, storage, facilities, equipment, permitting, and security were considered while comparing costs between methods. Indirect costs related to disease spread consequences, environmental impacts, public perception and related business impacts, international demand, and losses in related regional income were also identified as factors. Potential revenue offsets from byproducts were included (Jin & McCarl, 2008).

Twelve simulations of disease outbreaks were considered based on a stochastic, state transition simulation model. Model output mortality ranged from approximately 16,000 to 8,500,000 heads with epidemic length ranging from 46 to 113 days. For the largest mortality result, variable costs ranged from $113-439 million. Lactic acid fermentation was the least expensive, burial was the next least expensive, and anaerobic digestion was the most expensive. But, in the case of fermentation, the fixed costs are high and the number of facilities is insufficient to meet the need (Jin et al., 2006; Jin & McCarl, 2008). Distance to disposal locations is also an important consideration, especially when combined with facility capacity, size of the outbreak, and outbreak duration. These limitations can make some technologies infeasible. For example, in the largest mortality scenario, some technologies would take more than 10 years to deal with the carcasses based on current capacities. Therefore, portable technology and the ability to transport carcasses over long distances to other facilities needs to be considered in emergency response (Jin et al., 2006).

Researchers also focused on effects of the rate of accumulation of carcasses, strategies to slowing down the slaughter rate, environmental impacts, cost estimation, welfare slaughter, and regulatory considerations. Results indicated vaccination or other strategies that reduce carcass flow can reduce costs by 15%. Data indicates vaccination may transition from being considered an undesirable option to a more desirable option as carcass disposal costs and concerns increase. This is especially true if welfare slaughter can be reduced or animal products can be salvaged for some positive use. Reducing welfare slaughter can reduce disposal costs by up to 40% in some scenarios (Jin & McCarl, 2008).

In 2012, New Zealand began a carcass disposal project aimed at FMD preparedness building on the previous findings and developing better guidance on carcass disposal. The guidelines will:

- Be based on sound science and evidence;
- Add onto previous findings;
- Meet local and international biosecurity and legal requirements;
- Have board agreement from industry, government, and other interested parties;
- Focus on simplicity and low technology solutions;
- Be able to be implemented immediately upon decision to depopulate; and
- Include a decision-making process if disposal guidelines do not cover a situation (Pollard, 2012).

It is anticipated that multiple options will be utilized in the case of a large-scale outbreak. In addition, national, regional, local and on-farm options will all be a part of the solution. On-farm disposal is considered the preferred option because all off-farm disposal options require biosecure transit. On-farm options to be considered are burial, air-curtain incineration, composting, and pyre burning. Off-farm options to be considered include burial on a nearby farm, mass burial sites, landfills, composting on a nearby farm, mass composting site, composting in a landfill, whole carcass rendering, pre-processing before rendering, air-curtain incineration, pyre burning, and disposal at sea. Disposal alternatives that are not considered feasible and will not be studied are: lactic acid fermentation, alkaline hydrolysis, anaerobic digestion, depolymerization, plasma arc, refeeding to alligators/crocodiles, napalm, pyrolysis, non-traditional rendering (flash dehydration, fluidized-bed drying, extrusion, expeller press), and any other non-traditional, novel, or unusual technologies or methods of disposal (Pollard, 2012).

Burial remains a primary focus with an understanding it has to be implemented well to reduce environmental impacts. Air-curtain incineration or fixed incineration units are likely to be used in limited capacities and pyre burning is unlikely to be used except in isolated areas. Composting is an option that has been given new attention and may provide a practical alternative. Composting expertise has grown substantially and it offers a simple, low tech solution. The key issue is that research must show that composting can eradicate the FMD virus; if it cannot, composting can only be a pre-process. The sourcing and stockpiling of composting materials also needs consideration and discussion. In comparison to burial, the environmental impacts are lower; the process is quicker, easier, and more effective; and site rehabilitation is simpler. Rendering remains a limited capacity option in New Zealand, although available capacity is likely to be utilized. Disposal at sea is also identified as a practical option with fewer environmental impacts. Little scientific evidence supports the pollution impact and those that exist need to be compared with the environmental impacts of other disposal options. It is likely only to be used as a last resort (Pollard, 2012).

The New Zealand study group is also assessing the decision-making process. Attention is focused on involvement of all groups and organizations, not just government entities. The resulting approach should be one that is standard, consistent, transparent, and acceptable to all involved (Pollard, 2012).

Decision support tools are also being developed to support the decision-making process. The New Zealand process will incorporate three tools for disposal analysis: decision criteria, decision tree, and decision matrix. The decision criteria is aligned with the OIE Terrestrial Animal Health Code and intended to provide a common understanding and consistent approach to the decision process. The decision tree is a structured, logical approach to the criteria and disposal options. It is designed to be used with other tools and depends on decisions from previous steps. Indecision or disagreement in one step will cause a delay in the overall response.

The decision matrix is designed to work with the decision criteria and tree and serve as a record-keeping tool of all relevant decisions. The decision-making process is the discussion itself and the tools are intended to support that discussion (Pollard, 2012).

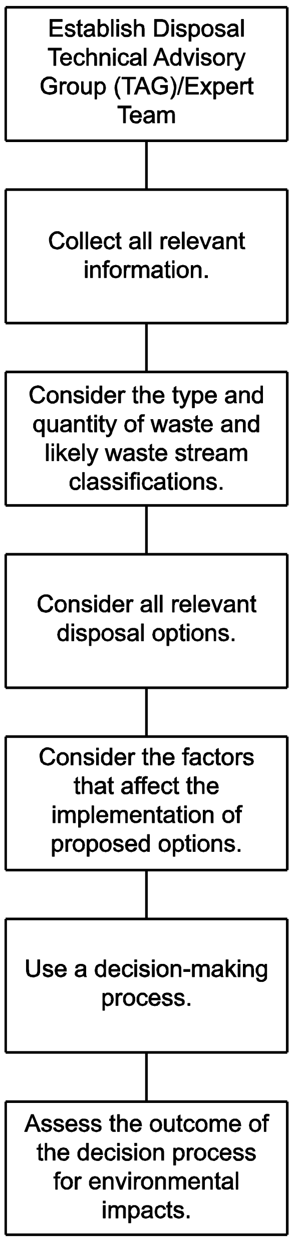

Figure 3-4 Proposed New Zealand decision making process (Pollard, 2012).

The decision criteria included in the New Zealand decision process include:

1. Time and spread of resolution – how quickly will the method be in place, sufficient time to identify, collect and deploy needed physical resources, is the FMD process inactivated by the selected method;
2. Occupational health and safety – is the method safe for staff and operators;
3. Cost effectiveness – is the method cost effective;
4. Biosecure transport – is sufficient transportation and equipment available;
5. Public/stakeholder/industry/political opinion/community concerns – does public opinion align with decision, is there consensus, are industry/farmer concerns addressed, do those with political influence support decision, is decision process able to withstand legal challenge, is decision agreed upon and accepted by participants even if they do not agree with the outcome;
6. Legislative and regulatory requirements – are appropriate administrative and legislative mechanisms in place;
7. International organizations and trading partners – does method align with international standards and agreements and is it acceptable to international jurisdiction and trading partners;
8. Economic impacts – are short- and long-term economic impacts clear;
9. Human/physical resources and logistics – are there sufficient human and physical resources for implementation in the field and to deal with non-field components, are domestic or international reserves available, are there sufficient resources for security of high-risk sites, can resources be scaled up rapidly, q43 logistics in place for disposal of other items; and
10. Environment impact – impact on environment, sufficient knowledge of physical geography, accounted for weather pattern and season (Pollard, 2012).

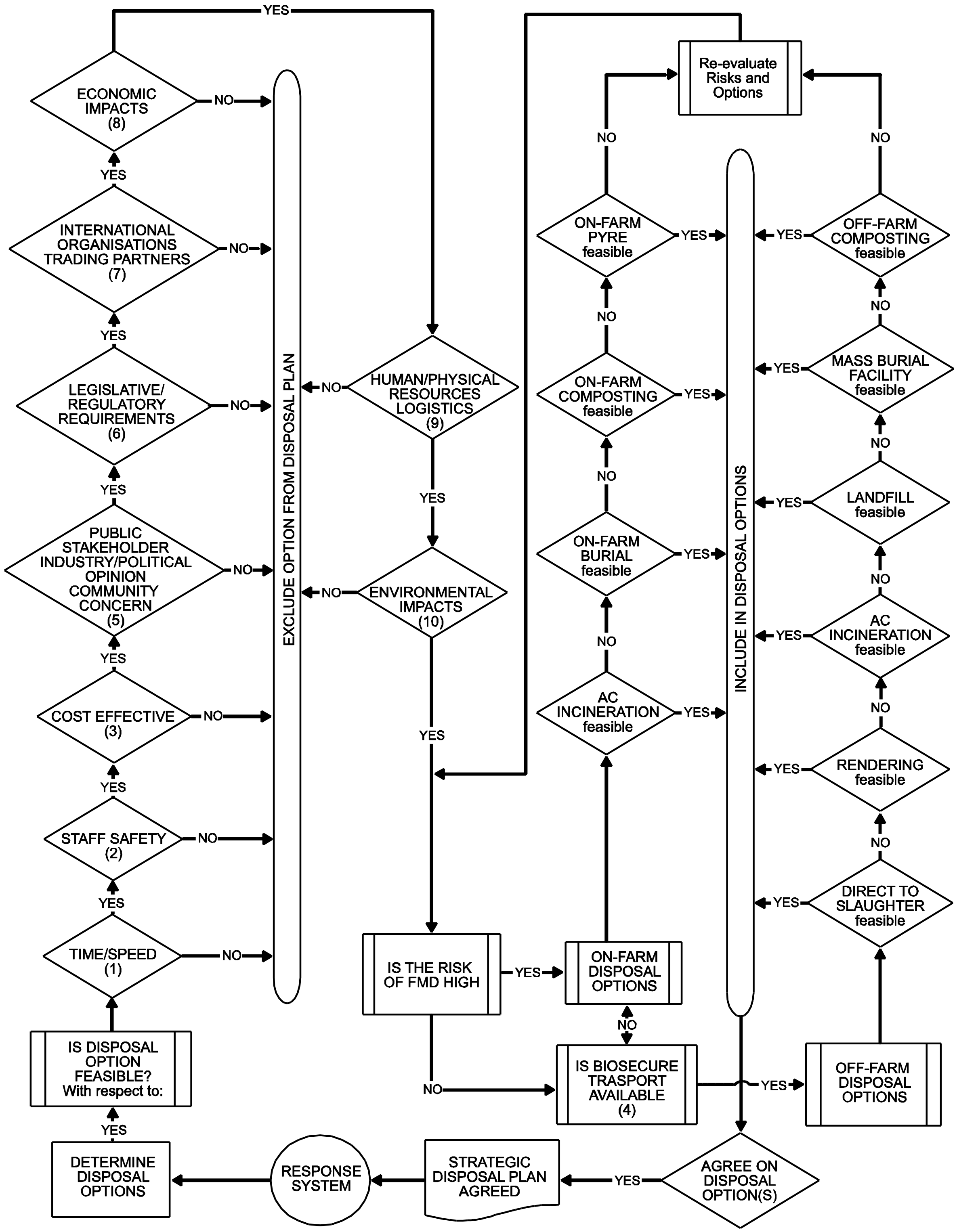

Figure 3-5 Proposed New Zealand decision tree (Pollard, 2012).

Carcass disposal plans must be flexible and adaptable. Regardless of its content, once a disposal plan has been developed, it needs to be documented in policy. Many carcass management policies and regulations are not based on science and are not updated with development of new technology. As is the case in California, the only approved method is rendering, so even research on other methods is challenging (King et al., 2009).

There are benefits to understanding the quantitative and qualitative impacts of control and disposal strategies and other aspects of infectious disease dynamics. In order to do so, farm data, location of animals, location and type of facilities, disease characteristics, and control and disposal data must be factored in so that the model will have enough information to influence policy (Royal, 2002).

Any animal health plan must include at least these points for consideration when determining the appropriate disposal technology. Any plan should include multiple methods of disposal and steps need to be taken before an emergency to prepare for the usage of multiple disposal methods (Ekboir, 1999; Harman, 2001). If plans are based solely on what is cheap and fast, poor decisions may be made. For example, in Alberta, "Dr. Gerald Ollis noted that burying carcasses is the cheapest disposal method because rendering and incinerating can cost several times more than an animal is worth" (Teel, 2003).

Animal health officials are examining preemptive slaughter strategies across the country. In Kansas, as an example, the policy that all animals within an infected zone should be destroyed has been questioned. Feedyard concentration may impact the feasibility of such a policy. If an animal in a feedyard is infected, it may not be necessary to destroy animals more than ½-mi away if there are no cattle immediately surrounding the feedlot. There may be no way for the disease to be carried from one lot to another and the hot, dry climate of western Kansas does not lend to easy survival of FMD (Bickel, 2003).

The impact on the environment will be greatly impacted by any change in rural economy and agricultural policy regarding large animal death loss and specifically carcass disposal. Water, air, soils and biodiversity should all be considered. Recent outbreaks have proven that limited time to select burial or burning locations, rapid authorization of disposal permits, communication difficulties between agencies, and public contentions all were directly related to environmental concerns (Harman, 2001). The impact on public health as a result of environmental impacts as well as other physical and psychological issues is also a concern.

Another issue to be discussed is the need for interagency cooperation and clearly defined responsibilities amongst those agencies. State interagency coordination is fundamental to being prepared to handle an animal health emergency (Ekboir, 1999). These issues need to be addressed between local, state, and federal governments as well as between agencies at any government level. Jurisdictional conflicts exist and must be resolved prior to the onset of an emergency situation. Few states have comprehensive disposal plans in place although such plans are critical to making efficient and effective decisions in the face of both small- and large-scale death losses. Therefore, there is a critical need to further review and recommend policy and regulation guidelines (Ellis, 2001). In the US every state has regulations regarding the disposal of dead animals; therefore, each state must approve the disposal method before it is used based on their regulations (Morrow & Ferket, 1993). For example, in Kansas KDHE must approve disposal method and potential disposal sites. Some sites have been pre-approved for expedience in an emergency.

Summary of Lessons Learned

The historical experiences related to large-scale carcass disposal have provided lessons from which policymakers can learn. The choice of disposal technologies utilized should involve a number of factors based on lessons learned from previous mass disposal experiences.

Animal health protection is paramount. Disposal and the related depopulation efforts must limit disease spread and protect animal health. This must be a top priority and speedy decisions and implementations are necessary to most effectively hamper the spread of disease.

Any large-scale animal death loss will create significant economic costs. The disposal of large number of carcasses will be expensive, and fixed and variable costs will vary with the choice of disposal method. In addition, each method will result in indirect costs on the environment, local economies, livestock producers, and allied industries. Decision makers need to better understand the economic impact of disposal technologies. Broader policy considerations involving carcass disposal and a large-scale animal disaster need to be identified and discussed as well.

Previous experiences dictate that strong interagency relations, cooperation, and communications are critical to effectively dealing with a large-scale animal disaster. Federal, state, and county regulations related to carcass disposal may be unclear or in conflict with one another. Interagency issues may result in additional problems or the extension of the disaster. Steps must be taken to identify interagency relationship problems and develop a comprehensive plan for dealing with a large-scale carcass disposal.

A disaster-level animal death loss event will cause significant public concern. Historical experience shows that the disposal of carcasses creates public dismay and apprehension. To assure positive public perception, decision makers handling massive livestock mortality and carcass disposal must have access to expert public information professionals and agree to make communicating with the public a top priority.

Serious issues mandate the need for a security system during carcass disposal operations. Examples of security threats related to carcass disposal include potential equipment theft, angry and discontented livestock owners, an uninformed public, and unintentional animal or human activity. The most important aspect of security is keeping the disease from being spread from the disposal site to other areas. A well-designed security system would control these issues.

Carcass disposal events can result in detrimental effects on the environment. The specific impacts vary by carcass disposal technology, specific properties of the location, weather, the type and number of carcasses, and other factors. Environmental monitoring will be necessary to accurately determine the impact of a specific carcass disposal event on the environment. Geographic information systems (GIS) should play a significant role in the management of mapped or spatial data prior to, during, and after carcass disposal events. At the simplest level, GIS can provide maps, and at the more complex level, it can serve as a decision support capability.

The disposal of carcasses following a large-animal disease event will likely require transportation to an off-site disposal location. The transportation of large numbers of diseased animals or carcasses requires significant planning and preparation to prevent further dissemination of the disease to animal and human populations.

Chapter 4 - Vaccination

Over the last dozen years, there has been an overarching attitude change about the use of vaccination as an emergency measure in responding to a foreign animal disease (FAD), instigated primarily by the U.K. foot and mouth disease (FMD) outbreak. Prior to the U.K. FMD experience, mass depopulation and disposal were considered the clear policy choice to stop disease spread. Concern over available resources, public reaction, environmental impacts, and animal welfare have driven the debate and made vaccination a more likely alternative. However, the decision to implement emergency vaccination protocols remains a controversial policy decision.

"Vaccination will remain pivotal to the control of many livestock diseases, especially in view of the ease with which intensive production systems facilitate the easy transmission of pathogens between individual animals, and will be absolutely essential if domesticated livestock are to be reared on a scale and intensity sufficient to feed a significantly high proportion of the world's population" (Shirley, Charleston & King, 2011, p. 115).

Vaccines are designed to produce immunity in defense of a specific disease agent (APHIS, 2007). The use of emergency vaccination in an animal disease outbreak is a complex policy question and a number of factors need to be considered, including vaccinology, cost, feasibility, public acceptability, trade impacts, tourism, economic factors, animal welfare, as well as social, cultural, and religious issues (Garland & de Clercq, 2011; Barnett et al., 2013).

While the debate over the use of vaccination in dealing with emergency animal disease applies to multiple diseases, emphasis will be placed on FMD for the purposes of this discussion. Classical swine fever (CSF) and avian influenza (AI) examples will be discussed minimally when appropriate for the purpose of comparison and to provide a broader understanding of vaccination policy issues. Due to the complexity of vaccination, there is no single policy approach that can be applied to all animal disease emergencies.

Historical Experience

Vaccination has historically been used as a prevention and control strategy in some countries on a routine basis while not used at all in other nations and regions. Emergency vaccination has been implemented in some regions that had previously been FMD-free while stamping-out has been used in other cases. A few examples are shared in the following sections.

By 2004, more than 200 million cattle across the world received biannual vaccination against FMD (Premashthira, 2012; Hutber, Kitching, Fishwick, & Bires, 2011). Previous experience with FMD outbreaks indicates the disease status of a country or region will determine the appropriate vaccination approach. Endemic areas are more likely to use a routine vaccination policy, while disease-free areas are more likely to utilize vaccination in combination with slaughter to control disease (Hutber et al., 2011).

In review of previous outbreaks where vaccination was not used, the need for rapid implementation of control strategies was critical; however, if vaccination is used, then rapid implementation of additional response strategies becomes less critical. Livestock with lower immunity will show more acute clinical signs and require a more rapid response and implementation of slaughter control to abate disease spread (Hutber et al., 2011).

In the case of FMD, disease responses against major outbreaks in Taiwan, the Netherlands, Japan, South Korea, and the UK have all involved extensive culling of infected and exposed animals combined with movement controls. In some cases, emergency vaccination was also used (Hagerman et al., 2012). While emergency vaccination was highly effective in the regional outbreaks of FMD in Korea in 2000 and the Netherlands in 2001, attempts to use targeted vaccination in Uruguay in 2001 and Korea in 2010-2011 failed and resulted in implementation of country-wide blanket vaccination. In some cases, vaccination has been effectively used to localize an outbreak, but it is not always successful (Muroga et al., 2012).

United Kingdom

The economic impacts of vaccination were considered when developing the strategy to control the disease outbreak during the 2001 FMD outbreak in the UK. While vaccination was not incorporated into the control strategy within the UK, it was used outside the borders in countries like the Netherlands in a targeted manner to reduce disease spread (Burrell & Mangen, 2001; Hutber, Kitching, & Pilipcinec, 2006). The spread of the outbreak in the UK would have necessitated significant vaccine reserves and a large number of vaccination teams to implement an effective vaccination program in the UK. Concerns over availability of resources and economic damage resulting from the delayed ability to reestablish disease-free status drove the policy decision to not allow vaccination and maintain a mass depopulation approach (Paton, Sumption, & Charleston, 2009). If a vaccinate-to-live policy had been implemented, 12 months of U.K. agriculture exports would have been lost. However, the epidemic itself lasted eight months and the succeeding ban added an additional three months, indicating it may have, in fact, been comparable to a ban associated with vaccination (Hutber et al., 2006).

One of the biggest lessons from the 2001 UK FMD outbreak is the impact disease control policy decisions have on animal welfare. While culling animals from infected premises or those with dangerous contact to animals from infected premises proved effective, culling livestock from farms contiguous to infected premises was not found to be necessary to control disease spread. Eighty percent of the livestock culled were disease free, and the depopulation was heavily reported in the media leading to a change in the U.K. response policy to consider vaccination in an FMD response (Hutber et al., 2011). Vaccination was repeatedly considered for use and was actually approved in Cumbria and Devon, but the industry, animal health community, and public was not supportive (Scudamore, 2007). The experience created a renewed focus in other FMD-free countries on vaccination as a component of disease response along with culling and other zoo-sanitary measures (Paton et al., 2009).

In the 2007 FMD outbreak, the use of vaccination was approved and, within five days of disease confirmation, was ready to be implemented with 300,000 doses and 50 vaccination teams. However, vaccination was not used because culling and movement control restrictions stopped disease spread and allowed for disease control (Hagerman, et al., 2012; Anderson, 2008). A decision tree was used to compare alternatives and decisions were made quickly. Concerns continue to exist amongst industry professionals about the proposed vaccination plans and the practical aspects of vaccination and handling vaccinated animals and products. The data system had not been tested with a realistic amount of data and the tracing system of vaccinated animals was not ready for use. Uncertainty over pros and cons of vaccination, economic impacts of the potential development of a two-tiered market (vaccinated and non-vaccinated animals) and trigger points that would cause vaccination to be implemented remain a concern (Anderson, 2008). During the 2001 and 2007 FMD outbreaks in the UK, the FMD vaccine bank located at Pirbright, Surrey, England was not used (Hutber et al., 2011) primarily due to the economic impacts expected from losing disease-free status for a longer period of time and policy indecision about the value and costs of vaccination.

Netherlands

During the 2001 FMD outbreak in the Netherlands, 26 cases of FMD resulted in the destruction of 268,000 animals including those vaccinated – an average of 10,000 animals destroyed for every confirmed case. It became apparent during their outbreak they did not have the capacity for preemptive culling and their animal destruction policy proved insufficient to control the spread of FMD (Kahn et al., 2002; Pluimers, 2001). The public demanded an alternative strategy and vaccine was used for targeted vaccination after approval was granted by the European Union (EU) government (Kahn et al., 2002; Pluimers, 2001). Twenty-six farms were infected, and emergency vaccination-to-cull was applied within 2 km of all infected farms. In one area, vaccination was applied in a larger area. The disease was contained in one month and the last vaccinated animal was culled one month later. An effort by farmers to keep vaccinated animals alive was not met with success due to the desire of the Dutch government to quickly regain FMD-free without vaccination status (Pluimers, Akkerman, van der Wal, Dekker, & Bianchi, 2002).

A study of the 2001 FMD outbreak in the Netherlands indicated that the economically optimal control strategy depended on animal density, course of epidemic, and animal culling and rendering capacity. The study concluded vaccination within a zone surrounding an infected area is the most economically viable strategy for densely populated livestock areas. Results also indicated vaccinated animals should be destroyed to minimize economic impact. If vaccinated animals were immediately destroyed, the livestock industry would suffer losses of .5% income and 1,340 person-years of employment annually. If vaccinated animals were allowed to live, it could extend the trade ban from four months to at least one year, causing the livestock industry to lose 2-3% of income and 7,000 person-years of employment (Kahn et al., 2002; Pluimers, 2001).

Uruguay

Vaccination has been a major component of national FMD programs in South America since the 1960s. In 1996, Uruguay achieved FMD-free designation without vaccination and boosted their export value by 50% and increasing revenue from U.S. imports by 20,000 t of beef and $110 million in revenue. In addition, the government saved $8-9 million annually in routine vaccination program costs (Knight-Jones & Rushton, 2013).

During a large FMD outbreak in 2001, vaccine helped lead to an eventual FMD-free designation in Uruguay. Farmers objected to a repeat of the slaughter control strategy used in previous outbreaks and vaccination was used instead. Initially, emergency ring vaccination was attempted but failed to stop the spread of disease and mass vaccination became necessary and was continued until 2003 (Diaz, Urdapilleta, Chowell, & Castillo-Chavez, 2005; Premashthira, 2012; Hutber et al., 2011). Vaccination costs made up 55% of the $13.6 million in outbreak costs (Knight-Jones & Rushton, 2013). Once in place, blanket vaccination achieved disease control in four months, but this compared to an FMD epidemic six months earlier that was controlled within one month through culling (Hutber et al., 2011).

Japan

During the 2010 FMD outbreak, stamping out and movement restrictions were insufficient in stopping disease spread (Muroga et al., 2012). More than 126,000 animals were vaccinated as a means of disease control but were eventually depopulated due to perceived disease risk along with 175,000 additional animals. More than 40% of animals depopulated were healthy vaccinates. Vaccination was employed in order to slow down depopulation and allow time to identify burial sites. This outbreak proved again an FMD outbreak is difficult to control and vaccination served as a method to aid in control and eventual eradication (Hagerman et al., 2012; Nishiura & Omori, 2010; Miller, 2011; Barnett et al., 2013; Muroga et al., 2012).

The decision to vaccinate was made 21 days after the initial report of FMD and vaccination began four days later (Muroga et al., 2012). Vaccination operations were slowed because of the onset of the rainy season (OLPC, 2012). Within five weeks, all vaccinated animals had been culled and buried (Muroga et al., 2012). The report of an inquiry commission after the outbreak indicated challenges existed in determining which entity and individuals had the authority to determine vaccination should be utilized (Tsutsui & Ban, 2012). According to Muroga et al. (2012), the delay in the decision to vaccinate indicated the importance of making a timely decision and concluded an earlier decision may reduce the number of animals vaccinated and eventually requiring depopulation (Muroga et al., 2012).

South Korea

Following the burial of livestock in South Korea in response to the 2010-11 FMD outbreak, officials identified underground water sources had been polluted with organic contaminants (Miller, 2011). Over three million head were destroyed and buried, and some reports also indicated some animals were buried alive (OLPC, 2012). This finding resulted in the Food and Agriculture Organization of the UN (FAO) advocating vaccination to balance animal welfare and environmental impacts (Miller, 2011). Government officials, upon realizing the disease was not being contained and response strategies were not effective, changed from their culling-with-no-vaccination policy to mass vaccination with no culling (Zentis, 2011). Vaccination of cattle began on December 27, 2010, and was extended to pigs on January 10, 2011 (Ahn, 2012; Bryant, 2011). Twenty days earlier officials had refused to vaccinate for fear of losing its FMD-free status (Bryant, 2011). Estimates from South Korea estimated more than 13 million head of hogs and cattle were vaccinated by January 2011, with secondary vaccinations planned for animals in infected provinces (OLPC, 2012).

Once South Korea decided to vaccinate, the vaccine antigen banks in Pirbright, England supplied 1.2 million doses of FMD vaccines in six working days rather than the standard four months (Zenopa, 2011; Bryant, 2011). South Korean officials also asked countries with vaccination supplies to donate vaccines. Belgium, for example, provided 800,000 doses (Zentis, 2011) and the North American FMD Vaccine Bank (NAFMDVB) provided antigen for the manufacture of 2.5 million doses of FMD (Hayden, 2011). The Korea Joongang Daily editorialized in February of 2011 that the government was distracted by the effort to keep its FMD-free status, effectively turned the country into a massive farm animal graveyard, and the more rapid use of vaccination protocols could have eliminated FMD quicker (Bryant, 2011; Miller, 2012b). Costs for culling, compensation, and vaccination were estimated to exceed $2.7 billion (Bryant, 2011; Ahn, 2012). While in the midst of dealing with the FMD outbreak through quarantine and limited vaccination, President Lee Myung-bak announced South Korea would pursue FMD vaccine development and manufacturing. Based on their findings, vaccination was the best response to control highly contagious animal disease. His announcement was met with some skepticism over the hastiness of his decision, the practicality of such an effort, and the impact it had on the immediate situation (Kim, 2011; Bryant, 2011).

During the outbreak, Juan Lubroth (2011), the FAO Chief Veterinary Officer, advocated strongly for vaccination and the need to consider animal welfare and the environmental impact in the decision process. He noted developments in vaccine technology, specifically related to the ability to differentiate vaccinated animals from infected animals, would make it easier for countries engaging in emergency vaccination to regain export access. “Emergency vaccination with the aim to disrupt disease transmission and assist progressive elimination is increasingly applied, particularly during the peak of an epidemic, so as to buy time during culling operations. Vaccination can also be applied to protect animals and keep them alive and productive” (Lubroth, 2011, p. 1).

Response Alternatives and Strategies

There are several possible FMD response strategies using stamping out, vaccination, or a combination of both:

- Stamping out, no vaccination;
- Stamping out, vaccinate-to-kill/cull;
- Stamping out, vaccinate-to-slaughter;
- Stamping out, vaccinate-to-live; and
- Vaccinate-to-live, no stamping out (Styles, 2011; Parent, Miller, & Hullinger, 2011; APHIS, 2012a).

The goal of modified stamping out with emergency vaccination-to-kill is to suppress disease spread and then destroy and dispose of animals at a later time following emergency protocols. This suppressive emergency vaccination strategy could be applied to highly-susceptible animals in the infected zone, control area, or vaccination zone. A common application of this strategy is ring vaccination. This approach will likely require traceability systems, animal identification, and permitting (APHIS, 2012a).

A variation on vaccinate-to-kill is vaccinate-to-slaughter which implies all vaccinated animals will be sent to slaughter facilities for normal processing and the food products will enter the food chain. Trace back, animal identification, and appropriate permits will be necessary (Parent et al., 2011). USDA Animal and Plant Health Inspection Service (APHIS) combines vaccinate-to-kill and vaccinate-to-slaughter as one policy alternative (APHIS, 2012a).

The goal of modified stamping out with emergency vaccination-to-live is designed to allow at-risk animals not infected or in-contact to be vaccinated and allowed to live. Animals intended for slaughter could still be slaughtered, but animals bred for breeding, milking, or other purposes could continue to serve in that capacity. This strategy can be effective with high-valued genetic stock, production animals, or in high-density animal populations. This system will require permitting, traceability, and identification as well. This strategy overlaps with the emergency vaccination-to-slaughter response (APHIS, 2012a).

The emergency vaccination-to-live with no stamping out response is designed to allow all infected and vaccinated animals to serve out their lives to meet their original purpose. This strategy is unlikely to be implemented at the beginning of FAD outbreak, but could be used if a disease was so widespread that resources are not available to meet stamping-out requirements. It could result in endemic status (APHIS, 2012a).

Emergency vaccination can be considered when a safe, effective vaccine is available and vaccination meets national and international protocols. High quality strategies for movement control, traceability, information technology systems, permitting, and epidemiological expertise are necessary if vaccination is used.

Types of vaccines

Vaccines are used to provide protection from infection by a pathogen, prevent clinical symptoms associated with infection, or reduce disease duration or severity. Vaccines are not expected to be 100% effective or to serve as a cure for the disease in question.

There are two traditional types of vaccines: modified live and killed inactivated. Modified live vaccines are distinguished by their ability to replicate in the host while showing limited clinical signs and inducing an immune response to help protect animals from the disease pathogen. Inactivated pathogens or antigenic portions of the pathogens are contained in killed vaccines and often require an adjuvant to stimulate an immune response (NAHEMS, 2011c; Williams, 2007). Vaccines may also be classified as non-marker vaccines (indistinguishable from natural infection by pathogen) and marker vaccines (immune response can be differentiated from natural infection) (Williams, 2007). The ability to differentiate vaccinated animals from those naturally infected is critical to business continuity, effective vaccination efforts, and surveillance of disease spread (APHIS, 2012c). Whether a vaccinated animal can be differentiated from a naturally infected animal is a critical issue when considering how vaccination will influence trade restrictions.

Most vaccines cause the development of antibodies to antigens associated with the infectious agent and make it difficult to differentiate whether the immune response is a result of the animal being exposed to the natural infection or the vaccine. DIVA vaccines provide a protective immune response, but do not contain some specific antigens associated with the pathogen. This allows the DIVA vaccine to be differentiated from the actual pathogen. DIVA vaccines are critical to disease eradication efforts because they allow for a clearer interpretation of disease causality and thus a quicker return to a disease-free status. Vaccines can be delivered by intramuscular or subcutaneous injection, transdermal injection, intranasal, ocular, oral, and spray/topical application. The necessity of proper handling, transportation, and storage of vaccines adds to the complexity of a mass vaccination effort (NAHEMS, 2011c). In addition, the ability to identify and trace animals through a livestock traceability system is critical to a successful response (NAHEMS, 2011c). The lack of a robust animal traceability system in the US will hinder response time and effectiveness (Hullinger, 2013).

Suppressive or protective purpose

Generally, in the case of an FAD, the use of vaccine could be suppressive or protective. A suppressive role indicates the vaccine is used to reduce potential virus production in exposed herds and to protect animals not already infected from clinical disease through development of sufficient immunity. Suppressive vaccine protocols are typically applied in the infected zone (Kahn et al., 2002; Williams, 2007). In many cases, these animals would eventually be depopulated or slaughtered. If the vaccination is intended to be protective, it is used to create a buffer and protect herds in the vicinity of an outbreak but not yet exposed. In most cases, exposed and diseased animals are eliminated, but it is possible to allow all vaccinated animals to live out life if they are confirmed absent of viral activity and clinical signs of infection (Kahn et al., 2002).

Protective vaccination can be narrowed into two categories: preventive and barrier. Preventive vaccination, also known as preemptive, is typically applied to animals at high risk for exposure and located in a zone likely to become infected. Barrier vaccination results in the delineation of a barrier outside the infected zone designed to slow disease transmission by vaccination of all susceptible animals in the zone. The zone can be determined by radius, geography, animal population and density, and other factors. Ring vaccination, border vaccination, and firebreak vaccination are all modes of protective barrier vaccination (Williams, 2007). In any case, speed is of the essence in developing the barrier. For example, it is better when establishing a ring vaccination zone to get it established quickly with a narrower radius and then expand it rather than take longer to gather resources and establish an initial vaccination zone with a wider radius. Strict movement controls must accompany a barrier zone for it to be effective (Geering & Lubroth, 2002).

Prophylactic and emergency methods of application

A number of different vaccination methods have been used in some countries to successfully control FMD and reduce the chances of or shorten the length of an epidemic. If the transition rate of susceptible animals becoming infected is greater than the rate at which they become immune then an epidemic occurs (Green & Medley, 2002). Effective control strategies have included:

- Prophylactic protection prior to an epidemic (typically in endemic or semi-endemic areas), such as
    - Blanket vaccination at regular time intervals across entire farms or regions;
    - Annual synchronized ring, firebreak, or targeted vaccination in specific geographic areas; or
    - Post-outbreak vaccination to abate an undetected subclinical challenge (Hutber et al., 2011; Leon, 2012).
- Regional vaccination during an epidemic or farm-level vaccination during an outbreak (typically in endemic areas), such as
    - Revaccinating to abate chronologically recurrent waves of disease transmission, or
    - Revaccinating with a new or different vaccine to abate a challenge from a new or different serotype (Hutber et al., 2011; Leon, 2012).
- Vaccination used with a ring, blanket, or target approach during an epidemic in combination with slaughter control (typically in disease-free regions), such as
    - Emergency vaccination-to-live where livestock are preserved post vaccination and may or may not enter the human food chain or
    - Emergency vaccination-to-cull where livestock are culled and may or may not enter the human food chain (Hutber et al., 2011; Leon, 2012).

Prophylactic vaccinations used during disease-free periods can help lessen the likelihood of extended epidemics. Pre-challenge vaccinations are 81-98% effective and when used with a booster vaccine administered 3-4 days prior to an FMD challenge increases the efficacy by up to 13%. However, if the high vaccinal protection is waning such as when vaccination was more than 75 days prior, subclinical disease and occult (hidden) transmission can occur. The risk increases in a corresponding manner as the level of protection decreases. Disease-free regions are unlikely to use regular prophylactic vaccination due to the economic impact of regular, multiple vaccinations and the possible onset of persistent subclinical disease if the herd is exposed to disease. In semi-endemic regions, disease-free status can be maintained by using prophylactic vaccine administration in sub regions. This is the case in Argentina and Brazil where the country is divided into vaccination and non-vaccination zones (Hutber et al., 2011).

Non-prophylactic vaccination can be used as a component of an emergency response in countries or regions traditionally disease free (Hutber et al., 2011; Leon, 2012). The EU has maintained a nonprophylactic policy since 1991 but supports use of prophylactics in countries near its borders. The success of such policies directly corresponds to the disease challenges in the region. If the challenge is low, then nonprophylactic policy is likely to work. In semi-endemic regions, it is less likely to be successful (Hutber et al., 2011).

Emergency ring vaccination can decrease disease spread while minimizing the number of animals to be vaccinated. It is a primary component in disease control policy in disease-free regions. In Uruguay, however, emergency ring vaccination failed to stop the spread of disease and it became necessary to use extensive emergency blanket vaccination. In other cases, emergency ring vaccination has been successful when combined with slaughter control. Another complication with emergency ring vaccination is that it can take 2.5-5 times as long to achieve immunity as it would take to cull the same herd. Emergency ring vaccination also allows for the possibility of disease spread beyond the ring via fomites, personnel, or illegally transported animals (Hutber et al., 2011). Leon (2012) notes ring vaccination does not significantly reduce the risk of FMD spread between premises compared to stamping out, but it is the best method to reduce virus circulation when stamping out is not an option.

In past cases, emergency blanket vaccination has been successful in disease control and has typically been used in conjunction with animal movement restrictions. As was the case in Uruguay, the use of blanket vaccination is unlikely to stop disease spread as quickly as depopulation. Adding to the lack of confidence in an emergency blanket vaccination policy is the fact that multiple vaccine administrations have been used in previous cases, which makes the efficacy (proportion of vaccinated animals protected) of a single vaccination uncertain. This is especially true with a variety of serotypes, differing rates of transmission, and a range in the strength of disease challenges. Therefore, blanket vaccination as an alternative over slaughter control remains controversial, because neither has been conclusively proven more effective. Both tools can be used as a component of the overall disease control strategy depending on the characteristics of the regions and epidemic (Hutber et al., 2011). Blanket vaccination or inaccurately targeted vaccination is not only costly but also increases the risk of hiding clinical signs of disease amongst carrier animals in challenged herds (Hutber et al., 2006). Blanket vaccination can be used when the size of the disease outbreak significantly exceeds expectations (Leon, 2012).

Targeted emergency vaccination can be useful in rural areas with high livestock density. Preventive targeted vaccination could be especially useful with pigs because they often function as massive replicators of FMD virus which makes them a tremendous potential source of infection to other susceptible species. Cattle could also benefit from targeted vaccination as a protective measure (Hutber et al., 2011).

Local factors will be critical in determining the best option for disease control, but the most critical component in the decision process is the region's disease status. These factors will determine where vaccines are used. Biomodels and cost-benefit analysis can indicate when vaccines should be used. A combination of local epidemiological factors and biomodels can help determine how vaccinations should be used. According to Hutber et al. (2011), there is no economic benefit to ring or targeted vaccination-to-kill above slaughter control, but there are economic welfare benefits to vaccinate-to-live policies. The potential economic benefit of emergency blanket vaccination over slaughter remains in question. The success of a vaccination program declines as the disease challenge increases, the wrong vaccines are utilized, epidemics are prolonged, and livestock numbers increase (Hutber et al., 2011).

Diagnostic testing

While vaccination strategies are critical to FAD control policy discussions, there are other factors and technologies related to animal diseases that need further research and discussion as well. Rapid and accurate disease diagnosis is one of these factors and is critical to effective disease response, including decisions about implementation of control strategies.

A quick and accurate diagnosis is critical to the effective use of vaccination. Diagnosis typically begins with trained personnel such as producers and veterinarians and is supported by laboratory tests to confirm the disease. Future advances in science and technology will improve diagnostic capabilities, but the time needed to transport suspect material to a laboratory for testing can be lengthy and slow down disease response. In some cases, when rapid diagnosis is critical, it will be more effective to base confirmation on clinical signs (Shirley et al., 2011).

Away from advanced laboratories, established and emerging technologies can be deployed onsite. These tests designed to support local decision making are known as point-of-care, pen-side or chute-side, portable, onsite, or field tests. These tests can facilitate more rapid decision making thus reducing the spread of disease, reducing costs, and avoiding unnecessary slaughter. Advancements in these technologies are due to the focus and investment on disease identification for humans and homeland security. Lateral flow devices (LFD) or dipstick tests and portable nucleic acid-based tests such as PCR are the two most common assay systems suitable for field use. In regard to FMD, an LFD has been developed identifying all seven serotypes. While the analytical sensitivity is lower than PCR, confidence in the result can be increased at the herd level by testing multiple animals. These resources could be used to provide rapid and objective support to local professionals in determining response strategies but need to be incorporated into hardware platforms suitable for use by veterinarians, animal health professionals, and livestock producers (Shirley et al., 2011).

During a large-scale animal disease outbreak, in multiple locations or states, the USDA deploys rapid diagnostic tests to identify infected livestock. Such tools were used in the END outbreak in California and the AI outbreak in Virginia. These tests were done at local laboratories. Pen-side tests, while being researched, have not been validated. Even if pen-side tests are further developed, confirmation tests would be required because tests are designed to be sensitive not specific. The USDA believes in extreme caution in disease identification. Validated tests managed by experienced diagnosticians are necessary (GAO, 2005).

Early detection, combined with a shortened interval between infection and implementation of a response such as vaccination, has the most significant impact on duration and extent of an outbreak. Surveillance, awareness, reporting, rapid diagnosis, and immediate tracing of animals movements are necessary. Inexpensive and accurate pen-side tests allowing for rapid confirmation are critical to an effective disease response. Like most infrequently-utilized emergency response technologies, including vaccination, there is little economic incentive for private development of these technologies (Rubira, 2007). The development and planned use of rapid diagnostic tests are critical to an effective response and important to the decision and actual implementation of an emergency vaccination protocol.

ARS researchers at PIADC worked with a biotechnology company to develop an improved diagnostic test for FMD after a 2002 request from Congress. It can detect RNA from the FMD virus in less than 2 hr using real-time PCR. USDA uses the test in the National Animal Health Laboratory Network and labs across the US can use the test to diagnose samples rapidly in the case of an FMD emergency. However, the disease is not considered confirmed until after results are available from PIADC. These tools could be used along with vaccination to help address an FMD outbreak (DHS, 2012, July 9).

Considerations and Challenges

Vaccination has advantages as a disease control measure. Some slaughter of non-infected animals may be avoided which reduces the accompanying social and psychological challenges. There may be significantly less carcass disposal and the viral excretion from infected premises can be reduced or eliminated. But, as with any policy choice, there are also disadvantages. Vaccination of large numbers requires a significant amount of trained manpower, extensive post-vaccination surveillance, and may require accumulative administrations of vaccine to achieve prophylactic protection (Hutber et al., 2006).

Advantages and disadvantages

Williams (2007) identified advantages and disadvantages of emergency vaccination as an emergency animal disease control strategy. Advantages include:

- Potential reduction in the number of animals infected,
- Potential reduction in the number of animals destroyed,
- Potential reduction in resource demands (through reduction of depopulation and disposal as well as disease transmission),
- Maximization of animal protein for its intended use (in a vaccinate-to-live or vaccinate-to-slaughter versus vaccinate-to-kill scenario),

- Protection of public health, and
- Protection of high-value animals and endangered species (Williams, 2007).

Williams noted the importance of a risk-based approach in determining if vaccination is used and identified the following disadvantage and limitations:

- Vaccine effectiveness in terms of efficacy, vaccination protocol, and time for immunity response;
- Reversion of live vaccine agents to a previously virulent state or inadequately inactivated vaccines;
- Effect on the evolution of more pathogenic strains of an organism;
- Potential for molecular reassortment;
- Potential for vaccines to become contaminated and cause other disease;
- Existence of carrier and subclinical animals (especially of concern in suppressive vaccination campaigns);
- Creation of a false sense of security;
- Initially high demand on resources and personnel;
- Risk of disease transmission by vaccination teams;
- Difficulties with handling vaccines, such as maintaining a cold chain;
- Difficulties surrounding, resources required for, and significance of follow-up surveillance;
- Pressure from government and industry to eradicate disease quickly;
- International trade restrictions and economic implications;
- Consumer resistance to vaccinated products could lead to short- and long-term demand shifts or the need to destroy vaccinated animals and their products to keep them out of the food supply;
- Public health and occupational safety of animal health workers;
- Environmental issues; and
- Need for caution in developing and executing vaccination protocols (Williams, 2007).

Overarching concerns

Mass vaccination protocols "rarely result in all animals developing a protective level of immunity" (Rubira, 2007, p. 337). Vaccination may be more useful in an endemic situation due to costs, trade barriers, and the need for the vaccine to work against all strains. It will be very resource intensive, may divert limited resources from other needs, is difficult to implement in a timely manner resulting in the development of a protective level of immunity, and may be an attempt to buy time. Vaccination may be most useful when there has been a delay in detection leading to widespread disease and exceedingly long disease duration (Rubira, 2007).

The use of vaccination can potentially reduce the number of animals identified for depopulation. In many cases, infectious disease control response tends to be reactive rather than preemptive. Culling is used to stop disease spread but can be contentious when healthy animals are destroyed. The response decision is often influenced by the fraction of transmission occurring before the infected animal shows disease symptoms (Charleston et al., 2011).

Decision makers need to act quickly to determine if vaccination is to be used in dealing with an FAD in order for its use to have an impact. However, limited resources of personnel, vaccine, and equipment may keep authorities from meeting the demand even if the decision is made in a timely manner (Williams, 2007). Because vaccines for some animal and poultry disease are not readily available, effective, or differentiable, veterinarians and animal health officials are limited in the ability to control disease spread and cannot implement the most effective or appropriate control measures (Gilsdorf, 2009). Vaccination is more likely to be effective if the interval between vaccination and exposure is longer allowing for immunity to build. Some animals will continue to shed the virus after vaccination even if protected from clinical signs. Other vaccines suppress such transmission (NAHEMS, 2011d).

A poorly executed vaccination program will likely result in a slow and uneven spread of disease which is harder to detect, may extend the duration of the outbreak, and increase likelihood of disease becoming endemic (Geering & Lubroth, 2002).

In 2011, Shirley et al. noted the recent rapid expansion of genetic sequence data available is a key component to the development of tools and strategies to control livestock diseases, such as novel diagnostics and vaccination strategies. These strategies can make a significant difference to our ability to deal with disease outbreaks, but they will require a commitment of financial and human resources. Commitments need to be made to increasing the availability of trained personnel; strengthening the veterinary infrastructure; international cooperation, transparency, and data sharing; and acceptance of the difference of importance in certain diseases between developed and developing countries (Shirley et al., 2011).

Disease control is most effective when vaccination is used with diagnostics to monitor disease epidemiology. Rinderpest eradication can serve as a template for disease control and eradication. In the 18th and 19th centuries, slaughter and quarantine worked to eradicate Rinderpest from Europe and Russia. Development of live attenuated vaccines with lifelong immunity, combined with sanitary controls, led to eradication in China in seven years. Vaccination alone worked in India but took 40 years. Mass vaccination, requiring international coordination and external funding, was successful in Africa. Small scale, focused vaccination guided by the FAO was effective in the final stages of disease eradication. A few examples of diseases that could benefit from new effective control measures and a global eradication effort are East Coast fever (ECF), African swine fever (ASF), FMD, and haemorrhagic septicaemia (HS) (Shirley et al., 2011). Veterinarians have also stated vaccine usage may be most feasible in dealing with Rift Valley fever (RVF), Nipah virus, and AI (Monke, 2007).

The only vaccination option available for ECF is highly effective but highly complicated, inconvenient, and expensive. Access to new genome data will be critical to development of new vaccines that do not require live organisms. There are no safe ASF vaccines available for its control, and the need to identify cross-protective antigens for use against a variety of viruses is a challenge for researchers. Even though vaccines and diagnostic tests are available, as with FMD and HS, there remains a significant need for improvement in diagnostic capability and vaccination systems to facilitate eradication and disease control (Shirley et al., 2011). With FMD, there is no universal vaccine and one of the additional challenges is to develop methods to select vaccine antigens to protect against newly emerging strains – similar to the challenges faced with influenza (APHIS, 2007; Shirley et al., 2011).

Economic and Cost Factors

"The decision on whether or not to vaccinate or pursue a stamp-out eradication strategy will likely be based on economic factors…" (Bates, Carpenter, & Thurmond, 2003, p. 806). Economics can play a critical role in the selection of a disease control strategy, both in regard to short-term costs and long-term economic consequences. "The control of infectious diseases often times is determined by the economical resources as well as the accessible control measures" (Diaz et al., 2005, p. 1). "The motivation behind not vaccinating is an economic one" (Junker et al., 2009, p. 55). The economic advantages and disadvantages and how they are distributed will impact policymakers in their selection of response strategies. "The economic impact of epidemic diseases is largely influenced by the methods used by countries to control and eradicate outbreaks" (Horst, de Vos, Tomassen, & Stelwagen, 1999, p. 369).

The economic impact of disease response strategies affect individual farms and producers, related industries (including potential costs passed on to consumers), agricultural sectors, consumers, government, national economies, and international economies (Horst et al., 1999). The direct costs of vaccination protocols include the investments costs related to vaccine development, availability and delivery infrastructure; variable and recurrent costs related to the actual vaccines, vaccination supplies, and delivery; and costs associated with animal identification, traceability, and serological surveillance. Lost productivity caused by animal stress, disruption of routine, and negative reactions to the vaccine may create additional indirect costs. Blanket vaccination programs will be more expensive than targeted strategies. Feeding and caring for the animals during a quarantine period will add costs, and there will likely be reduction in market price if animals are kept beyond prime market weight after vaccination and before slaughter (NAHEMS, 2011d).

The economic justification to use emergency vaccination as an FAD control method is worthy of consideration. It is first necessary to determine if vaccination is technically viable. If it is, then economic viability can be considered by evaluating the impact on international trade and the use of vaccination to protect the livelihoods of farmers and ranchers. Conflicting results may exist, so weighing the impacts and finding the appropriate balance to meet the objectives is necessary. The funding source for vaccination and the cost effectiveness of vaccine delivery must also be considered (McLeod & Rushton, 2007).

The economic impact of various vaccination strategies increases the complexity of the decision of 'if' and 'when' to vaccinate against FMD. An economic differential exists between the decisions to vaccinate-to-live versus vaccinate-to-kill. The international FAO/OIE ban on agricultural exports to FMD-free countries is at least six months for vaccinate-to-live and three months for vaccinate-to-kill after the final infected or vaccinated premise is culled. The ban is three months for culling without vaccination. The 2001 U.K. FMD outbreak was controlled by culling for a number of reasons, but was strongly influenced by the economic advantages of a shorter ban on exports. The dilemma of whether or not benefits from vaccination outweigh a shorter ban on exports is a controversial question (Hutber et al., 2011).

A number of approaches have been used to analyze the economic pros and cons of using vaccination as a tool in FMD control and will be discussed in an upcoming section. Research had been done assessing the overall economic benefit or deficit related to direct costs of vaccination compared to disease control by slaughter. Quantifying the length and prevalence of the epidemic under different control strategies allows for a comparison of the costs of slaughter as a control mechanism versus vaccination with an export ban (Hutber et al., 2011).

In an exporting country, a successful stamping-out campaign is likely to allow a faster return to trade. Large farmers and ranchers who export have a greater safety net than small-scale producers who depend more on cash flow with limited safety nets. In the case of smaller producers, vaccination will result in greater economic benefits if the disease can be controlled with little depopulation, national markets are minimally disrupted and quickly restored, and impacts on economic sectors such as tourism and local communities are minimized. Larger farmers and ranchers are more concerned with the time export markets are closed being as short as possible (NAHEMS, 2011d; McLeod & Rushton, 2007). If a country is primarily focused on a domestic market rather than an export market, vaccination-to-live is considerably advantageous (McLeod & Rushton, 2007). While an abundance of research indicates depopulation may be more beneficial economically, Dr. Bruce McCarl noted vaccination-to-live can reduce the costs of carcass disposal efforts by as much as 15%. Salvaging some usable product from the exposed animal even for a lower value will likely reduce the economic consequences (WARRP, 2012).

An economically effective strategy of disease response needs to consider costs related to livestock loss, public health hazards, environmental impacts, and economic impacts on government, industry, and consumers (Jin, Huang, & McCarl, 2005).

Vaccine Development

Vaccine development for some of the most threatening animal diseases is a critical and significant technological development in animal disease control, especially when a vaccinated animal can be differentiated from a naturally infected animal (Elbers & Knuttson, 2013).

The NSTC subcommittee on FADT identified the need for significant investment in a vaccine countermeasure program. Specifically, they called for increased research on the speed and efficacy of existing vaccines to control disease spread and infection and the development and licensure of new generation marker vaccines providing rapid and long-term disease suppression while being safe to produce in the US. Basic research and discovery needs to be transitioned to applied research and product development to meet vaccine program research needs. Vaccine platforms producing different vaccine products for specific FADs were also identified as a research need. In addition, the subcommittee noted the need for exploring immunomodulators to complement vaccines and stimulate the immune system between the time of administration of vaccines and the onset of protection (Marburger, 2007).

The NSTC FADT subcommittee defined the ideal vaccine as:

- Compatible with a vaccinate-to-live strategy,
- Able to differentiate between infected and vaccinated animals,
- Initiates rapid onset of innate and adaptive immunity,
- Significantly reduces or prevents virus spreading and shedding,
- Prevents host animals from developing carrier states,
- Suitable platform for rapid mass inoculation,
- Able to be administered in one dose and in mass delivery methods,
- Shelf stable and rapidly deployable, and
- Provide cross serotype protection (multivalency) (Marburger, 2007, p. 13).

As Horn and Breeze (2003) described the incentive for vaccine development, "There is an old saying that it is better to have a vaccine and no epidemic rather than an epidemic and no vaccine" (p. 5).

Historical perspective – FMD vaccine

In 1897, two Prussian researchers, Friedrich Loeffler and Paul Frosch, leading the Research Commission on FMD issued the first description of an animal disease virus. Their original charge was to develop a vaccine for this disease. Since the early 1900s, inactivated FMD vaccines have been available with industrial production beginning in the 1950s. Originally, vaccines were developed from tongue epithelium infected with FMD virus and inactivated with formaldehyde. Cell-suspension cultures replaced primary cell usage in the

1960s and eventually ethylene imines replaced the formaldehyde inactivation. Inactivated FMD vaccines today consist of killed virus without nonstructural viral proteins (Gay & Rodriguez, 2011).

These vaccines have helped eradicate FMD in some regions of the world and repressed clinical disease in other regions. FMD vaccines represent more than 25% of livestock vaccine sales worldwide, which is the largest single share in the marketplace (Gay & Rodriguez, 2011). While effective in preventing clinical disease, inactivated FMD vaccines do not necessarily prevent viral replication and can result in persistent infections in more than half of naïve and vaccinated animals when exposed to FMD. These carrier animals create a difficult challenge in the control and eradication of disease. These types of vaccines also make vaccinated animals indistinguishable from infected animals. Therefore, there has been a need for FMD vaccines capable of preventing infection and clinical signs, and with antigenic markers to allow vaccinated animals to be differentiated from infected animals (DIVA testing) (Gay & Rodriguez, 2011).

In 2004, 15 different vaccines were manufactured internationally to protect against the multiple FMD serotypes in a variety of combinations (Breeze, 2004). Even as vaccines become more readily available, the lag time in an emergency outbreak after disease detection and before the supply of the correct vaccine is available would allow for significant disease spread. Vaccine markets have always been problematic due to sporadic demand, production lags, ineffective strains, and government influence on price (Hennessy, 2008).

There has been ongoing FMD vaccination research for a number of years, but there are few research centers with the necessary resources for long-term research efforts. An ideal vaccine would be given orally, immediately effective in stopping viral replication and disease spread, and allow meat to be used for human consumption. Such a vaccine may not be practical, but would potentially meet needs for both emergency and routine use (Paton et al., 2009).

FMD vaccines have improved significantly and manufacturing process changes are helping to address the differentiation of infected animals from vaccinated animals. However, major differences exist between manufacturers and vaccines used in FMD-free and FMD-endemic regions. Three formulations exist representing a majority of inactivated FMD vaccines: high-potency vaccines for emergency use, oil-emulsion conventional vaccines for routine control, and aluminum hydroxide vaccines for use in cattle. In regard to potency, OIE recommends six PD_{50} (protective dose for 50% of animals) because high potency provides greater defense against heterogeneous strains, creates immunity more quickly, and expands protection against viral shedding and transmission. However, use at the PD_{50} level (which is twice normal potency) would quickly diminish the number of emergency vaccines in international FMD vaccine banks (Geering & Lubroth, 2002; Gay & Rodriguez, 2011).

Current FMD vaccines protect animals from clinical signs assuming the strain matches and ample time exists for immunity to set in before animals are exposed to FMD. However, current vaccines do not protect against infection and do not eliminate virus transmission (Leon, 2012). Generally, protective immunity needs at least four to seven days to develop after vaccination, so disease control strategies need to handle this delay. The development of vaccines meeting the DIVA strategy of vaccinate-to-live continues to be a concern as well. These inefficiencies, concerns, and other vaccine issues are the focus of vaccine research as efforts are being made to improve FMD vaccination capabilities (Gay & Rodriguez, 2011).

It is important to note, while efficacy is crucial for all vaccines whether they are to be used in routine or emergency vaccination protocols, the preferred characteristics of vaccines in these scenarios are different. In a routine vaccination protocol, high priority is placed on thermostable formulation, long-lasting protection, low risk of virus release, and low production costs in addition to efficacy. However, in an emergency situation, priority would be on rapid formulation, rapid onset of immunity, and existence of a negative marker, in combination with high efficacy and low risk of virus release (Paton et al., 2009).

It is the goal of the OIE, the FAO, and other international organizations to eradicate FMD by 2030. The majority of vaccines currently available will not serve this goal because they induce only short-term protection, do not cross-protect against multiple serotypes and subtypes, have a short shelf life, require cold chain from production to delivery, require expensive biosafety lab facilities for virus production, do not protect against infection, are too expensive to produce, and do not fit regional needs. In order to meet the goal of eradication, fit-for-purpose vaccines must be developed and used in combination with appropriate diagnostics and control strategies tailored to each region (Gay & Rodriguez, 2011). If vaccine development is a priority, then research must also be focused on understanding and predicting viral persistence and emergence as well as development of better diagnostic tools to improve vaccine selection (Paton et al., 2009). Currently, only exporting countries will likely be motivated to invest the resources necessary for complete eradication, and investments from outside stakeholders may be necessary in disease-endemic countries. International cooperation and collaborative research will be required in combination with incentives, cooperative agreements, and the necessary resources (Gay & Rodriguez, 2011; Paton et al., 2009).

Recent developments

FMD vaccine

In 2007, ARS along with the DHS Targeted Advanced Development (TAD) unit and GenVec, Inc., a Maryland-based biopharmaceutical company, announced the development of a new experimental FMD vaccine with significant potential – the first FMD vaccine that could be produced in the US. At the time, ARS announced the vaccine had been tested on swine and cattle, and it worked quickly. It demonstrated effectiveness within seven days and created a minimum of 21 days of immunity in cattle. The vaccine was the first molecular-based FMD vaccine for cattle and would allow for the US to plan for adequate supplies for the USDA AHPIS National Veterinary Stockpile (NVS). It is administered in a non-replicating adenovirus, does not require expensive production facilities, and can be safely produced in the US. It can also allow for the differentiation between vaccinated animals or animals carrying antibodies through infection. Future testing would examine the vaccine's commercial viability and effectiveness against multiple serotypes (McGinnis, 2007).

Marvin Grubman, the lead researcher on the ARS FMD vaccine development project, also examined the joint administration of interferons, proteins produced by the immune system, with FMD vaccine to provide non-specific antiviral protection during the seven days after the vaccine is administered before full immunity occurs (McGinnis, 2009).

In November 2011, John R. Clifford issued a Field Safety Trial Notice for the FMD vaccine developed under the direction of ARS and DHS. The field study, required to be done under typical animal husbandry conditions before it could be licensed by USDA, allowed vaccination of cattle with a recombinant virus product containing genes from the FMD virus. Because there was no live or weakened FMD virus in the vaccine, the field study created no risk of a disease outbreak. The field study vaccinated about 500 cattle in Michigan, Missouri, and Nebraska and observed them for post-vaccination reactions. The Food Safety and Inspection Service (FSIS) approved the vaccinated animals for slaughter after a 60-day withdrawal period

(Clifford, 2011). Immunity was induced in cattle and pigs within seven days and offered protection for at least 42 days (Cima, 2012).

After the successful field study, GenVec, Inc. announced in 2012 that USDA APHIS Center of Veterinary Biologics (CVB), had issued a conditional license to Antelope Valley Bios, Inc. for their FMD adenovirus vaccine in cattle. This is the next step necessary to make the vaccine available to be distributed to animal health with the authorization of USDA officials in the case of an FMD emergency. This provides authorities a tool they have never had before to deal with a potential FMD outbreak in the US and removes U.S. dependency on foreign laboratories for vaccine development. Because no live virus is ever handled, it reduces risk while complying with U.S. law prohibiting handling live FMD virus outside of Plum Island Animal Disease Center (PIADC). The vaccine proved highly efficacious in the DHS testing and the study trials confirmed it could be safely administered under normal cattle production conditions. In addition, GenVec licensed to Merial the rights to develop and commercialize the proprietary FMD vaccine technology for cattle (GenVec, 2012, June 7; Benchmark, 2012, June 16). Public-private efforts encouraging industry and government to develop strategic partnerships, such as this one, in next-generation molecular vaccines are critical to the development of FMD vaccines and should be expanded to other high-priority FADs if NVS is to meet their objectives (Elsken et al., 2007).

DHS also touted the development of this licensed vaccine for one strain of FMD and indicated several vaccines for other serotypes will soon enter the licensure process. It took seven years for the vaccine to be developed and licensed. PIADC Director Dr. Larry Barrett called it the biggest news in FMD research in more than 50 years and noted it supported a vaccinate-to-live strategy in FMD response. Grubman indicated this development means it is no longer necessary to destroy all exposed animals when only a few animals have been infected. Research continues on the FMD vaccine production process, developing FMD vaccines effective against other strains, and developing vaccines against CSF, ASF, and RVF (DHS, 2012, July 9; DHS, 2012, July 2). While the intent is for the newly developed vaccine to be included in the NVS, a spokesperson of USDA APHIS indicated it had not been determined if it would be included in the NVS or used in an emergency response (Cima, 2012). As of December 2013, according to USDA APHIS officials, this vaccine is not included in the NVS and no contracts have been signed for its manufacture in the case of an FMD emergency in the U.S. Therefore, vaccines would still have to be sent overseas for manufacturing after the strain is matched extending the time vaccines would become available to 2-3 weeks after the disease is identified (personal communication). Continued research is expected to focus on increasing potency, decreasing potential costs, developing vaccines with broader immune response that can protect against multiple serotypes, and addressing remaining challenges related to FMD vaccines (Cima, 2012).

Validation and approval

While research is developing new vaccines and determining when it is most effective to vaccinate, other challenges exist in vaccine development. The validation of vaccines is a bottleneck in the application of new products. Studies are laborious, expensive, and require extensive resources and infrastructure. The development of additional prescreening options will be critical to overall vaccine development. The development of better vaccines and diagnostics depend on utilization of resources from the genomic era and the further investigation of the host-pathogen relationship. The use of new methodologies such as comparative genomics, transcriptomics, preteomics, and metabolomics will be critical to vaccine development rather than dependence on attenuated or killed vaccines (Shirley et al., 2011). One risk associated with use of vaccination is the risk of disease spread as an unintended consequence if any live virus exists in incompletely inactivated vaccine (Kahn et al., 2002).

FMD Vaccination Considerations

"The question of whether or not to use vaccines during an epidemic of foot-and-mouth disease (FMD) has interested veterinary administrators for many decades" (Hutber et al., 2011, p. 18).

Because FMD replicates rapidly, is highly contagious, and affects a number of domestic and wild species, control of the disease is difficult (Paton et al., 2009). In order to control the spread of FMD, three critical measures must be considered: eliminating the source of the infection, interrupting contact between infected and susceptible animals, and decreasing the proportion of susceptible animals. Vaccination is the key to this third control measure, but continues to be the most controversial control measure because of the need for the infected country to quickly regain disease-free status (Leon, 2012).

The likelihood FMD can be stopped through vaccination depends on vaccine efficacy (proportion of vaccinated animals protected), the time between onset of outbreak and beginning of vaccination protocol, the time between vaccination and onset of immunity, and the proportion of susceptible animals vaccinated (Leon, 2012). The control of FMD based solely on vaccination measures is unlikely and other measures need to be implemented simultaneously for control strategies to be effective (Leon, 2012; Paton et al., 2009; Premashthira, 2012).

More than two billion animals are vaccinated annually worldwide, but policy strategies are not uniform amongst countries. Vaccination is used in a very limited manner in many African and southeast Asian nations. Large-scale programs in China, South America, India, and the Middle East use the majority of FMD vaccine (Paton et al., 2009; Premashthira, 2012).

A number of concerns about the use of FMD vaccine have been discussed and debated. The greatest concerns include:

- Risk of virus introduction by the actual vaccine or the vaccination teams,
- Delays in the resurgence of international trade,
- Increased culling due to lack of differentiation between infected and vaccinated animals,
- Increased culling because of vaccinate-to-kill policies,
- High costs of implementation, and
- Shortage of necessary personnel and vaccination equipment (Hagerman et al., 2012).

USDA APHIS identifies specific challenges related to the production and use of FMD vaccines:

- Conventional inactivated FMD vaccines are not allowed to be manufactured in the US,
- Biosafety level (BSL) 3 facilities are required for growth of wild-type virus in cell culture in large volumes to produce vaccine seeds,
- Supplies of non-formulated antigen concentrates are required as formulated vaccines have a short shelf life,
- Newly emerging antigens have to be identified and stockpiled due to antigen drift and new field isolates,
- The antigen in an outbreak must be identified for vaccine to be formulated (causes a one to two week delay),
- Variability exists among serotypes for stability and immunity,

- Vaccines must be highly pure to be able to differentiate vaccinated animals from infected animals,
- Vaccines provide only serotype-specific protection,
- Onset of immunity is not immediate,
- Duration of immunity will vary by species and vaccine, and
- Diagnostic testing is required to differentiate vaccinated animals (APHIS, 2012c).

If emergency vaccination is used as a response to FMD, it should be ceased as soon as practical and no more vaccinations made more than 28 days after the last case of FMD is recognized (APHIS, 2012c).

Virus variants

The FMD virus is present in seven serotypes – O, A, C, SAT (South African Territories) 1-3, and Asia I – each with immunologically distinct properties (Premashthira, 2012; Paton et al., 2009). FMD viruses evolve quickly due to quasispecies dynamics, large virus population size, and high replication rates resulting in intraserotypic subtypes. Current serotypes are region specific and different regions require tailored vaccines for vaccination to be effective. Most of the serotypes follow a natural regional distribution and progression with the most diversity in Africa where there is the least incentive to tailor vaccines. Interestingly, the newest serotype FMD virus variants have been identified in countries of the Middle East, including Iran, and had not previously appeared outside the region (Paton et al., 2009).

One of the most obvious challenges related to use of vaccines in an FMD outbreak is the serotyping and matching of a vaccine to the challenge strain (Hutber et al., 2011). The serotypes have indistinguishable clinical signs but distinct immunological responses. Vaccination or infection with one serotype does not confer immunity against another, and there are a large and indeterminate number of subtypes and variants. The continuous monitoring of new strains to keep up with needed efficacy of actual vaccine formulations is necessary for vaccination to be an effective policy option (Leon, 2012). As Leon (2012) states, "extensive genetic heterogeneity is considered one of the major obstacles for control of FMD by vaccination" (p. 37).

The lack of cross-protection between serotypes and the incomplete protection with some subtypes influences the efficacy of vaccination. These challenges are exacerbated by the emergence of new variants. In an FMD outbreak, the first step is to determine the virus serotype and implement the vaccine-matching assays to identify a vaccine strain (Leon, 2012).

If an FMD vaccine matches the type and subtype, it will prevent against clinical signs but not necessarily FMD infection (APHIS, 2007) and occult transmission can continue. The control of FMD must be seen as bigger than any one nation as long as susceptible species are traded across borders. Regional efforts have been used in South America, Southeast Asia, and Europe (Paton et al., 2009).

Conventional versus emergency vaccination

It is necessary to make a distinction between conventional and emergency FMD vaccines (Leon, 2012). Emergency vaccines reduce the amount of virus shed by the vaccinated animals and protect against clinical disease signs. If used, it may slow disease spread, reduce outbreak size, and result in speedier disease control. Japan and Brazil are examples of countries utilizing an emergency vaccination protocol (Hagerman et al., 2012). Emergency vaccination may be designated as ring vaccination in that animals are vaccinated within a ring surrounding the outbreak, focused on specially designated high-risk animal groups, or limited to a certain region or area (Hagerman et al., 2012).

FMD vaccination has been used in a number of countries over the last century as a means of disease control, but its use is influenced by the developmental stage of the country and whether it is an importer or exporter. For large developed countries, vaccination has tended to be used in emergency cases while in developing countries is it used as a prophylactic measure (Paton et al., 2009).

Immunity

Inadequate immune response to vaccine is directly influenced by antigenic match of vaccine to virus and timing of vaccine relative to exposure (Kahn et al., 2002). The use of vaccination against FMD has had fairly positive but somewhat inconsistent immunity results. FMD vaccine can help control disease transmission as well as prevent clinical disease. It is not likely to be effective if animals have not had enough time to develop immunity between vaccination and disease exposure. Vaccination against FMD is limited by the fact vaccines provide only serotype-specific protection which is dependent on the similarities between vaccine and the field strain as well as vaccine potency (APHIS, 2012c).

Most vaccines will not completely prevent infection because they are based on the development of an immune response often taking 10 days or more for maximum efficacy (DeHaven, 2005). When a herd is vaccinated, it is typical for some animals to fail to develop immunity. If those animals get exposed and infected, it is possible they could excrete large enough amounts of virus they could overcome the immunity of other animals and become infected as well (Kahn et al., 2002). It is even possible for a strong FMD challenge to infect a vaccinated herd with high levels of herd immunity (Hutber et al., 2006) suggesting vaccination efforts may prove to be completely ineffective. Booster vaccines can be used to extend immunity past the typical duration of protection, but it requires additional resources (Kahn et al., 2002).

A number of questions exist regarding the time necessary for the onset of immunity with FMD vaccines. APHIS notes immunity in cattle is not immediate and may not be in full effect for two to three weeks although a decrease in viral shedding and clinical signs may occur within four days (APHIS, 2012c). Cattle have shown to be protected in as soon as four or five days in some studies with high potency vaccines, but in other studies, protection at 10 days was still partial with full protection not occurring for three weeks (NAHEMS, 2011d). With cattle and sheep, even if onset of immunity against FMD occurs in three to four days with a high potency vaccine, at least 10 days is required for clinical protection. Similar, inconclusive results have been seen in swine and goats (NAHEMS, 2011d). APHIS indicated swine may not be completely protected for three to four weeks. Leon (2012) estimates full protection ranges from seven days to three weeks for swine (Leon, 2012). Subsequent infection in all species is also possible because no vaccine available provides sterilizing immunity (APHIS, 2012c).

Efficacy

High potency FMD emergency vaccines have an efficacy (proportion of vaccinated animals protected) of 81-98% with a critical inter-vaccinal period of 2.5 months, after which vaccinal efficacy declines and herds become susceptible to disease. This knowledge makes it more possible to accurately predict the impact of vaccination in biomodels (Hutber et al., 2011).

Disease transmission

One of the factors making it possible for FMD to be controlled without mass depopulation is related to the speed of disease transmission. It is transmitted amongst cattle at about half of the speed it was traditionally thought and not immediately infectious when clinical signs are first evident. These factors make vaccination more suitable and mass culling less necessary (Charleston et al., 2011).

In 2011, Charleston et al. investigated transmission rates of FMD in cattle. They found the mean infectious period to be 1.7 days and found animals were not infectious until half a day after clinical symptoms appear (This finding is not consistent across species). These results led the authors to conclude the need for preemptive culling of at-risk animals is likely overestimated and the need for better surveillance and preclinical diagnosis tools is critical. Being able to identify FMD 24 hr earlier would significantly enhance response capabilities while reducing the number of animals needing to be depopulated. Researchers further noted development of prophylaxis or antivirals for use on at-risk animals have the potential to be a more effective tool in preventing transmission. These findings, while specific to FMD, could be similar for other animal disease outbreaks (Charleston et al., 2011; Strak, 2011, May 6).

The goal of emergency vaccination is to reduce virus reproduction, incidence of clinical infection, and limit disease spread. Emergency vaccination helps protect cattle, sheep, and hogs from FMD clinical disease and may reduce viral transmission. The virus can be excreted through lesions, so reducing clinical signs and preventing lesions can decrease shedding (Halasa, Boklund, Cox, & Enoe, 2011; Parida, 2009).

In addition, vaccinated cattle infected with FMD can serve as asymptomatic carriers of the FMD virus. While cattle are protected by emergency vaccination, they are more likely to serve as carriers than swine or sheep. Thus, the virus can be hidden and transmitted for a long time period, which could lead to an extension of trade restrictions and increase in economic impact. While likely not a popular decision with the public, the depopulation of vaccinated animals resolves this dilemma. Otherwise, strict surveillance and screening is necessary over a long period of time (Halasa et al., 2011; Parida, 2009).

Species variability

Different species result in different considerations when vaccination is an alternative. Cattle are the most susceptible to disease spread by aerosol or close animal contact and are the most frequently vaccinated under prophylaxis or emergency vaccination. Vaccinated cattle are more likely than other species to produce significant numbers of occult infected and persistent sub-clinically infected animals. When challenged with FMD, up to 47% of herds receiving regular vaccination can produce subclinical disease. Pigs excrete the highest levels of FMD virus, but do not produce subclinical disease. Infected pigs provide the greatest threat to other species (Hutber et al., 2011). It is almost impossible to completely protect pigs with vaccination if they have direct contact with clinically infected animals (Kahn et al., 2002). Therefore, for disease-free regions with multiple species, culling of potentially infected pigs may be the most effective strategy. This policy approach may not be the best alternative when the majority of livestock are swine and other livestock are not at risk from infection, because pig-to-pig transmission is less effective via aerosol (Hutber et al., 2011). In these cases, vaccination can be used to decrease viral excretions in emergency situations. Sheep excrete a lower level of virus and intraspecies transmission is slow and self-limiting. These low transmission rates allow for more traditional disease surveillance and may not require vaccination as rapidly as with other species (Hutber et al., 2011).

Accessibility of vaccines

Few vaccines are available for many of the FADs of greatest concern to the US including FMD. While USDA ARS is developing some new vaccines, it is improbable, if not impossible, to develop vaccines for the vast number of strains and subtypes for each disease. In addition, a terrorist could introduce a new genetically engineered strain (GAO, 2005).

The majority of FMD vaccines stored in the US is concentrated and not stored in a ready-to-use state. To be activated, they must be sent to the UK so the FMD additive can be added where the process of activation can take up to three weeks. Activated vaccines have a shelf-life of only one or two years, and their creation is expensive. This procedure does not meet the objective dictated by HSPD-9 calling for vaccines to be deployed in less than 24 hr – clearly creating a policy dilemma and contradictory priorities. If animals cannot be vaccinated, the USDA has no choice but to slaughter animals for disease control. This could lead to greater numbers of animals being destroyed than necessary and greater economic losses (GAO, 2005).

The recent developments in FMD vaccines allowed to be manufactured in the US has the potential to addresses these concerns to a degree, but new vaccines are not available for all serotypes and the newly developed vaccine is not under contract for production by USDA.

Time for implementation

One of the challenges faced by decision makers in the case of FMD is determining when to use vaccination. Vaccines must be specific to the strain of disease and, usually, have a shelf-life of 18 months or less. With FMD, having stocks available may be prudent, but it is not considered cost effective to have a continuous supply of each strain of each disease. The existing decision trees are complex and may take too long for a decision. But, a more rapid decision-making process will still not reduce the time to select, deploy, equip, and direct vaccination. Days are needed before a full-scale vaccination program could be in place, and procedures based on speed could be detrimental. Recent and future development of marker vaccines to be used on at-risk livestock allowing differentiation between infected and vaccinated animals will play a strategic role in disease control and eradication efforts and allow for more flexibility in animal movement (DeHaven, 2005).

The administration of vaccines and subsequent immunological response leading to protective immunity will take several days, in addition to time needed to serotype the strain and match a vaccine. This compares to culling which in some cases could be completed within 48 hr (Hutber et al., 2011).

Surveillance needs

For protocols to be implemented in a timely manner, strong surveillance systems need to be in place for disease control with nonvaccinated and vaccinated populations. Because virus excretion can begin up to four days before the onset of clinical signs in some species, the typical two-week surveillance period based on the FMD incubation period of 24 hr-14 days needs to be extended to 21 days to deal with the possibility of emerging subclinical disease (Hutber et al., 2011; Leon, 2012). Disease incidence in nonvaccinated populations can be as high as 100% and the number of expected secondary cases is dependent on the infectiousness of agent, contact rate, and duration of the infectious period. Additional variable factors include management differences, stocking rates, movements within herd, and nature of physical facilities (Leon, 2012). Surveillance of clinical signs remains critical when dealing with vaccinated populations as well because transmission can be occult and may have preceded diagnosis (Hutber et al., 2011).

Trade restrictions

"For a country with a strong export orientation and pronounced net exporting position, any FMD outbreak, no matter the control strategy selected, causes severe damage to the industry" (Junker et al., 2009, p. 56).

The use of vaccination extends the export bans implemented at the direction of international trade officials. While serological samples may distinguish vaccinated carrier animals from non-infected vaccinated animals, current tests for most FMD vaccines do not reach full diagnostic sensitivity and could leave some carrier animals undetected (Hutber et al., 2011). Being able to differentiate vaccinated from naturally infected animals is critical, and serological tests must be reliable (Kahn et al., 2002). The export bans will reduce potential disease transmission outside of the infected country or region when surveillance fails to identify carrier animals. These export bans become more critical when vaccination is used because the risk of animals transmitting disease sub-clinically increases. It also creates additional challenges to fulfill the need for repeated surveillance and vaccination in extensive epidemics. In these cases, the export ban creates a final "line of defense" against disease spread (Hutber et al., 2011, p. 21). Limited information exists about the reaction of export markets to emergency vaccination (Boklund, Halasa, Christiansen, & Enoe, 2013). Success in convincing trading partners to accept products from vaccinated animals would positively impact the economic effects of the trade restriction due to an animal disease outbreak (Backer, Bergevoet, et al., 2009).

Environmental and waste implications

FMD control strategies excluding vaccination may cause problems other than those associated with trade status. The traditional stamping-out approach in the absence of vaccination will likely result in a greater number of animals being destroyed leading to a waste of animal protein and serious environmental concerns related to disposal (Parent et al., 2011). This same dilemma applies to a vaccinate-to-kill strategy and adds the risk of the vaccine being dispersed in environment through disposed carcasses.

Welfare considerations

While vaccination is typically seen as more welfare friendly than mass depopulation, there are a number of welfare issues to consider in a vaccination strategy. The public may be more negative about a vaccinate-to-kill approach than a stamping-out approach and may not understand why vaccinated animals should be destroyed. Even in a vaccination-to-live approach, movement restrictions keeping feed and supplies from reaching live animals may lead to welfare problems and potential welfare slaughter. Animals that cannot be moved to slaughter may reach weights exceeding typical production weights resulting in welfare concerns. If vaccination results in more extensive trade restrictions, the increase in domestic supply could reduce prices to the point where farmers and ranchers are not receiving the revenue to adequately care for their animals or are destroying animals rather than taking a greater financial loss. As noted by Horst et al. (1999), it is even possible the government could engage in a buyout program to prevent severe domestic market disruptions resulting in destruction of healthy animals and additional welfare concerns.

Public acceptance of food products

Meat and other products from livestock with FMD are safe for public consumption. European animal health authorities have modified EU regulations and propose modification of international recommendations to allow vaccinated cattle to be kept alive and allow products to enter the food chain and international markets. If this change occurred, it would be possible to mitigate economic losses associated with use of vaccine as long as a country is free of infection and there is a demand for the product. It is possible that FMD vaccines could cause lesions lowering the carcass value and images of which could influence consumer demand (Kahn et al., 2002).

Limited information exists about the willingness of consumers to eat meat and products from vaccinated animals. Food industry leadership is also concerned about potential labeling of vaccinated versus non-vaccinated products. EU regulations would differentiate vaccinated products and require separate processing. While food manufacturers and retailers indicate they back vaccination, support will be soft if the public is not confident in the safety of vaccinated products (Scudamore, 2007). While vaccination is a normal animal husbandry practice, the general public is likely unaware of these practices and may be concerned if emergency vaccination is implemented. There has been a dramatic increase in the general public’s concern over food safety and their demand for food products to be pure without additives or residues. Consumers know little about animal vaccination, especially in the case of an emergency. The public has expressed its disapproval over mass depopulation in an animal emergency which has helped lead to more discussion of vaccination. But, significant gaps exist between scientific reality, public perception, and consumers' confidence in the safety of food products from FAD vaccinated animals. The perceived societal acceptance of vaccination will likely have an impact on policymakers when faced with the decision to vaccinate (Scudamore, 2007).

Retailers in the UK were unwilling to market animal products from vaccinated animals because they were worried about consumer acceptance. Regardless of conflicting information provided by the British Food Standards Agency that meat from FMD vaccinated animals presents no health risks, 45% of U.K. consumers believe it is too risky to eat meat products from animals vaccinated for FMD (Kahn et al., 2002). On the other hand, the public could see the destruction of vaccinated animals as abhorrent and a waste of valuable protein. This was the case found by some Dutch officials in dealing with animal destruction after the Netherlands outbreak. The Federation of Veterinarians of Europe agreed and do not support killing of healthy animals for disease control where vaccination is seen as a possible alternative (Kahn et al., 2002).

A consumer survey in the UK during the 2001 outbreak expressed concern about food safety, but post-outbreak surveys indicated consumers would have been willing to consume milk and meat products from vaccinated animals as an alternative to mass culling. Those interviewed during the outbreak were concerned about the health impact of eating vaccinated product, or simply preferred not to eat it even if they thought it was safe. Efforts to reassure customers that vaccinated products are safe should be a key component in a vaccinate-to-live strategy. While some consumers have indicated labeling should be required, segmentation of the products by labeling is not recommended. Vaccination plans should be in place and shared with all stakeholders before an outbreak, and conditions should be clear regarding when it will be implemented (NAHEMS, 2011d).

In a 2012 survey of consumers, most respondents saw vaccination as a routine, necessary practice protecting humans and animals, but some did express concern vaccine would be passed to people who ate or drank product from vaccinated animals. When more information was provided, confidence in the safety of the product increased (Ahlem, 2013). In an EU FMD outbreak with accompanying trade restrictions, most countries will have more meat products than can be consumed by their own citizens, meaning they will need to export meat products to other countries where meat production does not meet demand. The potential negative perception of consumers about vaccinated meat products will create an additional obstacle and likely cause a decrease in product value (Elbers & Knuttson, 2013). If products from vaccinated animals enter the food chain, are not labeled, and consumers are afraid to eat them, it could further decrease demand for meat or milk products and compound the negative economic impact.

An effective communications strategy implemented by government and industry to encourage the public to continue to purchase and consume products from vaccinated animals will be critical. The existence of an educated public will reduce the potential economic impacts of a disease outbreak (Swallow, 2012). The opinions of the public related to mass depopulation and animal welfare and their willingness to consume meat and milk products from vaccinated animals will influence their reaction to vaccination policies. In general, the public, consumers, and producers, have reacted negatively to the mass culling of seemingly healthy animals (e.g. UK, Netherlands, and Uruguay). Not all farmers and ranchers may agree, because large exporters may have a different opinion than small farmers about the use of vaccination. While no human health risks have been associated with eating products from FMD vaccinated animals, the public tends to be concerned about food safety and the purity of their products and may not accept such products (NAHEMS, 2011d).

Decision Criteria for an FAD Outbreak

Because emergency vaccination may be used in an FAD outbreak, a decision to modify the stamping-out approach should be based on descriptive, analytic, and evaluative epidemiological principles of response (APHIS, 2012a). "It is not possible to delineate *a priori* the specific factors that might signal the need to modify the response to a FAD outbreak" (APHIS, 2012a, p. 2-22). The decision to vaccinate will be made by the incident commander, the state animal health officials, and the USDA APHIS VS administrator. The FAD response goal if vaccination is used calls for the rapid request of resources if the decision is made to vaccinate and full engagement in a public awareness campaign explaining the use of vaccination (APHIS, 2012a).

Williams (2007) identifies a number of factors to consider when deciding to include vaccination in an emergency disease response: rate of disease transmission, ability to differentiate between infected and vaccinated animals, performance of vaccine in the field, population density, vaccine availability, trade requirements, high-value animals and endangered species, public health, resource needs, costs of vaccination and surveillance, food security, and exit strategy from vaccination (Williams, 2007).

The NAHEMS guidelines provide a policy for strategic vaccination. If an effective vaccine exists for the identified disease and a known supplier is available, the USDA chief veterinary officer (CVO) will order vaccine. Before the vaccine arrives, the CVO will use a vaccine decision tree matrix to determine if the vaccine will be utilized. If use of vaccination is approved to help prevent disease spread, a vaccination plan will be used to direct the appropriate use and distribution of vaccines. Vaccination may be a part of the stamping-out policy. Emergency vaccination may be used to create a firebreak around the infected zone. The decision to use vaccine will be influenced by vaccine availability, availability of human resources, socio-political factors, and economic impact. Vaccinated animals must be identified with a specific, tamperproof permanent mark, so they could be eventually culled to allow the country to regain disease-free status. Emergency vaccination of rare, endangered, or valuable animals may also be considered (NAHEMS, 2005b).

USDA APHIS identifies multiple factors to consider when determining if emergency vaccination should be used in an FAD emergency situation. Table 4-1 outlines the factors noted by APHIS as adapted from the EU Council Directive 2003/85/EC.

As noted in the previous section, the decision to use vaccination for FMD is highly complex. Table 4.2 outlines the factors recognized by USDA APHIS that deserve consideration when determining the appropriate response strategy for FMD.

Table 4-1 *Factors Determining Viability of Emergency Vaccination*

	Vaccination Decision Points	
	For vaccination	Against vaccination
Suitable vaccine for FAD agent	Available	Not available
Public health assessment	Supports vaccination	Does not support vaccination
Population density of susceptible animals at high risk of becoming infected	High	Low
Movement of infected animals, products, or fomites out of control area	Evidence of widespread movement	No evidence of widespread movement
Origin of outbreak	Unknown	Known
Spread of outbreak	Rapid	Slow
Distribution of outbreak	Widespread	Limited or restricted
Public reaction to total stamping out (may vary by species, scale, and disease)	Strong opposition	Neutral reaction or weak opposition
Domestic stakeholders' acceptance of regionalization with vaccine zones	Yes	No
Third-country acceptance of regionalization with vaccination zones	Known	Unknown
Assessments and economic analysis of completing control strategies	It is likely that a control strategy *without* emergency vaccination will lead to significantly higher economic losses or longer duration of the outbreak	It is likely that a control strategy *with* emergency vaccination will lead to significantly higher economic losses or longer duration of the outbreak

Note. Adapted from APHIS (2012a, p. 2-23).

Table 4-2 *Factors Influencing a Response Strategy or Strategies for U.S. FMD outbreak*

Factor or criterion supporting the response strategy	Strategy			
	Stamping out	Stamping out modified with emergency vaccination-to-slaughter	Stamping out modified with emergency vaccination-to-live	Emergency vaccination-to-live without stamping out
Suitable vaccine for FMD outbreak	Not available/feasible	Available	Available	Available
Resources for stamping out (such as disposal)	Adequate	Adequate	Limited	Limited
Resources for vaccination (such as diagnostic testing, tracing efforts, and permitting activities)	Limited	Adequate	Adequate	Adequate
Population density of susceptible animals at high risk of becoming infected	Low	High	High	High
Population density of virus amplifying animals	Low	Moderate	High	High
Movement of infected animals, products, or fomites out of control area	No evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement
Origin of outbreak	Known	Unknown	Unknown	Unknown
Location of	Isolated premises	Livestock	Livestock	Livestock

Factor or criterion supporting the response strategy	Strategy			
	Stamping out	Stamping out modified with emergency vaccination-to-slaughter	Stamping out modified with emergency vaccination-to-live	Emergency vaccination-to-live without stamping out
initial outbreak		producing area	producing area	producing area
Spread of outbreak	Slow	Rapid	Rapid	Rapid
Distribution of outbreak	Limited or restricted	Widespread	Widespread	Widespread
Risk of infection in valuable, rare, endangered, or high-value genetic livestock	High	High	Moderate	Low
Likelihood that FMD could become prevalent in feral swine, deer, or other wildlife	High	High	Moderate	Low
Public acceptance of stamping-out strategy	Neutral reaction or weak opposition	Weak opposition	Strong opposition	Strong opposition
Surveillance, diagnostic, and laboratory resources for serosurveillance after vaccination	Limited	Limited	Available	Available
Domestic stakeholders' acceptance of regionalization with vaccination-to-live or vaccination-to-slaughter	No	Yes	Yes	Yes

Factor or criterion supporting the response strategy	Strategy			
	Stamping out	Stamping out modified with emergency vaccination-to-slaughter	Stamping out modified with emergency vaccination-to-live	Emergency vaccination-to-live without stamping out
Third-country acceptance of regionalization with vaccination-to-slaughter	N/A	Accepted	N/A	N/A
Third-country acceptance of regionalization with vaccination-to-live	N/A	Not accepted	Accepted	Accepted
Assessments and economic analysis of competing control strategies (particularly for producers)	It is likely that a control strategy without stamping out will lead to significantly higher economic losses or longer duration of outbreak.	It is likely that a control strategy without stamping out modified with emergency vaccination-to-slaughter will lead to significantly higher economic losses or longer duration of the outbreak.	It is likely that a control strategy without stamping out modified with emergency vaccination-to-live will lead to significantly higher economic losses or longer duration of the outbreak.	It is likely that a control strategy without emergency vaccination-to-live will lead to significantly higher economic losses or longer duration of the outbreak.

Note. Adapted from APHIS (2012c, p. 4-16).

In the case of highly pathogenic avian influenza (HPAI), the primary control and eradication strategy in the US is mass depopulation. If stamping out cannot keep up with disease spread or if other factors come into consideration, emergency vaccination may be used. Such a decision will be based on the outbreak's prevailing epidemiological circumstances, because it is not possible to delineate before an outbreak the specific factors resulting in a decision to vaccinate. While stamping out remains the preferred option, emergency vaccination-to-live and emergency vaccination-to-kill strategies are options. Elements to consider include the probability that the disease can be contained, proximity of disease to high-value genetic birds, poultry density in the area, risk of introduction to neighboring countries, availability of human and physical resources, socio-political factors, consumer confidence in poultry industry, potential of zoonotic infection, impact on international trade, economic consequences, disease spread to waterfowl, wild birds, backyard flocks, live bird markets, and valuable, rare, or endangered nondomestic species. Figure 4-1 illustrates a decision tree for emergency vaccination in domestic poultry (APHIS, 2012d).

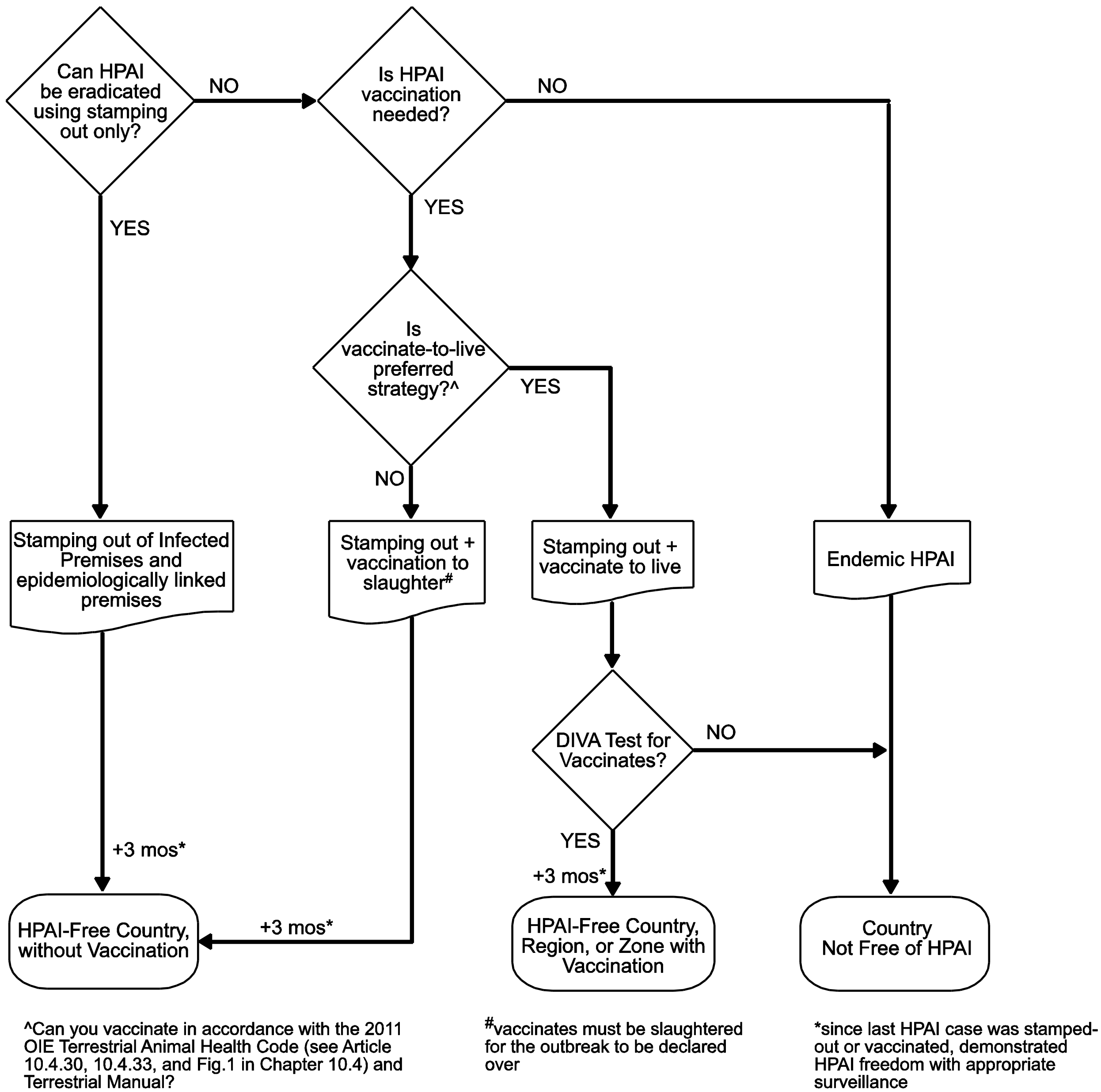

Figure 4-1 Decision Tree for Emergency Vaccination in Domestic Poultry (APHIS, 2012d).

For a vaccination program to be successful the FAO identifies *essential prerequisites* to include political and community support, commitment of stakeholders, planning based on epidemiological evidence, availability of safe and potent vaccines, accurate knowledge about serotypes and strains, availability of cold chain and necessary storage, accessibility to livestock, well-trained and sufficient veterinary support, and sufficient disease surveillance systems to monitor and detect potential infections (Geering & Lubroth, 2002).

Current FMD Policies

There are four principles related to the control and eradication of FMD:

1. Reducing access of the virus to susceptible animals (accomplished through quarantines, import controls, movement controls, biosecurity practices, etc.);
2. Eliminating contact between infected and susceptible animals (accomplished through zoning, quarantine, and livestock movement controls, etc.);
3. Reducing the number of infected and potentially infected animals (accomplished through depopulation and disposal); and
4. Decreasing the number of susceptible, at-risk animals (accomplished through depopulation or vaccination) (Geering & Lubroth, 2002).

World Organization for Animal Health

Sixty-seven of 178 OIE countries are recognized as FMD free, and 65 of these do not practice vaccination. Eleven countries have disease-free zones with or without vaccination, and 96 are endemic or have never proved absence of FMD. In addition, five countries previously FMD free are dealing with reemergence (Leon, 2012; Barnett et al., 2013).

In FMD-free countries, FMD control strategies include emergency vaccination, movement restrictions, biosecurity protocols, and culling of infected and exposed animals. In most cases, vaccinate-to-kill is often not considered as ethical or as economical as vaccinate-to-slaughter or vaccinate-to-live (Parent et al., 2011). FMD vaccination of susceptible animals is a common and established strategy in countries and regions where FMD is endemic (Kahn et al., 2002).

The OIE establishes guidelines for international trade of animals and food products between countries with different zoosanitary status. Countries that are FMD-free with vaccination and those FMD-free without vaccination are recognized separately by the OIE. Countries FMD-free without vaccination have the advantage because they can export live animals and animal products to all other countries, regardless of the importing country's status. For the UK, for example, FMD-free status is worth more than $1.75 billion annually (Kahn et al., 2002). International policy has historically encouraged exporting countries to rapidly slaughter and dispose of all animals exposed or vaccinated against FMD (Kahn et al., 2002).

The OIE code relative to FMD has changed over the years.

- 1971 – FMD was added to the OIE code
    - FMD-free status applied to vaccinating and non-vaccinating countries
    - Systematic vaccination countries had to be disease free for 2 years and nonvaccinating countries for 3 years to receive disease-free status
    - Recovery waiting period after a disease occurrence was an additional 6 months for all countries
- 1992 – Vaccination for FMD was banned in Europe due to poor performance of vaccination in South American outbreaks
    - OIE declared two different statuses – FMD-free country not practicing vaccination (12 months to achieve) and FMD-free country practicing vaccination (2 years to achieve)
    - FMD-free status with vaccination was deemed inferior and the waiting period was extended 12 months after vaccination ended to become FMD-free without vaccination (totaling 3 years)
    - Recovery waiting period remained an additional 6 months for non-vaccinating countries and was extended to 12 months for vaccinating countries
- 1998 – OIE statuses changed to FMD-free country where vaccination is practiced and FMD-free country where vaccination is not practiced
    - Changed the recovery waiting period from an additional 6 months to 3 months for a non-vaccinating country that used emergency vaccination-to-cull in an outbreak (3 months after last vaccinated animal was destroyed in addition to initial 12 months)
    - Time frames did not change if vaccinated animals were not destroyed (2 years)
- 2002 – Pressure to make vaccination more acceptable and introduction of new DIVA diagnostic tests led to changes in OIE policy

    - Reduced the 12-month waiting period to 6 months to earn FMD-free status where vaccination is not practiced when emergency vaccination is used without depopulating vaccinates
    - Recovery period for FMD-free country where vaccination is practiced was reduced to 6 months with DIVA surveillance (totaling 18 months)
    - Introduced concept of freedom from infection versus freedom from disease due to potential subclinical infections (Geale, Barnett, Clarke, Davis, & Kasari, 2013; Kitching, 2002).

The OIE can currently designate countries as:

- FMD-free country where vaccination is practiced,
- FMD-free country where vaccination is not practiced,
- FMD-free zone (geographically defined region of a country or territory) where vaccination is practiced,
- FMD-free zone where vaccination is not practiced,
- FMD-free compartment (an animal subpopulation contained in one or more establishments under a common biosecurity management system), and
- FMD-infected country or zone (APHIS, 2012a; OIE, 2012a).

The 2004 OIE International Conference on the Control of Infectious Animal Diseases by Vaccination participants determined, based on ethical, ecological, and economic reasons, mass depopulation as a primary means of FMD eradication was not acceptable and vaccination policies needed to be developed as alternatives (NAHEMS, 2011d; Schudel & Lombard, 2007).

Previous OIE policies indicated a country applying rigorous surveillance and using stamping out of all infected herds could earn FMD-free status in 3 months. If a country used vaccination to help control disease spread, the period before FMD-free status granted was at least 12 months unless all vaccinated animals were depopulated. This period was deemed necessary because of the risk of ongoing viral circulation and the possible existence of undetected carrier animals (Paton et al., 2009).

In Article 8.5.9, the current OIE Terrestrial Animal Health Code indicates FMD-free status can be reinstated 3 months after the last known disease case has been depopulated when stamping out without vaccination combined with serological surveillance has been applied. Under vaccinate-to-live with stamping out, the OIE will consider an application to reinstate

FMD-free status 6 months after the final case or last vaccination whichever was last. The country must also provide serological surveillance evidence that the disease is absent from vaccinated herds allowed to live. This policy assumes marker vaccines were used and vaccinated animals can be differentiated from naturally infected animals (Paton et al., 2009; NAHEMS, 2011d; Leon, 2012). If vaccinate-to-kill is used, FMD-free status is regained 3 months after the last vaccinated animal is destroyed (NAHEMS, 2011d; Leon, 2012).

To promote vaccination, the OIE agreed to a reduction in the holding period time frame before freedom from disease can be declared if vaccination was used (McLeod & Rushton, 2007). If the US vaccinates-to-live, it will extend the waiting period for at least 3 months. The benefits of vaccinating must outweigh this delay in FMD-free status.

If no stamping out is included in the policy response, the OIE will consider reinstating FMD-free status after 12 months have passed with no outbreak, no evidence of infection, no vaccination, and no vaccinated animal has been introduced into the country or region (OIE, 2012; Leon, 2012). If emergency vaccination-to-live and surveillance with no stamping out is applied, the reinstatement of FMD-free status could likely take 18 months (Miller, 2011). For countries where routine vaccination is practiced, it takes 6 months to regain free status when stamping out, emergency vaccination, and continued surveillance occurs. If they do not apply a stamping-out approach, it takes at least 18 months to regain status (Leon, 2012). If significant long term emergency vaccination is needed, it is also possible a country could obtain FMD-freedom with vaccination as an intermediary step before moving back into an FMD-free status without vaccination. This would extend the OIE restrictions to at least two full years and FMD-freedom without vaccination could not be regained until 12 months after the last vaccination is administered (APHIS, 2013b).

History indicates it will take longer than the official waiting period for the OIE ban to be lifted because a lag exists for administrative and bureaucratic processes to be completed. The infected country has to complete a dossier explaining control measures, surveillance activities, and results. This information has to be evaluated and approved by various OIE commissions which extends the recovery period (Junker et al., 2009). The OIE Scientific Committee must meet and make a recommendation which is then forward resolution for consideration and vote by the OIE World Assembly (OIE, 2012). The OIE will consider regionalization of trade restrictions within a country so trade limits only affect the infected region and other regions of the country can continue to trade without restriction (Paton et al., 2009). If zoning is accepted, the area outside of the containment zone would return to its previous status in 28 days. While the OIE recognizes regionalization based on animal disease status and legal or geographic borders and it is becoming more accepted as a trade concept, trading partners do not always accept such delineation for trade purposes (Junker et al., 2009). As an example, U.S. regulations (US 9 CFR part 94) only recognize disease-free status on a nationwide basis and would not allow for recognition of a regional disease-free approach for trading purposes (Swallow, 2012).

On June 27, 2012, the OIE and the FAO unveiled a new global strategy for controlling FMD. Officials noted animal diseases do not have boundaries and a global response is required for effective disease control. Lost trade opportunities, impact on human development, and the ability of the disease to affect farmers in developing countries with hunger and economic ruin were cited as reasons for global action. The Global Strategy is focused on developing veterinary services and systems with an emphasis on surveillance and long-term disease eradication (OIE, 2012, June 27).

Potential for change

The lengthening of trade restrictions placed on a country choosing vaccinate-to-live as an FAD response policy creates a disincentive to vaccination and works in contradiction to the OIE's encouragement of vaccination over mass depopulation. For a country designated as FMD free where vaccination is not practiced, a more rapid return to trade and minimization of economic losses requires culling despite public and ethical concerns. It took Korea 12 months to regain FMD-free status after their second round of vaccination was implemented during the 2000 FMD outbreak (Barnett et al., 2013). There is great value in achieving a premium export market. It is estimated that meat products from OIE designated FMD-free countries realize price premiums of 10-50% in world markets (Rich & Winter-Nelson, 2007; Schroeder, Pendell, Sanderson, & McReynolds, 2013). Before 1997, Uruguay spent between $7-9 million annually to vaccinate. Once free of FMD, it gained a U.S. beef market worth nearly $20 million a year (McLeod & Rushton, 2007). It is important to note that this study like many of the others discussed accounts for economic impacts on producers only and does not account for the potential gains to consumers from lower prices on the domestic market.

Vaccination can help address the social value concerns associated with depopulation, but OIE policies should be more supportive of vaccination policies. Because vaccination is more successful the earlier it is used, policy decisions need to be made simpler and not be contradicted by OIE policies. An internal EU policy already allows trade between EU members post-emergency with vaccination use if clinical and serological surveys confirm the absence of FMD (Barnett et al., 2013).

Barnett et al. (2013) examined the benefits, efficacy, performance in differentiation, and potential use of higher potency and purity emergency vaccines formulated in vaccine banks. They conclude such vaccines reduce FMD virus subclinical circulation and risk of carriers. Recommendations for OIE include the development of formal definitions (time of use and composition) of emergency vaccination and vaccines, broader recognition of DIVA tests, and alignments of waiting periods between vaccinate-to-live and vaccinate-to-die (Barnett et al., 2013). They argue surveillance intensity is much more critical than waiting periods to the risk of spreading FMD and specifically call for the OIE to establish "an acceptable level of statistical certainty for surveillance or target probability of freedom to substantiate the absence of FMDV" (Barnett et al., 2013, p. 15).

The current waiting periods do not reflect specific scientific rationale; rather, they are based on historical precedence and considered expert opinion. Waiting periods should evolve and other risk management tools should be utilized as science and technology advance. OIE policies and individual countries' trade policies should recognize the positive aspects of vaccinate-to-live policies with the intent to no longer incentivize the destruction of healthy, vaccinated animals solely for trade and economic gain (Barnett et al., 2013; Geale et al., 2013). "According to [Netherlands State Secretary and Minister of Agriculture Sharon] Dijksma, there is no scientific evidence to justify delays in the recovery of the disease-free status of countries following their use of certified vaccines" (Moesker, 2013, p. 1).

Additional international trade restrictions

A country vaccinating is never considered equivalent to a country free of FMD without vaccination. Even if the designated post-vaccination period is over and testing shows an absence of the FMD virus, there is no guarantee trading partners will accept imports from a country that has experienced an FMD outbreak. The OIE recovery waiting period is just one trade issue to be realized following an outbreak (Parent et al., 2011; Geale et al., 2013). A country free of FMD may choose not to import from countries having used vaccination regardless of OIE timeframes (McLeod & Rushton, 2007). Importers may choose to ban products (most likely fresh meat products) for an unknown length of time because trading partners' decisions are not based solely on OIE recommendations (Miller, 2013). The US does not currently recognize all of the countries and zones on the OIE FMD-free lists as FMD-free for import purposes (APHIS, 2012c).

In addition, even if trade is allowed, trading partners may choose to discriminate against another country by paying a lower price for commodities derived from vaccinated animals. Trade response and willingness of customers to accept vaccinated products will have a critical influence on economic impact of an FAD outbreak (Geale et al., 2013).

During the HPAI epidemic in Texas in February 2004, more than 44 countries banned poultry imports from the US. While the OIE recognized the outbreak as regional, most trading partners did not. The outbreak was limited to three locations, lasted only three weeks until all birds has been depopulated, and was followed by a 4-week surveillance period. Although no vaccination was used, trading partners did not reopen markets until August 2005. This response indicates trading partners would likely further extend the trade ban beyond the OIE standards regardless of the use of vaccination (Parent et al., 2011).

The 2003 U.S. BSE incident provides an example of the imbalance in trading partners' actions to quickly close markets but be slow to open markets even after trade restrictions have been lifted by the OIE. Trade restrictions can be economically devastating. As an example, from 2004-2007, the economic loss due to trade restrictions on beef was estimated to be nearly $8 billion from lost trade with Japan and $7 billion from trade lost with Korea (International Trade Commission [ITC], 2008).

While many countries opened markets to U.S. beef in 2004, many others did not. In May 2007, based on regulatory changes implemented by USDA FSIS and an improved BSE surveillance program, OIE recognized the US as having a controlled risk for BSE which indicates all trade restrictions should be lifted. Korea partially lifted the ban in 2007 but maintained a ban on bone-in beef cuts until 2008. While Japan opened their markets to U.S. beef in 2006, they only allowed cattle 20 months of age and younger. In both cases, restrictions were more stringent than OIE recommended. A full four years after the BSE case, countries that made up one-half of the beef export market maintained some level of restrictions (ITC, 2008) and China remains closed to U.S. beef. Japan increased the age limit to 30 months in 2013 which has finally helped return beef trade revenues with Japan to pre-2003 levels (Andrews, 2013).

In January of 2013, the chief of the OIE, Bernard Vallat, called on China, Japan, South Africa, Saudi Arabia, and Jordan to open their markets to Brazilian beef after they closed them due to a reported atypical BSE case found in Brazil in 2010. Vallat argued the closure was not justified and that according to OIE standards no restrictions were justified. Brazil threatened retaliation if bans were not lifted (MercoPress, 2013). After the BSE crisis in the EU in 1997, the US closed its import market to EU beef. In November 2013, U.S. officials announced the release of a final rule changing its import regulations to be in line with OIE's risk status protocols, which reopened import markets to EU beef. This change will make the U.S. more in line with international standards set by the OIE. While the stance may not significantly increase imports, it is likely to influence future negotiations with other countries regarding U.S. beef exports. Leaders from the EC applauded the move, although they noted it was late in coming and that the ban was unjustified and did not follow OIE recommendations. Earlier in 2013, the US was declared a negligible risk for BSE by the OIE (Andrews, 2013; MeatPoultry.com, 2013; Driver, 2013).

While these examples are based on BSE and related trade restrictions, the key point to consider is that countries tend to close their borders to imports faster than they open them, and they do not necessarily follow the guidance of the OIE. Relative to an FMD outbreak, the actual length of trade restrictions will likely depend more on each trading partner's individual response and less on the OIE.

In December 2013, the US announced it intended to allow importation of fresh meat from Brazil. Previously, due to concerns over FMD, Brazil could only export pre-cooked meat to the U.S. The decision is based on a risk analysis of the exporting region and evaluation of Brazilian FMD protocols. In order to export, Brazil must certify that no beef originated in an area with FMD until 12 months after the last FMD case has been eradicated (a time frame longer than OIE requirements). USDA APHIS must continue to assess Brazil's FMD mitigation program and publish a final rule before importing can begin (Roybal, 2013).

As another example, if trade partners followed guidelines, an emergency vaccination-to-kill strategy would not extend the trade ban and, if vaccination shortened the duration of the outbreak, it may lessen the impact on trade (Hagerman et al., 2012). However, if they do not follow OIE proposed guidelines, the impact could be far greater economically than otherwise anticipated.

For further illustration, in a comparison done by USDA APHIS, the time required to regain FMD-free status from the OIE was compared to the time required to be granted official U.S. recognition as FMD-free for trade purposes. On average, the US recognizes freedom from FMD 721 days after the last FMD case while the OIE averages 200 days. When vaccination is not used, the average time for the US and the OIE is 372 days and 151 days, respectively, to grant another country FMD-free status. With both the US and OIE, the use of vaccination delays the approval of FMD-free status (APHIS, 2013b). The US policy in regard to FMD freedom might indicate that other countries will likely extend trade bans against the US in the case of an FMD outbreak.

Other countries and regions

European Union

In a directive issued in 2003, the EU called for development of a vaccination protocol with the ability to differentiate vaccinated from infected animals (Paton et al., 2009). According to the EC website section on animal health and welfare, accessed on November 1, 2013, Council Directive 2003/85/EC identifies control measures designed to control and eradicate FMD with the objective to regain disease-free status. The EU strategy is described as committed to eradication of FMD as quickly as possible while minimizing the economic damage. Control strategies are founded on stamping out infected and in-contact herds and regional movement restrictions of susceptible animals and their products. Provisions are also made for the use of emergency vaccination to prevent disease spread using ring vaccination with a radius of 1-3 km around infected herds. However, it is noted this response should only be considered temporary for animals awaiting depopulation when insufficient culling and disposal capacity exists (EC, 2013a; EC, 2013b). Routine vaccination was practiced in the EU until the early 1990s. After completion of a cost-benefit analysis, the EC reversed their vaccination policy in 1991 to one of non-vaccination to increase international trade opportunities and ensure high quality animal health standards, resulting in savings of £1 billion by 2001 (Prempeh, Smith, & Muller, 2001; Burrell & Mangen, 2001).

United Kingdom

While the UK did not use vaccination in 2001, current policy indicates the use of high-potency emergency vaccines on infected and exposed farms is a likely response strategy (Parent et al., 2011). In addition, the UK has updated their stock of vaccines, prepared a vaccination distribution system, developed an automatic national stop-movement order at the first diagnosis of FMD, improved their animal identification and records system, and established protocols on swine feeding and sheep transportation (Paton et al., 2009).

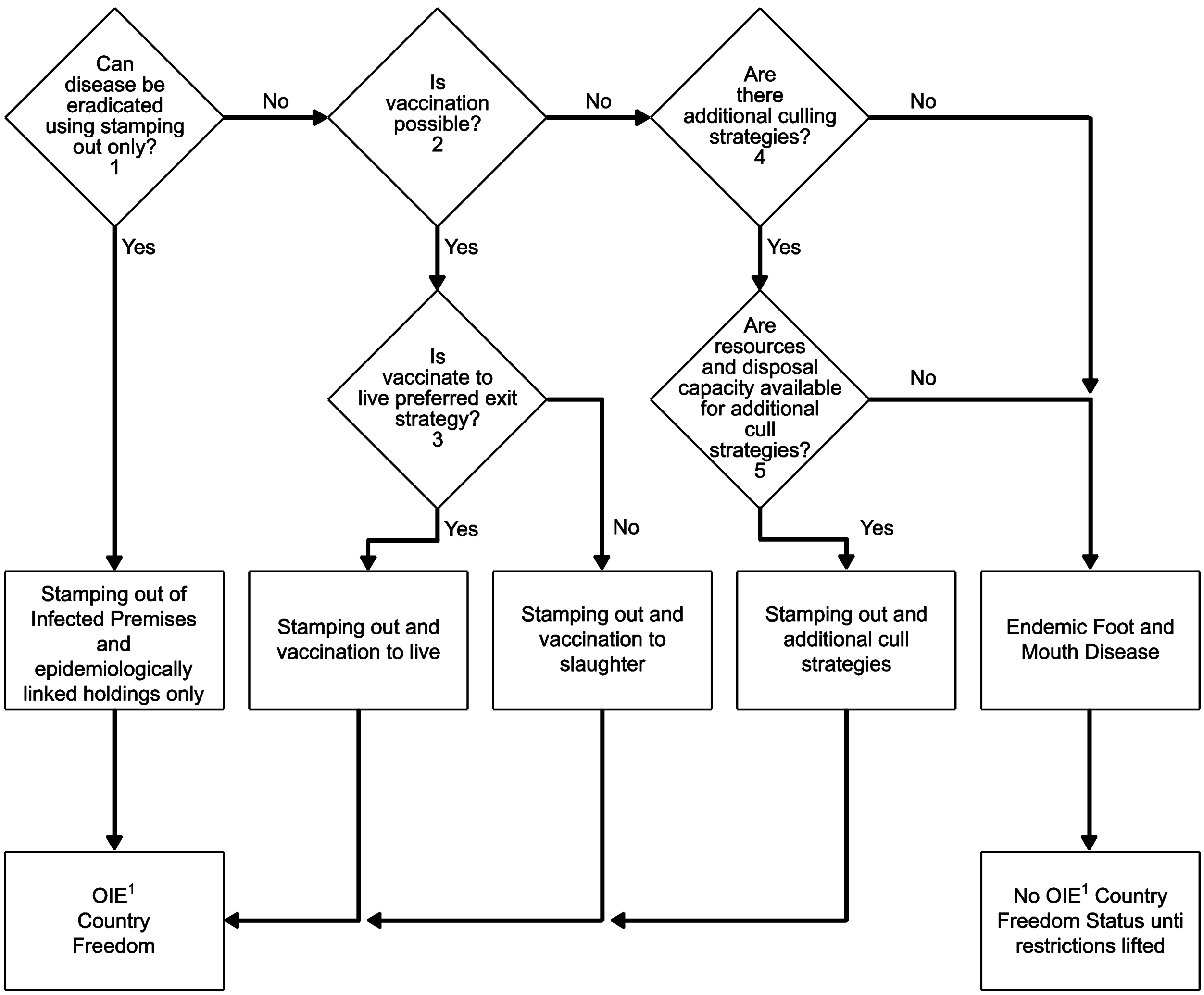

Figure 4-2 DEFRA vaccination decision tree (NAO, 2005).

Netherlands

The Netherlands, which has experienced epidemics of CSF, FMD, and HPAI, has engaged in policy debates over the use of emergency vaccination. FMD vaccination protocols found emergency vaccination can stop disease spread just as well as culling in densely populated agriculture regions (Elbers & Knuttson, 2013). There is public concern over mass depopulation, but contradictory objectives exist between agriculture and general society making a policy resolution difficult (Backer, Bergevoet, et al., 2009). In the 2001 FMD outbreak, 260,000 animals were culled for disease control purposes and 186,645 of them had been vaccinated but were destroyed for trade purposes (Garner et al., 2007).

The Dutch FMD contingency plan approved in 2005 lists emergency vaccination as preferred over mass depopulation, but questions remain in regard to its effectiveness. Concerns are based on the effectiveness of ring vaccination over ring culling because of the time necessary for the onset of immunity, cost effectiveness, potential increases in subclinical infection, and the risk of sub-clinically infected animals avoiding detection and instigating another disease outbreak in country or being exported and causing an outbreak elsewhere. The Dutch Ministry of Agriculture, Nature, and Food Quality commissioned an investigation and report on FMD vaccination to evaluate options. Results were intended to support policymakers in the decision-making process over FMD response. The study is further discussed in the section on FMD vaccination research (Backer, Bergevoet, et al., 2009).

The Netherlands newly revised CSF contingency plan lists emergency vaccination as preferred to mass depopulation because it has been found to be equally safe and effective in research completed by Backer, Bergevoet et al. (2009) as discussed in the section on CSF vaccination. The biggest concern is the marketing of animals after vaccination because the intent would be to implement a vaccinate-to-live policy (Elbers & Knuttson, 2013). Dutch leadership played a critical role in getting the EU to accept emergency vaccination but is still arguing for the marketing of products of vaccinated animals. The State Secretary and Minister of Agriculture in 2013, Sharon Dijksma, said she was personally committed to a vaccinate-to-live approach and “obtaining international acceptance of emergency vaccination as a legitimate measure in the fight against infectious animal diseases” (Moesker, 2013, p. 1).

New Zealand

The New Zealand Ministry for Primary Industries (formerly known as the Ministry of Agriculture and Forestry) has adopted a prioritization tool designed to guide the decision-making process on the use of vaccination during an FAD outbreak (Dunn et al., 2010). New Zealand is an FMD-free country, and vaccination is included in the New Zealand FMD response plan as an interim measure to induce immunity and reduce viral shedding. All vaccinated animals would be depopulated, which allows FMD-free status to be regained 3 months after the last vaccinated animal is culled. The advances that have occurred in vaccination technology to differentiate between infected and vaccinated stock could lead to a policy change in New Zealand and allow vaccinated herds to live out their traditional life cycle. Industry and government are working together to develop FMD vaccination policy based on evidence available (New Zealand Combined Government and Industries FMD Preparedness Working Group [NZFMG], 2011).

Australia

The Australian Veterinary Emergency Plan for emergency animal diseases identifies the use of vaccine in four policy frameworks:

- Vaccine is the primary element and can be used alone or in conjunction with stamping out,
- Vaccine is a secondary element used to complement stamping out and other disease-control methods,
- Vaccine is a tertiary element and is only used if the disease spreads extensively and a long-term eradication campaign becomes necessary, and
- Vaccine is not used due to resources, trade restrictions, safety standards, etc. (Williams, 2007).

North America

According to the North American Guidelines for FMD Vaccine Use produced by the North American FMD Vaccine Bank (NAFMDVB), if FMD can be eradicated through depopulation, then vaccination should not be considered. If USDA APHIS concludes it is necessary because of the region infected, suspected origin of the outbreak, and disease spread, then vaccination can be used as a component of the response (APHIS, 2010; APHIS, 2012c; Hagerman et al., 2012).

Canada, Mexico, and the US jointly developed the NAFMDVB in 1982 under a contractual agreement to provide rapid access to killed FMD vaccines with proven safety and potency. The NAFMDVB is located in the US at the USDA Foreign Animal Disease Diagnostic Laboratory at the PIADC. Each country contributes $500,000 to the Bank annually. The chief veterinary officers of all three countries would have to agree in order to activate the Bank. It stocks concentrated, inactivated FMD virus antigens for several types and subtypes. The antigens are stored at ultralow temperatures over liquid nitrogen allowing for them to be kept indefinitely and used for specific vaccine development at production facilities abroad (Kahn et al., 2002; APHIS, 2007). U.S. regulations do not allow for traditional FMD vaccination production within the borders which can also delay the start of a vaccination protocol (Miller, 2013). Because the US prohibits the manufacture of conventional inactivated FMD vaccines, antigens would be shipped to the country where the antigen originated for formulation and manufacture if needed. If the manufacturing methods and production facilities are approved, vaccines manufactured internationally can be stored for just-in-time use if they meet efficacy, potency, purity, and safety standards. Commercial vaccines from FMD-endemic countries may be used instead of emergency vaccines but are often less potent as discussed in a previous chapter. If a new vaccine needs to be prepared to meet a new disease strain, development and manufacturing can take up to six months. As human adenovirus 5-vectored empty capsid FMD vaccines and associated DIVA tests are developed for use in the US, they can also be stored in the NAFMDVB. Because they do not contain a live virus, they can also be manufactured in the US. To date, the NAFMDVB has never been activated (NAHEMS, 2011d). USAHA recently noted the NAFMDVB has limited vaccine supplies with emergency stocks significantly below those needed for an FMD outbreak in multiple states or in a livestock-dense region (U.S. Animal Health Association [USAHA], 2013).

Another multinational cooperative vaccine bank has been developed in the EU and Australia; New Zealand and other partners have developed a third international vaccine bank (NAHEMS, 2011d; Aftosa, 2007). Some small, noncommercial vaccine banks exist in other countries, such as the UK, Japan, and Argentina. An international FMD vaccine bank network was created under the OIE in 2006 with the goals of vaccine standardization and reserve maintenance (NAHEMS, 2011d; Hagerman et al., 2012).

In an outbreak, the strain would be compared with antigens in the Bank and, if an antigen is identified to be protective against the virus, the concentrate would be sent to a contracted company for finishing into final doses within three weeks. Protocols associated with the NAFMDVB written policy for decision making calls for all vaccinated animals to be permanently identified, placed under movement restrictions, and slaughtered as soon as possible. The related decision tree defines relevant factors as rapid disease spread or probability of spread and the involvement of swine or multiple species in the disease outbreak. The Bank enforces strict quality measures and rigorous assessment of safety including virus inactivation (Kahn et al., 2002). The NAFMDVB requires all vaccinated animals be permanently identified with an official NAFMDVB pink metal ear tag with an individual identification number. Full records must be maintained following USDA APHIS guidelines (NAHEMS, 2011d).

Figure 4-2 outlines the NAFMDVB decision tree for the use of vaccination in an FMD outbreak (APHIS, 2012c). The criteria in the decision tree will also influence vaccine distribution protocols and priorities, with emphasis placed on number and density of susceptible animals and herds in vaccination zone, geographic spread of herds, rate of disease spread, species and farm types in infected zones, ability and capacity to depopulate, contact rate, natural barriers, wildlife presence, and climate (APHIS, 2012c).

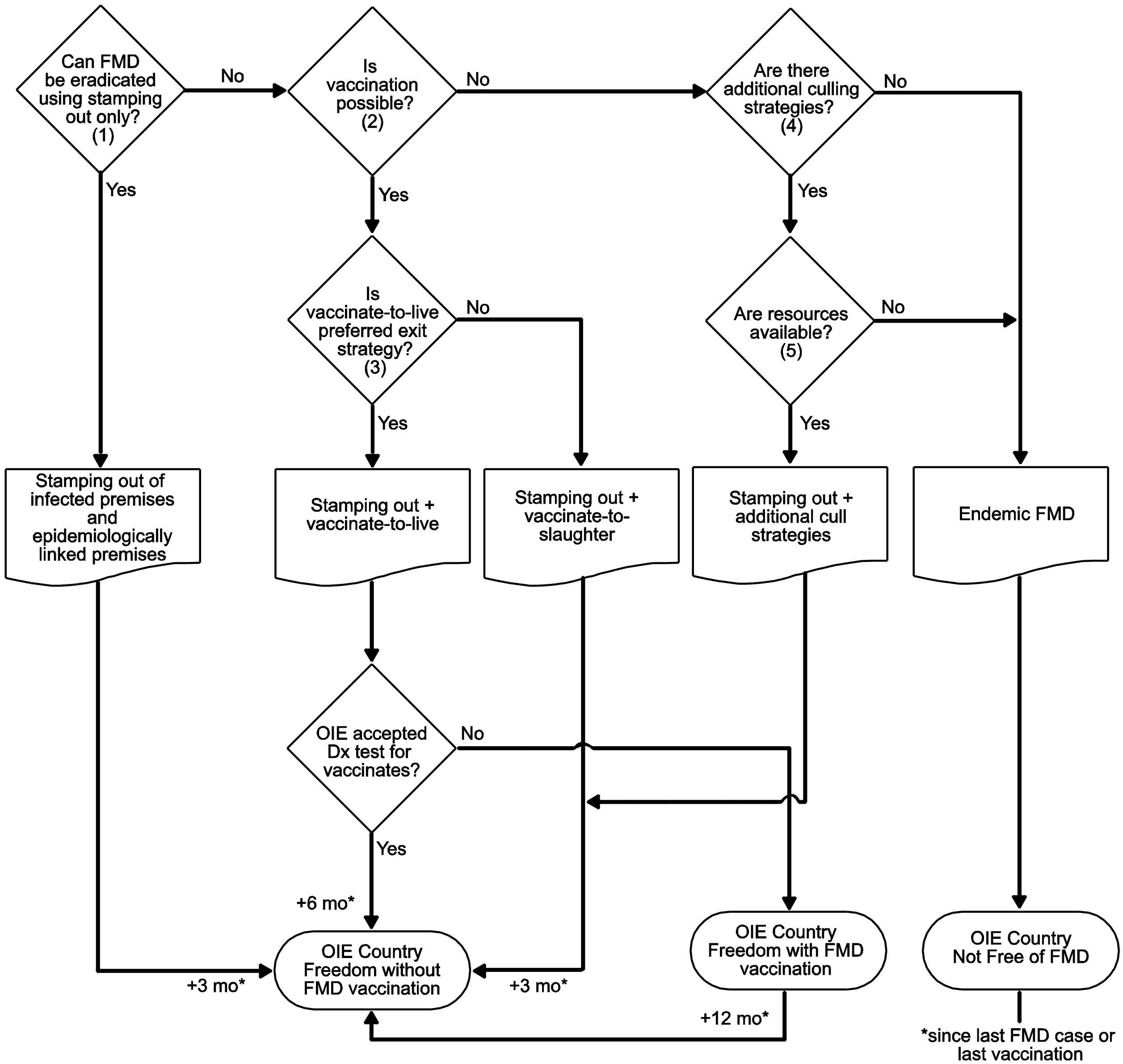

Figure 4-3 North American Foot and Mouth Disease Vaccine Bank Guidelines for FMD Vaccine Use (APHIS, 2012c, p. 4-22).

The decision tree was updated in 2007 to reflect changes in OIE policy and the need to make the vaccination decision quicker after the onset of an outbreak. It is designed to be used with decision matrices because a decision tree is linear and sequential and cannot evaluate multiple factors. A matrix, however, is limited in use independently because decision makers cannot consider all factors simultaneously. Each decision box is supported by a matrix in which appropriate factors have been identified for consideration with emphasis on outbreak factors (contact rate, host or species, status of outbreak, and environmental) and mitigation factors (physical and human resources, sociopolitical factors, economic considerations). The support factors for the decision tree are outlined in Table 4-3 (APHIS, 2012c).

Table 4-3 *North American Foot and Mouth Disease Vaccine Bank Decision Matrix for FMD Vaccine Use*

Decision Box		
Box #1 - Can disease be eradicated with stamping out only?	Time to detection	How long before disease was identified, age of lesions
	Contact rate	Kind of farms, type of direct and indirect contacts (movement of people, animals and fomites), movement distances, efficacy of movement controls
	Host	Species infected and species at risk
	Status of outbreak	Number of affected herds, number of foci of infection, rate of spread
	Environment	Livestock density and distribution, livestock management (size of operations), casual access by humans and vehicles, physical barriers, climate
	Physical resources	Slaughter capacity, transportation capacity, disposal capacity
	Human resources	Sufficient trained staff for emergency response system, movement control, epidemic projections, surveillance
	Social-political	Legislative authority, public opinion, legislative will, perception of government, industry acceptance, socioeconomic status of producers or region (sophistication of producers, influence, need for genetic preservation)
	Economic	Funding for compensation, value of exports, regionalization
Box #2 – Is vaccination possible?	Physical resources	Vaccine strain available, vaccine doses available, vaccine logistics, vaccine distribution, laboratory capacity, time
	Human resources	Emergency response system, movement control, risk of FMD introduction, epidemic projections
	Social-political	Legislative authority, public opinion, perception of government, industry acceptance, socioeconomic status of producers or region (sophistication of

Decision Box		
		producers, influence)
	Economic	Cost of vaccination, value of exports, regionalization, compensation for decreased value of vaccinated animals
Box #3 – Is the exit strategy vaccinate-to-live?	Physical resources	Slaughter capacity, disposal capacity, time
	Human resources	Emergency response system, movement control, epidemic projections
	Social-political	Legislative authority, public opinion, perception of government, industry acceptance, socioeconomic status of producers or region (sophistication of producers,
	Economic	Cost of vaccinate slaughter, compensation, value of exports, regionalization
Box #4 – Are there additional cull strategies to consider?	Social-political	Legislative authority, public opinion, legislative will, perception of government, industry acceptance, socioeconomic status of producers or region (sophistication of producers, influence, need for genetic preservation)
	Economic	Compensation, value of exports, regionalization/zoning
Box #5 – Are resources available to perform additional culling strategies?	Physical resources	Slaughter capacity, transportation capacity, disposal capacity, time
	Human resources	Emergency response system, movement control, epidemic projections

Note. Adapted from APHIS (2012c).

Canada is a member of the NAFMDVB, and Canadian contingency plans in the case of an FMD outbreak calls for the use of vaccine. Their policy calls for stamping out but allows for vaccination of susceptible species in a designated buffer zone. They would then continue with a vaccinate-to-slaughter approach to protect their trade status. The intent of the Canadian policy is to slow the spread of the disease until slaughter. These contingency plans have been developed in consultation with US and Mexico (Kahn et al., 2002).

Canada has a shortage of personnel, scarce rendering resources, and limited disposal equipment. Based on the findings following the Netherland outbreak, these limitations make rapid slaughter and disposal a challenge. Thus, vaccination is acceptable, but a shortage of personnel to administer the vaccines is also a problem (Kahn et al., 2002).

Kahn et al. (2002) noted Canada imports meat products from Brazil, a country that vaccinates for FMD, and Canadian consumers frequently eat the product and many travel to Brazil and eat meat there with no concern over FMD.

United States

CFR Title 9, Part 53.4(a) on the destruction of animals in the case of FMD calls for all animals infected or exposed to FMD to be killed promptly and disposed of by burning or burial, unless specified otherwise by the Administrator. This wording has been in place since 1929 (Miller, 2011).

Because the US has been free from FMD since 1929, FMD vaccination has not been used to date. The disease is not in the country and import prohibitions exist to keep the disease from infecting U.S. herds. Imports of livestock and their products from all FMD-infected regions are restricted (APHIS, 2007). In 1929, stamping out was an effective strategy to rid the US of FMD (DeOtte & DeOtte, 2009).

FMD vaccine cannot be used in the US without USDA authority (Parent et al., 2011). The USDA has historically had a number of reservations about ever using FMD vaccine within the US. It would be possible to spread the disease from one farm to another when vaccination is implemented if vaccine teams do not strictly follow proper sanitary measures. Another concern is that vaccinated animals could become infected if challenged, carry the disease for an extensive period, and eventually spread the disease. Moreover, the U.S. livestock trade would face restrictions that could cost producers billions of dollars, and vaccination would delay the ability to reenter international markets. Therefore, USDA’s first response has traditionally been stamping out, imposing animal movement restrictions, and eradicating the disease (APHIS, 2007).

Breeze (2004) argued the US had determined the most profitable response to an FMD outbreak is a policy of animal mass depopulation that did not use vaccination, created the best option for market access, and worked against other countries choosing to vaccinate. “It is important to appreciate that government policies on how to respond to FMD are not related in any way to the seriousness of the illness in an animal or herd: they do not depend on animal health, welfare, pain, or suffering. They are purely financial and based on estimates of the lowest costs that will ensue for animal agriculture as a whole (not for the whole rural economy)" (Breeze, 2004, p. 253).

Change in policy approach to consider vaccination

By 2005, the UK reevaluated their FMD response policies and included vaccination as a more prominent part of their response, but U.S. policy remained the same as it had for more than 50 years. While the USDA did not previously identify vaccination as a viable alternative, the GAO reported in 2005 some USDA officials acknowledged vaccination, in combination with culling, may be a necessity to deal with an FMD outbreak. The GAO noted the USDA had discussed the strategic use of vaccines to create barriers around infected animals. Their policy required a complex decision tree with multiple matrices to evaluate multiple factors. The process was deemed so complex it would not serve the need for rapid-decision making in the case of a disease outbreak. The decision tree included availability of human resources, public opinion and perception of government, industry acceptance, vaccination costs, slaughter and disposal capacity, location, and trade restrictions. The GAO recommended the development of stockpiles of ready to use vaccines that could be quickly deployed in the case of a disease outbreak. They also recommended simplifying the decision-making process for determining the appropriate use of vaccines to control an outbreak to guarantee rapid decisions are made in the event of an attack (GAO, 2005).

DHS officials also identified concerns with mass depopulation and disposal during a preparedness exercise conducted in 2008. When faced with identifying the veterinary work force needs necessary to meet animal disease outbreak scenarios as a part of national preparedness plan developed by White House Homeland Security Council, DHS found the number of personnel required for traditional animal disease response efforts to be based on an infeasible assumption. The plan calls for the traditional U.S. response of mass slaughter of all exposed animals, and DHS found this scenario improbable and determined other strategies should be identified when assessing workforce needs. As an example, they noted the possibility of using vaccination and reducing the number of animals to be culled and disposed. Because vaccinate-to-live had not been considered in the US at that time, contingency plans did not exist to determine workforce or other needs to implement the plan (GAO, 2009).

APHIS officials have noted one way to reduce depopulation and disposal concerns is to alter traditional control strategies and increase the use of vaccines for at-risk animals, thus reducing the number of animals needing to be depopulated and disposed (GAO, 2011). Dr. John R. Clifford (2011, Sept. 13) noted in testimony before Congress that the US needs a new approach to animal disease control strategy, specifically FMD. He testified that it is critical to take steps in the best interest of the livestock industry and take advantage of new technologies, such as new vaccines, requiring fewer animals to be downed while still stopping the disease. "We cannot just have a scorched earth-type policy where we go out and kill and destroy millions and millions of animals, like we saw in the UK with burning carcasses" (p. 26). Lori Miller, at the time an employee of USDA APHIS, expressed that in order to protect the environment and the economy, depopulation and disposal should be minimized and vaccination should be utilized. Stamping out will generate more mortalities than can be managed effectively, so current policies to stamp out and bury need to be reconsidered (Miller, 2011).

One of the greatest concerns with the stamping-out policy is depopulation and disposal become infeasible with large numbers of animals, especially in large feedlots. Multiple carcass disposal workshops and emergency response exercises have demonstrated these challenges. These approaches should be only one component of an overall comprehensive strategy including early detection, isolation, and selective vaccination (DeOtte & DeOtte, 2009).

Emergency vaccination can play a supporting role in FMD control if there is an outbreak in an FMD-free country, specifically serving to create barriers between infected and non-infected areas. However, vaccines could not be developed until the type and subtype of the virus has been identified, so it is unnecessary to keep large amounts of developed vaccine on hand. If USDA officials determined FMD vaccines could be used and state officials requested vaccine, they would work together to determine vaccination regions and inform producers and consumers about the process and procedures of vaccination (APHIS, 2007).

Large-scale vaccination may be necessary in an FAD outbreak to "minimize the impact on animal and public health, ensure continuity of the U.S. food supply, and minimize the economic impact of food producers" (NAHEMS, 2011c, p. 1). But, in some cases depopulation without vaccination may lead to the most rapid return to disease-free status and allow trade to resume more quickly, vaccination supplies may not be available, or vaccination may be impractical if vaccinated animals cannot be differentiated from naturally infected animals (NAHEMS, 2011c; NAHEMS, 2011d).

Vaccination can, however, slow the spread of disease or reduce the shedding of infective pathogens. If vaccination is used in a widespread disease outbreak, its use will likely be determined by the size and scope of the outbreak, the disease in question, the accessibility and efficacy of vaccines, and disease- or vaccine- related trade restrictions. Strategies for vaccination may include targeting certain animals, such as high-valued animals, genetic lines, production animals, zoo animals, endangered species, or dense populations of uninfected, but susceptible animals. Ring vaccination may be used to suppress disease transmission from leaving an infected zone. Barrier vaccination can be used in a similar manner. Other strategies include predictive and blanket vaccination (NAHEMS, 2011c; NAHEMS, 2011d).

Miller stated on a conference call with state animal health departments in 2011 that all available tools needed to be used for FMD response and the US needed to vaccinate-to-live. She noted meat is still okay to be used for its intended purpose and is safe to eat. She further stated stamping out should only be used in small outbreaks and would never be feasible with large feedlots (Miller, 2011). Miller further stated in May 2012 that APHIS has decided to vaccinate when appropriate so mortalities can be minimized. USDA continues to refine vaccination policy and support the development of next-generation vaccines for FMD (Miller, 2012b). These comments do not recognize the authority of state officials in the vaccination decision.

Emergency vaccination strategies may be considered in an FMD outbreak if the disease cannot be contained by stamping out and if the vaccine matches the specific serotype. The region infected, suspected origin of the outbreak, and disease spread may influence USDA APHIS to make vaccination a component of the response. It is likely a combination of strategies will be implemented (APHIS, 2012c; APHIS, 2010; Hagerman et al., 2012). The current USDA FMD policy supports emergency vaccination only when culling cannot control disease spread (Hagerman et al., 2012).

If stamping out cannot control, contain, and eventually eradicate FMD, alternative strategies will then be considered. Factors influencing the selection of a response strategy for an FMD outbreak include:

- Consequences of the outbreak on commerce, trade, national security, food security, animal health, the environment, the economic, and regulatory concerns;
- Social and political acceptance from local, state, national, and global communities;
- The scale of the outbreak (premises, species, distribution, number of animals);
- Rate of disease spread;
- Availability of veterinary countermeasures; and
- Accessibility of necessary resources to carry out response (APHIS, 2012c).

The USDA Center of Veterinary Biologics (CVB), who holds regulatory authority for licensing and permitting vaccines, coordinates with the NAFMDVB and NVS on the purchase of vaccine antigen concentrates and manufactured emergency use vaccines. The traditional comprehensive evaluation of new vaccines is not likely feasible in an animal disease emergency. The USDA CVB has developed expedited processes for conditional approval of vaccines for use in an emergency. Conditionally licensed products still must be tested for purity and safety, and have a reasonable expectation for efficacy and potency. In addition, the APHIS administrator may exempt any veterinary biological product from any licensing or permitting requirement if it will be used under the USDA control for an official USDA program, an emergency animal disease situation, or an experimental trial (Elsken et al., 2007). Such regulatory flexibility is necessary for timely emergency vaccine development, but may also have a negative impact on consumer and producer confidence in the safety and efficacy of the vaccine.

DeOtte and DeOtte (2009) maintain vaccination should remain a last resort. Because vaccinated animals cannot enter the food chain for 60 days, vaccination should only be considered for animals with at least 60 days remaining before slaughter. Vaccination could, however, serve as an effective firebreak involving thousands or tens of thousands of animals. Such methods would likely be ineffective in even larger outbreaks with hundreds of thousands of cattle.

Lack of clarity in decision process

The NAHEMS guidelines on vaccination do not indicate the exact steps to be taken, which provides flexibility, but also make it difficult to examine the effect of various policy approaches. If USDA APHIS does not have a clear process for determining the appropriateness of vaccination, decisions will be made in the middle of an emergency when time, information, sound decision-making processes, and other resources are lacking (Hagerman et al., 2012). While state animal health officials will make the request for vaccine if the preferred policy choice is to vaccinate, the decisions of whether or not to approve the use of vaccination will be made at the federal level and local decision makers must optimize strategies based on the federal directives (Kobayashi, Carpenter, Dickey, & Howitt, 2007b). The U.S. policy for determining when to use FMD vaccination lacks clarity, and the criteria used in the decision-making process is not clearly defined. "Planning and policy development for FMD vaccination in the U.S. is ongoing" (Parent et al., 2011, p. 793). Greater coordination between state and federal officials is needed to resolve these issues. These inconsistencies will likely delay the vaccination decision in an outbreak, exacerbating the situation. There is a need for well-developed criteria and execution strategies for FMD vaccination in the US that is supported by stakeholders, well-exercised, and extensively planned. Otherwise, an FMD response will not be executed effectively and the effect will be greater than necessary (Parent et al., 2011).

Parent et al. (2011) identified inconsistent policy approaches regarding the use of FMD vaccination in their interviews of seven potential animal health outbreak incident commanders. The total realistic number of incident commanders for an FMD outbreak in the US ranges between 25 and 30 individuals. They were presented a scenario and received a weekly update with changes in the scenario. In the situation presented to animal health decision makers, two chose vaccination after week one, two after week two, one after week three, one after week five and one opposed any vaccination in the scenario (Parent et al., 2011).

The incident commanders who indicated they were likely to support vaccination in week one of the scenario chose vaccination because of the rate of disease spread and desire to avoid a slash-and-burn approach. They indicated stamping out was still the first alternative and a vaccination strategy would be complicated to implement and must be started in the first week if it is to be effective. Those who did not select vaccination after week one indicated the outbreak was still limited in size, stamping out was a better policy alternative, vaccination would complicate the response, vaccination would lengthen impact on trade, and the incident commander would not have time to consider vaccination in an actual outbreak. Those who eventually selected vaccination did so because of disease spread, stamping out appeared to be failing, and FMD spread from cattle to swine (Parent et al., 2011). Few incident commanders may actually be in the position to make these decisions independently.

The animal health officials ranked nine factors to consider when determining if vaccination should be used, and the capability to stop disease spread by stamping out ranked as the leading factor. Other factors in order of ranking included: rate of disease spread, size of outbreak, livestock density in outbreak area, number and type of species and industries impacted, national security and economic impact, duration of outbreak, type of index case, and disease spread to wildlife. Only one decision maker indicated concern about identifying vaccinates from nonvaccinates, and one mentioned concerns about FMD carrier status (Parent et al., 2011).

In 2010, the U.S. Animal Health Association (USAHA), comprised of state and tribal animal health officials, animal production industry leaders, and associated processing industry representatives, passed a resolution asking USDA for clearer guidance on emergency vaccine use in dealing with FAD, such as FMD, CSF, and RVF (USAHA, 2010).

A group of private, public, and non-profit leaders in animal agriculture discussed current FMD policy at the annual meeting of the National Institute on Animal Agriculture (NIAA) in the spring of 2013. Further development of clear vaccination policy was listed as a top priority among producers, producer organizations, state veterinarians, animal health personnel, and government personnel. They further noted vaccination decisions need to be made quickly and cannot wait three to seven days because opportunity costs go up as the decision is delayed (National Institute for Animal Agriculture [NIAA], 2013).

In August 2013, steps were initiated by USAHA and NIAA, in conjunction with USDA APHIS, to develop a National FMD Preparedness Working group of animal health government officials, academic experts, and industry representatives to discuss and determine steps "to accelerate modernization and implementation of efforts to prevent, detect, contain, eradicate, and recover from an FMD outbreak in the United States" (USAHA, 2013, p. 1). Specifically, the group will consider the nation's capacity and needs related to FMD response strategies, including emergency vaccination (USAHA, 2013).

In October 2013, after noting the critical nature of optimal disease control and related business continuity, USAHA passed a resolution at their annual meeting urging the working group to collaborate with a broad range of stakeholders to identify capabilities, gaps, and exercise plans. Specifically, FMD vaccine quantity, capability, accessibility, deliverability, distribution mechanisms, electronic identification, and other vaccine-related issues were designated as a priority. USAHA also resolved that USDA APHIS should support and collaborate with working group efforts by providing information as well as integrating recommendations from the working group into preparedness and response plans (USAHA, 2013).

National Veterinary Stockpile

The NVS, the U.S. repository of critical veterinary counter measures, was established through HSPD-9 in 2004, and became operational in 2006. It is coordinated by the National Center for Animal Health Emergency Management (NCAHEM) in USDA APHIS. It provides logistical support to the NAFMDVB. The NVS is designed to provide states with the resources they need to respond to one of 17 animal disease outbreaks within 24 hr (APHIS, 2011b). However, there are no USDA-licensed vaccines for the majority of foreign diseases identified as concerning to the horse, cattle, swine, sheep, goat, and poultry industries. The NVS intends to acquire supplies for these 17 diseases, listed in order of importance, by 2016:

- HPAI,
- FMD,
- RVF,
- Exotic Newcastle Disease (END),
- Nipah and Hendra virus,
- CSF,
- ASF,
- BSE,
- Rinderpest,
- Japanese Encephalitis,
- Contagious bovine pleuropneumonia,
- Heartwater,
- Eastern equine encephalitis,
- Q fever, and
- Akabane virus (NAHEMS, 2011c).

The NVS stocks supplies, vaccines, personal protective equipment, animal handling equipment, antiviral medications, and diagnostic test kits. It also provides contracts for commercial support services such as emergency transportation of critical samples, laboratory facilities, and trained personnel with equipment prepared to help depopulate, dispose, and decontaminate. If USDA determined vaccination was appropriate, the NVS would coordinate the collection and delivery of the vaccines (APHIS, 2011b). However, in most cases, vaccines and diagnostic kits have not been developed or are too expensive for NVS to purchase. Vaccines are unlikely to be deployed within 24 hr because of time needed for manufacturing and the fact that the NVS business plan calls for storing vaccines in a nonready-to-use state to reduce costs of storage, maintenance, and expiration. This issue was the number one concern that state and U.S. territory animal health officials had with the NVS resources (GAO, 2011).

If the policy approach is to vaccinate and enough vaccine is not available, the government may need to compensate farmers and ranchers who did not receive adequate vaccine supplies for all losses incurred due to the shortfall. This could result in substantial costs (Breeze, 2006).

At a December 2013 FMD table-top exercises, USDA officials indicated there were antigens in storage to prepare 2.5 million doses of vaccines to be manufactured internationally and that no conventional inactivated vaccines are in storage at the NAFMDVB. It was clear in the discussion that at least one state intended to request 25 million doses but would not expect to receive it. Not only was capacity a limiting factor, but it was indicated it would be 2-3 weeks before vaccines may arrive to states that request it (personal communication). This length of time may render vaccines nearly useless in actual disease control and response. No plans are in place to determine how priority for distribution to states will be determined. In addition, a number of states indicated in-state distribution and priority plans were minimal. The overall feasibility of emergency vaccination based on adequate supply, distribution, and timing may limit the role vaccine can play in an FMD outbreak in the US.

Previous Economic and Epidemiological Research

The focus of a majority of the economic and epidemiological research on the use of vaccination is focused on FMD. The following sections discuss research findings from a number of epidemiological and economic models, cost-benefit analysis, and other research tools.

FMD vaccination

Berentsen, Dijkhuizen, and Oskam (1992) in a cost-benefit analysis of FMD control strategies found prophylactic vaccination was not a cost-effective strategy in areas where FMD is not endemic. The goal of their research was to determine if eliminating routine FMD vaccination in order to gain FMD-free designation was economically efficient. They used a three model system, including an epidemiological model that estimated size and duration of outbreak, a disease-control model that calculated direct losses for producers and government, and an export model that generated estimates of indirect losses to consumers, producers, and government. The models were integrated to estimate national economic losses. Costs considered were those generated by disease control measures including animal slaughter, ring vaccination, compensation payments, movement restrictions, related expenses, and idle production losses. Depopulation of cattle on infected farms with and without ring vaccination was compared under a scenario of annual cattle FMD vaccination and a scenario with no annual cattle FMD vaccination. Depopulation on serious contact farms was also evaluated. They assumed ring vaccination started three weeks after outbreak and included all cattle and hogs within 25 km of the infected herds. The highest number of outbreaks and largest economic loss were predicted to occur in a non-vaccinated population with depopulation of infected herds only. If serious contact herds were depopulated, the number of outbreaks and length of the outbreak were predicted to be greatly reduced. Direct costs were highly related to size and length of the outbreak. Indirect costs were estimated to be highest without annual vaccination. The lowest economic loss was predicted to occur with a vaccinated population combined with eradication of livestock on infected farms and a 25-km ring vaccination (Berentsen et al., 1992; Bates et al., 2003).

In 1995, Garner and Lack looked at multiple combinations of slaughter and vaccination as an FMD control strategy in Australia. Their stochastic simulation model, AusSpread, has served as the basis for a number of more recent studies. Macroeconomic input-output analysis was used to capture secondary effects of FMD on employment and income in related economic sectors. They also used a cost-benefit analysis to evaluate alternative strategies for disease control based on expected values of gains and losses. Their model indicated that if FMD spreads rapidly, then slaughter of infected herds and dangerous contacts reduced the economic impact of the disease outbreak. This was not the case in a slow-spreading disease outbreak. This finding is actually counter to the findings from USDA noted in Table 4-1 where rapid disease spread was a factor in using vaccination. Ring vaccination was not economically beneficial compared to slaughter, but, again, if implemented early, would reduce the size and duration of the disease outbreak. Zoning, if accepted by trading partners, was also predicted to be economically beneficial. The model also was extended to incorporate a GIS framework with real farm boundary and point-location data. This was designed to provide better tools for policymakers and management decisions (Garner & Lack, 1995; Schoenbaum & Disney, 2003; Elbakidze, Highfield, Ward, McCarl, & Norby, 2009).

Leforban (1999) found that, in the case of FMD, the implementation of routine vaccination in disease-free regions is economically counterproductive (Leforban, 1999). In the evaluation of direct economic costs to producer, if vaccination is used, vaccination-to-cull creates zero economic value. Vaccinate-to-slaughter would likely send animals to slaughter prior to normal slaughter weights which could offer additional challenges and reduce producer profit, but could reduce consumer costs. A vaccinate-to-live approach allowing all animals to live out their normal life would provide the best profit option and allow animals to be used for the highest and best available good, even though there will be an economic loss overall due to the outbreak (DeOtte & DeOtte, 2009).

Mahul and Gohin (1999) explored the concept of irreversible investment and how it affects optimal dynamic decision making when comparing vaccination and depopulation in response to an emergency animal disease outbreak. Vaccination creates additional costs that depopulation does not relative to decreases in value of vaccinated animals and their products and intensified trade restrictions. These costs are considered sunk costs and are irreversible. The gain in postponing consideration of vaccination must be weighed against the cost of delaying vaccination implementation. Results indicated there is a quasi-option value to policymakers to delay a decision to vaccinate if a widespread epidemic is not probable due to the benefit of waiting for new information. If delaying the vaccination decision results in a quasi-option value greater than the cost of waiting, the learn-then-act principle applies. If the cost of waiting exceeds the quasi-option value, the decision maker would apply the precautionary principle. Therefore, their findings indicate a widespread epidemic is not highly likely (less than 55% probability of widespread epidemic with uncertainty unresolved, or less than 75% with certainty) and a late vaccination strategy is more efficient than an early vaccination strategy, which allows decision makers to potentially save the otherwise sunk costs (Mahul & Gohin, 1999).

In 2000, Mahul and Durand used epidemiological and economic models to simulate an FMD outbreak in France. The input-output model assessed financial consequences of FMD on the breeding sector as well as other regional and national economic sectors based on the impact of international trade restrictions. They compared stamping out of infected and in-contact herds, extension of stamping out to dangerous contact herds, the addition of emergency vaccination, and ring vaccination of all susceptible animals within the control area. Herd size and density of livestock populations were considered. Stamping out of infected and dangerous contact herds was found to most often contribute to an estimated reduction in economic losses. If export losses could be offset by gains from reducing the duration of the epidemic, then emergency vaccination was predicted to be socially optimal which was possible in high-density livestock population areas if disease cannot be controlled. Economic consequences from international trade restrictions were estimated to be more significant than livestock losses and production and processing disruptions, thus increasing the importance of limiting lengths of trade bans (Mahul & Durand, 2000).

In 2002, Garner, Fisher, and Murray considered the consequences of an FMD outbreak in Australia. The policy goals were determined to be disease eradication as rapidly as possible and the preferred option was evaluated to be stamping out. Emergency vaccination was a consideration in some circumstances. They also found zoning could be beneficial but the expectations of premium exports such as Japan, Korea, and the US need special consideration (Garner et al., 2000; Perry, McDermott, & Randolph, 2001).

In a 2001 study by Keeling et al., researchers applied developed parameters of susceptibility and transmissibility to the U.K. FMD outbreak. Ring slaughter and ring vaccination both proved successful in their models but only if implemented rigorously, and ring slaughtering was projected to be more effective for disease control. Ring vaccination was estimated to reduce culling by 15%, and if only ring vaccination was used, total cull was estimated to double. The parameters developed by Keeling et al. have been used in a number of other models. Keeling found that a 10-km ring was predicted to decrease epidemic size by 20%, but focusing on nearby farms rather than high-risk farms was futile (Keeling et al., 2001; Le Menach et al., 2005; Elbakidze et al., 2009; Kitching, Taylor, & Thrusfield, 2007).

Ferguson, Donnelly, and Anderson (2001) completed an analysis of the U.K. FMD outbreak two months after the response began. Disease incidence was estimated and the impact of control measures were simulated using a model designed to capture differing spatial contact patterns between farms before and after movement restrictions. They compared temporal issues related to three incident time series from infection to reporting, reporting to confirmation, and confirmation to depopulation and found delays to be important to control strategy selection. It was assumed all infected farms were eventually identified and that depopulation occurred within24 hr of disease reporting without waiting on confirmation because delays would extend epidemic. They found that rapid implementation of infected farm depopulation was predicted to slow disease spread. Ring vaccination and culling were projected to be necessary for rapid control if applied aggressively with culling being more effective than vaccination. To have the same level of effectiveness between culling and vaccination, it was estimated that a much larger number of animals needed to be vaccinated compared to culling. They also found vaccination was not beneficial if all animals eventually would be culled for trade purposes (Ferguson et al., 2001).

Tomassen et al. (2002) developed a decision tree to support decision making by evaluating FMD control strategies to minimize direct costs and export losses. The decision tree creates a formal, structured approach that addresses uncertainty and leads decision makers in a chronological decision process to reach the best decision with limited information. Because a speedy, informed decision is critical to effective disease response, emphasis was placed on the development of a tool that could be used in the first three days of an outbreak based on information available in that time. The approach combined an epidemiological model based on a deterministic susceptible-infectious-recovered approach modeling the effect of an FMD control strategy on FMD dynamics, an economic model that converted the outbreak and control effects into direct costs and export losses, and a decision-tree module. Costs with an economic impact on livestock producers and the government responsible for disease control were considered along with the lost value of livestock and related products that could not be exported (Tomassen et al., 2002).

The four control strategies compared were stamping out and culling of high-risk contact herds, ring culling within 1 km of infected herd, ring vaccination within 1 km of infected herds, and ring vaccination within 3 km of infected herd. Movement control was implemented in all four responses. Livestock and herd density, possibility of airborne spread, and the high-risk period (HRP) (time between the initial infection and detection of disease) were used to define scenarios. Airborne spread outside of the ring was taken into account and susceptible animals located downwind were also culled or vaccinated. All vaccinated animals were depopulated as rapidly as feasible. Seven density examples, two airborne spread options (none or maximum), and three HRPs of 7, 14, and 21 days were considered. Analysis compared the difference between known and unknown HRP by policymakers which led to the ability to calculate the expected value of perfect information (Tomassen et al., 2002).

Livestock density was a critical factor. In densely populated areas, the economically optimal control strategy was ring vaccination due to a reduced number of infected herds and a shorter epidemic, but in sparsely populated areas, ring culling was projected to be economically optimal. In densely populated areas, limited estimated to be the biggest economic factor. For regions with density neither defined as densely nor sparsely populated, the length of the HRP and chance of airborne spread were predicted to be the most significant factors. The results indicated failure to select the economically optimal response will likely lead to additional negative economic effects (Tomassen et al., 2002).

In a study of U.S. vaccination strategies using spatial stochastic simulation modeling in a hypothetical FMD outbreak in California, Bates et al., (2003a) and Bates, Thurmond, and Carpenter (2003b) compared a USDA-mandated eradication strategy with supplemental depopulation and vaccination within a certain radius, slaughter of high-risk animals, and expansion of infected and surveillance zones. Strategies of preemptive depopulation of high-risk herds and vaccination within a specified radius both performed better than the baseline by decreasing size and duration of the epidemic. Specifically, slaughter of the 5 to 10 highest risk herds was more effective than depopulation of herds within 1-5 km. Key to the effectiveness of such a strategy is the ability to identify the highest risk herds. They determined vaccination caused a significant decline in the number of infected herds as well as epidemic duration. Increasing the infected areas from 10 to 20 km and the surveillance zone from 20 to 40 km led to a 48% decrease in the size of the epidemic which was the single most significant strategic benefit found in strategy comparison. It was also determined by increasing the vaccination zone to a diameter of 50-100 km from 5-10 km would result in a much smaller epidemic. In the three-county region used in the study, this increase would result in 2,161of 2,238 herds (97%)

requiring vaccination in just a few days (Bates et al., 2003a; Bates et al., 2003b). While expansion of the zone is epidemiologically beneficial, it may not be well accepted by producers, industry representatives, or state officials (Dykes, 2010). NAHEMS guidelines indicate while the selection of the size and shape of the vaccination zone is complex, it should be as small as possible to control the disease (NAHEMS, 2011d).

In a cost-benefit analysis extension of their simulation model, Bates, Carpenter, et al., (2003) evaluated FMD control strategies of vaccination and preemptive culling based on the associated costs and benefits. Direct costs considered included indemnity, slaughter, cleaning and disinfection, and vaccination. Lost wages, reduced future production, and lost exports were not included in the analysis. Depopulation of infected herds, sale yard closure, 10-km infected zone, and a surveillance zone of 20 km comprise the baseline strategy. Ring vaccination within 1-5 km and preemptive slaughter of one to10 high-risk herds in addition to the baseline were compared as control strategies (Bates, Carpenter, et al., 2003).

Vaccination protocols were estimated to be economically efficient, but mass depopulation was not. Selective culling of high risk herds was predicted to be the most preferred preemptive depopulation strategy. The most preferred vaccination strategy was projected to be the 5-km radius. Vaccine with high efficacy was found to be cost effective if vaccinated animals are not destroyed. Overall, preemptive depopulation was estimated to result in a negative net benefit while a positive net benefit was estimated to result from vaccination (Bates, Carpenter, et al., 2003).

Schoenbaum and Disney (2003) studied slaughter versus vaccination in the case of a U.S. FMD outbreak using a stochastic simulation model incorporating economic and epidemiological modules. Scenarios included slaughtering only infected herds, slaughtering herds with direct contact to infected herds, slaughtering susceptible herds within 3 km, and slaughtering herds with direct and indirect contact to infected herds (full preemptive slaughter). Strategies with no vaccination, vaccination within 10 km of two infected herds, and vaccination within 10 km when 50 herds were infected were investigated. Eradication costs, production losses, export loss, and indirect costs on other sectors were considered as total costs of an outbreak. Slaughter was considered to begin 5 days after FMD confirmation and conclude within 24 hr. In the case of vaccination, it was assumed that immunity occurred in 4 days and vaccinated animals were slaughtered within 30 days. Cost scenarios were run representing vaccinated animals being sent into normal slaughter processes and being depopulated and disposed of as was done with infected herds (Schoenbaum & Disney, 2003; Elbakidze et al., 2009).

Results indicated herd demographics and the rate of contact between herds were the key factors in determining the best response strategy. The optimal strategy was determined by the speed of disease spread, herd size, and population density. Slaughtering herds in contact with infected herds was less expensive than slaughtering only contagious herds and resulted in a shorter epidemic. Thus, it appeared to be the best strategy for controlling FMD infection but was based on an optimistic 100% traceback capability. Full preemptive slaughter was estimated to be more effective in fast disease-spread scenarios versus slow-spread cases. The most expensive slaughtering option estimated was slaughtering within 3 km. Ring vaccination was predicted to be more costly than slaughter alone, but if implemented early with preemptive slaughter, it was expected to decrease the duration of the outbreak. It was not found to be cost effective unless it was a fast-spread outbreak and there were not additional costs associated with slaughtering vaccinated animals. Targeted preemptive slaughter was predicted to improve the epidemiological and economic results. Higher capacity to slaughter and vaccinate was projected to lead to shorter outbreaks and lower costs (Schoenbaum & Disney, 2003; Elbakidze et al., 2009).

Le Menach et al. (2005), using a stochastic farm-based simulation model applied in France, assessed control policies in an FMD outbreak. They found depopulation of infected farms as a standalone measure was not expected to stop disease spread. Preemptive culling and ring vaccination in areas around infected farms had an estimated greater effect on reducing the number of FMD cases and the length of the epidemic. Which response strategy was projected to be more effective depended on the region where the outbreak was located. They concluded the results could serve decision makers when developing epidemic response planning (Le Menach et al., 2005).

Diaz et al. (2005) studied ring vaccination as a control strategy with specific emphasis on ring size and speed of implementation. They reviewed the 2001 outbreak in Uruguay and questioned if ring vaccination would have been more successful if it had been implemented quicker than 13 days after the outbreak and if the ring size of 10 km had been larger. Their study included analysis of a policy approach with isolation of infected farms, movement restrictions, and ring vaccination. Movement and isolation controls were estimated to be more effective when vaccination was included. The number of infected farms was projected to decrease by 21% when vaccination was used and continued to drop until the vaccination rate met 0.4, at which further investment did not result in estimated further declines in the number of infected farms. If movement restrictions begin on the 4th day after the initial outbreak and vaccination began on the 13th day as was the case in the 2001 outbreak, then the overall size of the epidemic was projected to be 16% larger than if vaccination would have also been implemented on the 4th day. Diaz et al. (2005) concluded ring vaccination is effective when used in conjunction with movement and isolation restrictions, implemented immediately upon notice of an outbreak, and the ring size must be larger than identified in 2001.

Hutber et al. (2006) developed a formula to help determine the economic viability of vaccination in the case of FMD. Economic viability = [prevalence without vaccination x unit compensation costs for culling] + [export loss for epidemic duration + export loss during post epidemic ban due to culling] – [cost of targeted vaccinations + cost of lost exports during ban due to vaccination] (Hutber et al., 2006).

The Hutber formula does not include the cost of implementing movement restrictions because the authors did not see these costs as significant on economic viability. This approach depends on implementing a vaccinate-to-live policy at the initial identification of FMD – any delay would decrease economic and epidemiological benefits. They also assumed all agricultural products enter the food chain; otherwise, an additional subtraction for the value of this product needs to be included. FFI refers to the number of farms impacted by FMD during the first two weeks of an outbreak and FFI can be used to predict both prevalence and duration. If FFI indicates the epidemic is unlikely to last for as long as an export ban, then vaccinate-to-live policy is inappropriate. If FFI indicates the epidemic will be greater than or equal to the length of a trade ban, the benefits of vaccination outweigh the costs if implemented within the first two weeks of the epidemic. Delaying vaccination implementation in a vaccinate-to-live program is estimated to reduce its economic and epidemiological benefits (Hutber et al., 2006; NAHEMS, 2011d).

In 2006, Zhao, Wahl, and Marsh used a bioeconomic framework to integrate epidemiological processes, dynamic livestock production, domestic consumption and international trade and to analyze effects of invasive species introduction (animal disease outbreaks) on decision making. FMD scenarios were simulated using stamping-out and vaccination scenarios. They assumed all beef exports were banned for 3 years, domestic demand decreased by 5%, and there was no disease reoccurrence after eradication. Depopulation rates of 60%, 70%, 80% and 90% of latent infectious herds without ring vaccination were compared. They also compared ring vaccination strategies that vaccinated susceptible herds at rates one, two, and three times larger than the number of infectious herds depopulated. Depopulation at 60% without ring vaccination was estimated to result in the best social welfare outcome. Researchers concluded animal disease management policy decisions are always about the balance between gains and losses (Zhao et al., 2006).

Tildesley et al. (2006) studied optimal reactive and responsive ring vaccination based on data from the 2001 U.K. FMD outbreak. They found optimal vaccination ring size to be dependent on logistical limitations and epidemiological parameters. They assumed a vaccinate-to-live policy was implemented with vaccine efficacy of 90%, a four-day delay between vaccination and protection, a goal of vaccination within two days of reporting, and a set limit on the number of vaccinations that could be done in one day. Culling occurred on infected and dangerous contact (deemed to be at risk due to epidemiological investigation) farms. Vaccination was initiated within a set radius from an infected farm with priority based on order of reporting with at-risk farms further from infected farm vaccinated first when multiple reports occurred on same day. They found that prioritizing vaccination closer to infected farms regardless of order and risk would reduce epidemic size regardless of the ring size. It was also estimated that increasing vaccine capacity would reduce the average epidemic impact and that ring size should be adjusted to capacity so supplies were not exhausted without vaccination completed within the pre-determined ring zone. A decrease in vaccine efficacy was estimated to extend the epidemic regardless of ring size. If vaccination was done by prioritizing farms closer to infected premises, the number of farms culled was projected to be reduced by 50%. Culling of contiguous premises was not assessed to be advantageous when vaccination was used (Tildesley et al., 2006).

Kitching, Taylor, et al. (2007) took issue with the Tildesley model and argued it was questionable as a decision tool. They found the model needed to be validated, was biased toward localized and pre-emptive disease control methods, and overestimated short-distance disease spread. Tildesley et al. (2007) countered the stochastic variability of the model adds to its usefulness in capturing realistic variability of disease outbreaks and that with limited vaccination resources, the order of vaccination does matter.

Rich and Winter-Nelson (2007) integrated a multimarket model with dynamic and spatial epidemiological model to estimate regional and aggregate impacts of animal disease control measures over the short and long run and analyze the economic impacts of FMD in the Southern Cone (Argentina, Uruguay, and Paraguay). Based on their findings, they assessed preventive vaccination is the best policy in the short term but is dominated by stamping out in the long run due to trade restrictions. Using mitigation strategies differentiated by region was shown as beneficial, because a spatially differentiated policy combining vaccination in Paraguay with stamping out elsewhere was estimated to result in the highest long run net revenues in the agricultural sector (Rich & Winter-Nelson, 2007).

Kobayashi, Carpenter, Dickey, and Howitt (2007a, 2007b) used a dynamic optimization model to evaluate FMD control strategies. Control strategies of depopulation and vaccination are optimized on a daily basis within the model to minimize regional costs during the outbreak. The model was applied to a three-county region in California. The optimization model allows for simultaneous consideration of all control options to find the optimal policy choice, which overcomes the limitation of models that consider predetermined choices. In this case, decision-variable levels are determined endogenously while minimizing the objective function. One limitation of the model is the inability to target depopulation or vaccination; instead these strategies must be applied uniformly to susceptible, subclinically infected, and nonvaccinated herds. Vaccination was modeled as immediately and perfectly effective in preventing disease and protecting susceptible animals (this is a significant simplification from reality) (Kobayashi et al., 2007a).

The costs in the model apply only to the three counties and are defined as the value of livestock herds depopulated for disease control, daily operational costs, and direct costs of disease control. Control measures were all implemented on day 21 of the outbreak. The model was set to minimize costs and minimize the number of herds infected with budget constraints of 700 million and one billion dollars. This simulates a decision makers' desire to minimize the consequences of an incident while attempting to deal with budget constraints. Vaccination with a vaccinate-to-live policy was estimated to reduce epidemic size and economic costs, but the cost savings would only be significant in a fast-spreading disease, particularly when the index case is in a sales yard. Epidemic duration and incidence were projected to be lower with the infection minimization than the cost minimization, but led to a higher estimated cost. Depopulation was the optimal choice projected under infection minimization, but vaccination was a more optimal choice under projected cost minimization. As the budget decreased, depopulation was supplemented with vaccination. When the model minimized the number of herds depopulated, results were similar to cost minimization except more herds were vaccinated instead of depopulated. Overall, preemptive depopulation was not predicted to be optimal, vaccination was projected to be optimal with more than 30% cost savings, increased vaccination capacity further reduced estimated epidemic costs, increased carcass disposal capacity estimated total costs, and it was determined dairy operations (high-value operations) should be given preferential treatment for the use of limited resources. It is important to note that costs incurred outside the region were not included in the model. Optimization models are not intended to replace simulation models, but do offer different advantages and can be used in iterative fashion with simulation models (Kobayashi et al., 2007a; Kobayashi et al., 2007b).

Riley concluded in 2007 prioritizing vaccination based only on distance from and dangerous contact with infected premises was predicted to be more successful at reducing the number of animals to be destroyed than other vaccination plans (Riley, 2007; Premashthira, 2012).

Barasa et al (2008) performed a cost-benefit analysis of FMD vaccination in South Sudan. They estimated prevalence and mortality of acute and chronic FMD and calculated a benefit-cost ratio of 11.5. More than 28% of the total FMD losses came from chronic FMD, indicating greater attention needs to be given to control of chronic losses. Special attention was given to the region's dietary dependence on milk. Seasonal variations create a hunger gap period during which households are highly dependent on milk and the FMD outbreaks prior to this period made human food security even more tenuous (Barasa et al., 2008).

Cattle are a central component of the economic and social wellbeing of more than 70% of the southern Sudanese. Once Rinderpest was eradicated in the region, diseases such as FMD became a focus of animal health officials. Previous researchers had identified FMD has little to no impact on productivity because African cattle suffered a mild version of the disease, but more acute cases occurred with movement of cattle for seasonal grazing. Prevalence ranged from 14.6-49% annually and mortality ranged from 1.1-5.3%. In areas such as south Sudan, government and economic instability make disease outbreaks a complex emergency with a focus on ethical humanitarian needs. In these cases, traditional economic decision-making tools are rarely used, and decisions are made by humanitarian program officials with little expertise in animal disease control or economic analysis (Barasa et al., 2008).

The dependency on milk increases at the end of the southern Sudan dry season and into the early wet season. There are typically limited amounts of grain available for purchase, but purchasing power depends on cattle ownership and cattle health. So, the humanitarian and economic impact of an FMD outbreak is directly related to its timing. The goal of the study was to look at safeguarding the milk supply while addressing the challenges of multiple variants, operational structure, and epidemiology complexity. The research team developed a benefit-cost model based on FMD prevalence, mortality, milk production, market values, and other values. Costs for FMD biannual vaccination with a 85% coverage rate included purchase and importation into Kenya, air transport into south Sudan, equipment and cold chain, training, supervision, and nongovernmental organizations' overhead and administration. Results indicated vaccination-based FMD control was justified on an economic basis. Estimated costs were decreased substantially from mass vaccinations if the vaccination protocol was solely based on humanitarian needs, while still creating an economic benefit. If economic values of social exchanges of cattle and agricultural products were included, the benefits were estimated to increase substantially. In this case, food security is a critical consideration in policy development (Barasa et al., 2008).

Organization for Economic Cooperation and Development (OECD) researchers qualitatively studied FMD-outbreak scenarios in the US, Canada, and the Netherlands and compared response strategies of stamping out, stamping out combined with regionalization, vaccination-to-live, and vaccination-to-live combined with regionalization. They utilized two modeling systems: one designed to evaluate impact on specific commodities and related market developments and the other focused on bilateral trade and welfare changes. Epidemiological factors are determined exogenously. Regionalization via zoning allows for an infected country to define an animal subpopulation based on geography or internal borders with a distinct animal health status (Junker et al., 2009).

A number of factors influencing supply and demand were considered and modeled by the research team in a comparative static analysis, including effects on domestic supply, domestic demand, and international markets as well as budgetary effects, spillover effects and externalities, and long-term production disruption. Scenarios are narrowed to the impact of the trade embargo, and export supplies are considered dumped on the domestic market. The models do not include assumptions about changes in consumer preferences or losses in production due to the disease itself. The three countries considered represent three different market structures. The US is an exporting country with a large domestic market, Canada is a large exporter with a smaller domestic market, and the Netherlands is an EU country with a highly developed livestock sector (Junker et al., 2009).

The length of time exports are restricted is projected to strongly affect the economic loss due to trade restrictions. In Canada, global welfare loss was estimated to decrease by 25% if stamping out is implemented rather than vaccination. The concept of regionalization was predicted to decrease the opportunity costs of trade limitations, and the estimated costs of regionalization were lower than the estimated gains. In general, the pork industry was preojected to experience a more negative economic impact than the beef industry. The market structure of a country fighting FMD will cause different control strategies to have different impacts (Junker et al., 2009).

For the US, vaccination-to-live was predicted to decrease annual export value by 80% while stamping out was estimated to reduce it by 50%. Welfare gains by consumers were not projected to make up for the losses faced by producers. Economic losses were consistently projected to be suffered by the FMD-infected country, but other countries were projected to gain and lose as well. Importing countries were projected to experience economic loss due to reduced international supply and higher prices, but other exporting countries were expected to gain when their competitors face export restrictions. If the US would experience an FMD outbreak, Canada, Mexico, and Japan were estimated to see a large negative impact because they import a large share of U.S. exports. Australia and New Zealand were estimated to receive the biggest gain in regard to expanded and diverted beef exports to higher price regions such as Japan. Argentina and Brazil were predicted to recognize gain from additional pork exports. Overall, the international economic consequence of trade restriction due to an FMD outbreak is estimated to be greater when vaccination is employed rather than stamping out due to the longer duration of trade distortion which has a nearly linear relationship with total costs to the economy (Junker et al., 2009).

Researchers in 2009 used a stochastic spatial simulation model to evaluate response strategies for an FMD outbreak in an eight county region of the Texas Panhandle, a high density livestock region. The scenarios were based on four different index herds (company feedlot, backgrounder feedlot, large beef, and backyard) and variations on three response strategies (time of detection, vaccine availability, and surveillance). Quarantines of infected premises and movement controls were assumed in effect in all scenarios. Vaccination was either targeted or administered in a 5-km ring vaccination zone. Vaccination was assumed to begin one week after disease confirmation, and all vaccinated animals were assumed to be depopulated. Experts and livestock industry leaders were used to help predetermine the realistic availability of resources needed for disease response. Early detection was the most useful in reducing outbreak duration and minimizing the number of herds depopulated. Vaccination when adequate supply was available did not provide significant advantages; in fact, it led to increased time to eradication with a large beef herd index case and to a higher average number of herds infected with a company feedlot index case. Vaccination becomes more effective in large outbreak where disease is being rapidly transmitted. In general, time of detection was the critical influence, while vaccination and surveillance had little effect (Ward, Highfield, Vongseng, & Garner, 2009)

In 2009, Elbakidze et al. investigated FMD mitigation strategies through the use of economic-epidemiologic modeling with a focus on early detection, enhanced vaccine availability, and enhanced surveillance. Such analysis presents numerous challenges because of the uncertainties of disease-outbreak and disease-spread parameters. Minimizing costs of ex-ante and ex-post strategies requires understanding the probabilities of disease introduction, disease spread rate, relative costs, ancillary benefits, and the effectiveness of mitigation strategies (Elbakidze et al., 2009).

Economic losses were predicted to be a result of decreased productivity, value of livestock destroyed, operational costs of response, reduction in consumer demand, trade losses, losses by supporting industries, declining stock prices, and environmental impacts. Most previous studies have found slaughter to be generally superior to vaccination primarily due to trade ban implications (Elbakidze et al., 2009).

The Wageningen UR researched FMD strategies using an interdisciplinary policy approach to compare epidemiological and economic consequences on behalf of the Dutch Ministry of Agriculture, Nature, and Food Quality. Initial results were reported in 2009 and detailed results and methods were published in 2012. The Dutch contingency plan calls for vaccination within a radius of 2 km of the infected premise under a vaccinate-to-live approach. Researchers compared this policy to culling within 1 km combined with vaccination in 5 km and the EU minimal strategy of culling infected and exposed animals, regulating movement, and tracing dangerous contacts. For the epidemiological portion of their study, they used a stochastic individual-based model coupling FMD virus transmission between and within herds. For the purposes of the model, culling was assumed to start on day 1 and vaccination on the 7th day. They found vaccination will be less effective in high-density livestock areas than depopulation efforts early in an epidemic because immunity has not built up and will lead to more minor outbreaks and greater need for surveillance. These findings are opposite the USDA expectation included in Table 4-1 that vaccination will be more effective in high-density areas. When modeled, the 2-km vaccination strategy was estimated to result in more infected farms and a slightly longer duration of the outbreak than a 1-km cull, but fewer farms were preemptively culled with vaccination. A 5–km vaccination strategy was estimated to result in a smaller epidemic with fewer farms affected and shorter duration than either of the other options. These results indicate vaccination will be better able to compete with culling for disease control if applied in a larger radius, but it will also require significant resources and may not be feasible. In the case of regions with low farm density, the EU minimal control strategy was projected to be sufficient. Researchers also determined hobby farms should be exempt from preventive culling with negligible impact on the epidemic (Backer, Bergevoet, et al., 2009; Backer, Hagenaars, Nodelijk, & van Roermund, 2012).

When considering the economic consequences, researchers looked at direct costs (infrastructure for control, depopulation and disposal, decontamination, destruction of related products and supplies, compensation, and vaccination), costs from export losses related to trade restrictions, ripple effects (effects felt upstream and downstream along the livestock chain), and spillover effects (effects on tourism and other services). In low cattle density areas, there was relatively little difference in estimated costs between the options, but culling is the best economic choice. In more densely populated areas, vaccination is the projected economic preference. In very high densities, the 5-km vaccination strategy was estimated to result in lower costs, but in other areas the 2-km strategy estimated to be the least costly. Excluding pigs from vaccination was projected to be less costly, caused relatively little estimated increase on the epidemic, was predicted to reduce the number of animals to vaccinate by half, and should be considered to potentially extend vaccination to more susceptible species (Bergevoet, von Wagenberg, & Bondt, 2009; Backer, Bergevoet, et al., 2009).

Greathouse (2010) studied the impact of disease control strategies in response to an FMD outbreak in southwest Kansas on changes in consumer and producer welfare. An epidemiological disease spread model and a multi-market equilibrium displacement model were used to evaluate three response scenarios, including depopulation of infected herds without vaccination, ring vaccination within 3 km implemented after one infected herd was detected, and ring vaccination within 3 km implemented after five infected herds were detected. Vaccinate-to-live and vaccinate-to-cull policies were also compared. The results indicated producer welfare losses are predicted to be larger with the use of vaccination and increase further with vaccination-to-cull policies and extension of trade bans (Greathouse, 2010).

In study of Spanish FMD policy, Martinez-Lopez, Perez, and Sanchez-Vizcaino (2010) compared six control strategies using a stochastic, spatial, disease state-transition model to estimate epidemic duration and magnitude. Depopulation of infected premises combined with movement restrictions in a 10-km zone, and movement tracing was the reference scenario. Other strategies considered included vaccination within a 3-, 5-, and 10-km radius and depopulation with 1 and 3 km. Depopulation measures were projected to decrease the magnitude of the epidemic by a median 78%. Preventive vaccination within 3 and 5 km was estimated to reduce the number of infected premises by 55%. Researchers concluded the reference strategy was not estimated to be the most cost-effective strategy and that depopulation within 1 km and vaccination within 3 km was predicted to be the most effective of strategies considered. The increase of preventive vaccination to 5 km and depopulation to 3 km was not found to be cost effective. They also concluded that because use of vaccination will extend the time period to recover disease-free trade status and lead to greater estimated impacts, depopulation may be more beneficial for exporting countries (Martinez-Lopez et al., 2010; Premashthira, 2012).

Ge, Mourits, Kristensen, and Huirne (2010) used integrated epidemiological-economic modeling to support dynamic decision making of FMD control measures. They noted the need for information to support the dynamic decision process reflecting ongoing uncertainty about epidemic growth in a disease situation. The model was applied to FMD in the Netherlands and was designed to perform static evaluation of pre-determined control strategies by providing guidance during the decision process, generating more realistic cost estimates, and reducing potential of under- or overreaction. The traditional EU strategy was compared with the addition of preemptive culling of nearby farms and the addition of emergency vaccination of nearby farms. The model was designed to find the optimal choice at each decision point. If explosive epidemic growth is expected with a medium to high level of uncertainty, emergency vaccination strategy was predicted to be the best response. If medium epidemic growth is expected, emergency vaccination was only predicted to be best choice if uncertainty is low. If an export ban is anticipated, then preemptive culling was projected to be the optimal choice (Ge et al., 2010).

Perevodchikov and Marsh (2010) used a bio-economic-epidemiological discrete time optimal control model incorporating price uncertainty, biological parameters, trade restrictions, and probability of disease incursion to assess the impact of FMD and disease control strategies on the Canadian cattle industry. Changes in cattle inventories, domestic and international trade impacts, producer and consumer responses, eradication costs, asset losses, and short- and long-term effects of control strategies were examined. They found it better to invest in surveillance and mitigation strategies that contain the outbreak faster to the point where marginal costs equal marginal benefits. Total economic welfare costs were anticipated to decline as level or surveillance and traceability increased, and investment measures that more quickly contained the outbreak were estimated to reduce total welfare loss. As the rate of depopulation increased from 30-90% of latent infectious animals, the percentage of total inventory depopulated, costs, and welfare losses were predicted to decrease. The most reasonable depopulation rate was projected to be 70% of latent infectious animals. Policies that decrease negative trade impacts were evaluated as yielding more substantial economic benefits, and vaccination was found to be costly and resulting in a longer estimated time for markets to remain closed. The goal of their research was to provide a decision-making tool for policymakers when considering disease control response options (Perevodchikov & Marsh, 2010). A 2011 study found similar results when applying the model to the Mexican cattle sector (Nogueira, Marsh, Tozer, & Peel, 2011).

Traulsen, Rave, Teuffert, and Krieter (2011) evaluated different FMD control strategies with a focus on preventive culling and emergency vaccination. They used a spatial and temporal Monte-Carlo simulation model to compare control options while varying airborne virus spread, farm density, type of index case (dairy, swine farrowing, and swine finishing), and a delay of 1-3 days in establishing control measures. Researchers assumed immunity started four days after vaccination, an efficacy of 98%, and no movement within vaccination zone. The baseline control measure was based on the EU directive calling for culling of infected farms, a 3-km protection zone, a 10-km surveillance zone, and contact tracing in and out of infected farms. Preventive culling within 1 and 2 km, emergency ring vaccination within 1, 5, and 10 km, and a combined strategy were compared to the baseline strategy (Traulsen et al., 2011).

They found the optimal solution depends on the situation, but the fewest farms were infected when preventive culling was applied with one kilometer and vaccination applied within a 10-km zone. The index farm did matter because the dairy farm as an index case was predicted to lead to more infected farms likely due to the more frequent contact between farms (milk tankers, etc.). As airborne spread increased, swine farms as the index case were estimated to be more severe. More delays occurred with vaccination due to approval required, and a 3-day delay was estimated to increase the number of farms infected. The effectiveness of emergency vaccination was assessed to decrease more than with culling in the case of a delay. Speed of implementation is shown to be more critical with vaccination than with culling. If resources were limited, culling was estimated to be more effective. Severe epidemics in densely populated livestock areas were predicted to be best eradicated with a large vaccination zone, and vaccine in one larger zone around infected farm was evaluated to be more successful than culling in multiple smaller zones. In low density livestock population areas, smaller zones were shown to be sufficient with a combination culling and vaccination strategy (Traulsen et al., 2011). The Netherland research team also evaluated the impact of a vaccinate-to-live policy on regaining FMD-free status compared to a mass depopulation strategy. Final surveillance and screening efforts were also evaluated. The results from the FMD transmission model discussed earlier served as the input for the final screening model by calculating the expected number of undetected infected animals and herds and the number to be tested. Results indicated vaccination yielded an estimated larger number of infected, undetected animals before final screening than preemptive culling. However, final screening was estimated to reduce the undetected, infected animals to extremely low, comparable numbers (but a few animals still went undetected). Undetected, infected animals were primarily found in nonvaccinated sheep herds and vaccinated cattle and sheep herds. Thus, testing of pigs could be done by sampling and more screening efforts can be dedicated to cattle and sheep. While it appears a vaccinate-to-live strategy can be just as effective, uncertainties remain in regard to real-world application. Products from vaccinated animals will need to be processed separately which creates logistical challenges, additional costs, and likely price differentiation. It is unclear if retail, consumers, and trading partners will accept products from vaccinated animals. The Dutch retail industry and livestock sector have tentatively agreed to distribute products from vaccinated farms only in country (Backer, Engel, Dekker, & van Roermund, 2012).

In 2012, researchers with the Naval Postgraduate School investigated the disease spread and outbreak parameters of FMD with the intent of identifying the effectiveness of different FMD control strategies for use in policy decisions. They conducted a simulation utilizing experimental design based on an FMD outbreak in California. Vaccination zones assumed all cattle within 10 km of an infected premise were vaccinated with 90% of the animals showing immunity within four days. Their findings highlighted the effectiveness of surveillance and the shortage of depopulation resources, but did not mention the vaccination strategies as a significant factor in their results. The importance of policymakers' ability to respond quickly and effectively was noted as critical to the success of any FMD response (Axelsen, 2012).

In 2012, Sith Premashthira generated input parameters for simulating a hypothetical outbreak of FMD to compare control strategies. His study area included 413 counties in six states (Kansas, Colorado, Nebraska, Oklahoma, Nebraska, New Mexico, and Texas). He used expert opinion from personal contacts to identify destruction and vaccination options. Premashthira expanded his work by simulating control strategies, including restricted animal movement, stamping out, and ring vaccination (Premashthira, 2012).

The baseline scenario was limited disease control with movement controls established within 10 km of infected premises, a destruction capacity of three premises per day, a destruction priority of detected premises followed by direct contact premises, and no vaccination. In comparison to the baseline scenario, the following strategies had the corresponding impact on infected premises:

- Strengthened restricted animal movement decreased infected premises by 29.3%,
- Initial ring vaccination on day 7 decreased infected premises by 23.7%,
- Initial ring vaccination on day 14 decreased infected premises by 23%,
- Additional capacity for trigger ring animal destruction within 3 km of infected premises decreased infected premises by 23.3%, and

- Additional capacity for animal destruction decreased infected premises by 21.2% (Premashthira, 2012).

There was no significant difference at a $P<0.05$ level between either initial ring vaccination strategy and trigger ring animal destruction, but all three of these control strategies were estimated to be significantly better than additional animal destruction. None of the strategies were predicted to shorten the duration of the epidemic. Restricted animal movement was the best strategy for reducing epidemic size because it reduced the number of infected premises more than destruction and vaccination strategies. The largest estimated number of animals destroyed in all scenarios was cattle on feedlots (16.3 million head in baseline and 15.8 million in restricted animal movement). Neither vaccination strategy was projected to decrease the number of animals destroyed (Premashthira, 2012).

Hagerman et al. (2012) examined the impact of standard culling versus standard culling combined with emergency ring vaccination in an FMD outbreak. Current U.S. policy would call for extensive culling resulting in a shift in national supply and trade restrictions. Previous studies indicated emergency vaccination can reduce the size of outbreaks and reduce virus shedding. In this case, vaccination was considered as a method to minimize animal losses, control costs, reduce welfare losses, and manage risks.

Epidemic-economic (epinomic) models were applied to single-event, short-run case studies in high-value production areas in California and Texas. Two epidemic models were used to simulate the outbreaks. A partial equilibrium model was utilized to identify potential market and trade impacts. The policy scenarios studied included vaccination versus non-vaccination and two time frames (7 and 14 days) for disease diagnosis. The U.S. policy for stamping out of infected and dangerous contact herds with associated surveillance and movement restrictions was used as was a modified stamping-out approach with emergency vaccination-to-slaughter. The concerns over timely delivery and administration of vaccine were addressed by including delays in the vaccine availability parameter and limitations on quantity which were relaxed over time. Because federal guidelines on emergency vaccination are not specific, researchers customized the vaccination application by region. In Texas, vaccination occurred in a 5-km ring around the infected 50,000-head feedlot and all herds were vaccinated-to-kill. In the California scenario, vaccination applied to only dairy herds within a 10- and 20-km ring around the infected 2,000-

head dairy. Vaccination costs were estimated on a per-dose cost of vaccine and a fixed cost per herd (Hagerman et al., 2012).

In the California scenario, the number of animals slaughtered reached 173,000 head and the number increased with vaccination. Under a 10-km ring with a 7-day delay, however differences were not significant. When comparing the 7- to 14-day diagnostic delays, there was a statistically significant increase in the number of livestock culled with the longer time before diagnosis. The duration of the outbreak lasted 88 days, resulting in a trade ban of at least 180 days. While vaccination slightly decreased the duration of the outbreak, it was not significant. The outbreak is shorter under a 7-day delay but increases under a 14-day delay in the 20-km vaccination scenario. National welfare losses are greater with vaccination, but are only significant in the 20-km scenario. These results indicate emergency ring vaccination is not economically advantageous in California (Hagerman et al., 2012).

In the Texas scenario, animals culled ranged up to 400,000 head. The number of animals slaughtered and herds quarantined increased with vaccination and diagnostic delay. Vaccination was a statistically significant factor in the increased number of animals culled and herds quarantined, so a 5-km ring vaccination does not appear beneficial at limiting the number of animals culled. Vaccination is statistically significant in reducing the maximum duration of the epidemic by 2 days in the 7-day delay scenario, but does not reduce the average duration of an outbreak. National welfare economic losses increase with vaccination in all cases, except in the 1-day delay scenario when vaccination reduces loss. But, in no case, is the difference statistically significant (Hagerman et al., 2012).

Risk aversion analysis was used to determine where the preference changes for decision makers between stamping out and modified stamping out with vaccination-to-slaughter. The risk aversion coefficients for decision makers have not traditionally been studied. Vaccination was evaluated as a risk management strategy. Since information on risk preferences for decision makers was not available, it was not possible to use stochastic dominance to evaluate the strategies. In the Texas and the California scenarios, the cumulative density functions for national welfare indicate a no-vaccination policy is a superior approach. In the California case, when analyzed as a risk management strategy, a policy of culling without vaccination is preferable when considering national welfare. Risk-neutral and risk-averse decision makers prefer no vaccination with a 7-day delay. Under a 14-day delay, the 20-km ring was preferred to the 10-km ring by risk-neutral and risk-averse decision makers. In the Texas scenarios, risk-neutral and risk-averse decision makers would prefer no-vaccination in regard to the number of livestock culled. In regard to national welfare, preference changes to vaccination (Hagerman et al., 2012).

In summary, with a risk-neutral approach in the California scenario, the additional slaughter and costs associated with vaccination outweigh the potential benefits. With a risk-averse approach, emergency vaccination becomes a preferred strategy if the focus is on reducing the number of livestock culled. Under a risk-neutral approach in Texas, the costs associated with slaughter, vaccination, and depopulation do not outweigh the welfare losses. If the decision maker is risk-averse and focuses on reducing the worst anticipated losses, then vaccination can be beneficial. Results also indicate vaccination may be used as a risk management strategy and diagnostic delay plays a role in determining when vaccination should be utilized (Hagerman et al., 2012).

One uniform finding in the research is the 7-day diagnostic delay results in less negative impacts than a 14-day delay. This is consistent with evidence from FMD outbreaks indicating the longer the delay in diagnosis, the longer the duration of the disease, the more challenging it is to eradicate, and the greater the overall impact of the outbreak. Culling alone was superior to a response including emergency vaccination because it resulted in lower animal and national economic welfare losses. However, emergency vaccination did prove effective as a risk management strategy. If culling cannot control an outbreak, results support the hypothesis that vaccination may play a more strategic role the longer the diagnostic delay. Hagerman (2009) found, in a 21-day delay in California FMD outbreak, vaccination reduced mean national welfare losses (Hagerman et al., 2012).

Trade ban durations were not varied in response to epidemic duration and the correlation between trade ban length and vaccination strategy was not accounted for in the study. Future work could assume a longer trade ban or assume no regionalization in trade implications. Study of a larger geographic region and longer outbreak duration would allow for inclusion of business interruption costs and delays in trade share recovery. Additional knowledge about the risk aversion coefficients for decision makers would add to the risk management study approach. Moreover, additional logistical issues, other than vaccine and labor resource availability, need further consideration. The methods included could be expanded to include advanced and DIVA

FMD vaccines, which could allow for inclusion of a modified stamping out with vaccinate-to-live policy (Hagerman et al., 2012).

In 2012, Tildesley, Smith, and Keeling modeled FMD control strategies in Pennsylvania with a defined goal of minimizing the number of livestock farms culled. They find it likely that models will be used to inform disease control policy decisions, and tested an FMD model based on a number of control strategies. The results were found to be highly dependent on the county where the disease originated in the model and the spatial scale of transmission. The location of the index case to other farms and to densely populated livestock areas had significant influence on the results. Ring vaccination and culling were predicted to reduce the size of the epidemic and the optimal radius varied depending on the county of origin. Their results indicated that a vaccinate-to-live strategy was generally preferred to ring culling in regard to an estimated reduction in the number of premises that are culled. Ring culling was not useful if the width of disease transmission was relatively small. Researchers concluded that no single control strategy can always be guaranteed to minimize disease impact, but that well-targeted control efforts can significantly reduce the size and duration of an FMD outbreak in Pennsylvania (Tildesley et al. 2012).

Boklund et al. (2013) used two stochastic simulation models and cost-benefit analysis to study the epidemiological and economic impacts of an FMD outbreak in Denmark with a focus on ring depopulation and emergency vaccination. Specifically, they evaluated four controls: base response of depopulation of infected herds with a 3-km protection zone and a 10-km surveillance zone, movement tracing, and 3-day national stop movement; ring depopulation in addition to the base response; protective ring vaccination (vaccinate-to-live) in addition to the base response; and suppressive ring vaccination (vaccinate-to-kill) in addition to the base response. Vaccinations were assumed to commence 14 days after disease detection or after 10, 20, 30, or 50 herds were detected to be infected. Direct costs for a cost-benefit analysis included surveillance, depopulation, cleaning and disinfection, empty stables, compensation, welfare slaughter, national standstill, and vaccination. Indirect costs included export losses for live cattle and pigs and their products and assumed a 25%-price reduction within the EU. It was also assumed that exports would begin again outside the EU as soon as the OIE ban was lifted following the necessary recovery waiting period and time for the veterinary committee to meet (Boklund et al., 2013).

The two models used for evaluation provided different numerical estimates, but lead to similar strategy recommendations. Vaccination was more effective when initiated after 14 days or after detection in 10 herds than after 20 or more herds were detected. In regard to ring size, vaccination led to shorter, smaller, and less expensive outbreaks when the vaccination zone was extended from 1 km to 2 or 3 km, but when extended to 5 km, resulted in a more costly epidemic. Epidemiologically, protective vaccination was preferred in a scenario where the outbreak started in a high-density area, but protective vaccination and depopulation had similar results if the outbreak started in a low-density area. Protective vaccination was the best way to minimize the number of animals destroyed. Cost-benefit analysis showed that depopulation was typically the best option from an economic perspective and suppressive vaccination was preferred in extreme epidemics, but protective vaccination was never cost effective. The majority of costs were due to export losses from trade restrictions. If the export ban was extended, suppressive vaccination was no longer a better option (Boklund et al., 2013).

In a study by researchers at Kansas State University, vaccination control measures were evaluated based on their ability to control epidemic duration and number of herds depopulated compared to a depopulation only strategy. They studied an FMD outbreak response in Wyoming, Colorado, Kansas, Nebraska, South Dakota, the Texas Panhandle, and northern regions of New Mexico and Oklahoma. Seventeen scenarios were compared using the North America Disease Spread Model (NAADSM) with variation in vaccine capacity, size of vaccination zone, number of infected herds before vaccination began, and priority of large feedlots over other production facilities. Vaccine capacity was varied between high and low capacity, with capacity being defined as number of herds vaccinated per day and determined as low if only administered by USDA officials or high if administered by private farmers, feedlot operators, and ranchers (availability of dosages was not considered). The number of infected herds required to trigger implementation of vaccination was varied between 10 and 100 infected herds, and size of vaccination zones was either 10 or 50 km. Large feedlots were prioritized due to high contact rates and large number of facilities in the central US. It was assumed all vaccinated animals were allowed to live out their normal production cycle (McReynolds, 2013).

The size of the vaccination zone had the most impact with the larger zone resulting in estimated decreases in disease duration and number of herds depopulated. The vaccination trigger and capacity had more limited and less consistent impacts, although increased capacity was projected to improve the control impact in all but one scenario. Researchers concluded that because the vaccination trigger was not an impactful factor that timing of the vaccination decision may not be critical. The depopulation-only scenario resulted in the largest number of herds depopulated of all 17 scenarios. When simulated biosecurity and movement controls were strengthened, vaccination no longer proved beneficial over depopulation only. It was noted that large vaccination zones and large vaccination capacity may be not be feasible if limited resources are available (McReynolds, 2013).

Ajewole (2013) completed a companion economic study estimating the economic impacts from simulated FMD outbreak responses using an equilibrium displacement model. The distribution of losses and gains to producers and consumers relative to FMD control strategies were evaluated and mitigation strategies were ranked based on potential reduction in economic losses and minimization of the severity of an FMD outbreak. The economic model integrates results from the NAADSM epidemiological model and analyzed the impact of the outbreak on domestic and international market sectors (Ajewole, 2013).

The focus of the study was on the vaccination-to-kill scenarios from the McReynolds (2013) study and assumed all animals were depopulated in the same quarter in which they were vaccinated. The three scenarios considered used two vaccination capacities and two sizes of vaccination zones. The number of herds infected as a vaccination trigger was the same in all three scenarios. Results were evaluated for beef, pork, and poultry sectors, including producer surplus for four market chains for beef, three market chains for pork, and two market chains for poultry. Consumer surplus was also estimated. In beef, the largest losses were estimated to occur in slaughter and feeder cattle market chains. The most significant loss was projected to occur in the feeder cattle market in the scenario with the larger vaccination capacity and the smaller vaccination zone. The greatest welfare loss in the pork industry was predicted to occur with the small vaccination capacity and small vaccination zone. Within the retail poultry sector, the largest surplus gain was estimated to occur with the larger vaccination capacity and smaller vaccination zone followed by the smaller capacity and smaller vaccination zone, indicating the size of the vaccination zone was the more critical factor. Impacts on wholesale poultry were negligible. When overall producer and consumer surplus was projected, increasing the size of the vaccination zone and vaccination capacity both led to a lower surplus loss. Consumer surplus was estimated to experience the greatest loss when vaccination capacity was larger and vaccination zones were small. In general, the size of the vaccination zone appeared to make a more significant economic impact than capacity. The study was limited in that it only considered three scenarios and did not account for government costs for implementing a vaccination program (Ajewole, 2013).

In another companion study to the McReynolds (2013) research, Schroeder, Pendell, Sanderson, and McReynolds (2013) estimated the economic impacts of alternative FMD disease control strategies with a focus on emergency vaccination protocols. Changes in consumer surplus and returns to capital and management for producers associated with alternative FMD disease management scenarios were estimated. Economic impacts on producers, consumers, and government of alternative FMD vaccination strategies, vaccination capacities, vaccination-to-live versus to vaccination-to-kill, and vaccination zone sizes were evaluated (Schroeder et al., 2013).

A multi-market and multi-commodity quarterly partial equilibrium model of the United States agricultural sector that incorporates both vertical and horizontal linkages starting with livestock production through to the final consumer, including international trade and grain sectors is used in conjunction with the NAADSM epidemiological model. It was assumed all feedlot animals vaccinated would go to commercial slaughter. For all other animals, those vaccinated-to-kill were depopulated within the same the quarter in which they were vaccinated and those vaccinated-to-live remained in their herds. Government costs were also incorporated, including costs for euthanasia, disposal, cleaning and disinfection, indemnity costs for animals that are depopulated, and vaccination costs (Schroeder et al., 2013).

Consumer demand was assumed to decrease. In outbreaks lasting less than one quarter, a 5% reduction in domestic consumer demand for beef, pork, and lamb and a 2.5% reduction in milk and dairy product demand were projected. Meat demand began to recover in the second quarter but was still 2.5% below the base year and full recovery occurred in the third quarter. Milk and dairy product demand was estimated to fully recover in the second quarter. For longer outbreaks, the decrease in demand was basically doubled. Demand shocks were also incorporated to represent implementation of trade restrictions. U.S. exports of red meat (beef, pork, lamb meat) were estimated to decline by 95% and export of live animals (cattle, swine, and sheep) was assumed to halt completely during the outbreak and for one full quarter after the last FMD case under scenarios with no emergency vaccination and vaccinate-to-kill responses. With vaccinate-to-live, it was assumed trade restrictions were in place for two quarters after the end of the outbreak to be consistent with OIE guidelines. Full recovery was predicted to occur approximately two years after the outbreak ended (Schroeder et al., 2013). These were the same assumptions used in the National Bio and Agro-Defense Facility site specific study (National Research Council (NRC), 2013).

Feedlots were considered a priority for vaccination as was the case in the McReynolds (2013) research, so economic results are most relevant to a scenario where feedlot cattle are vaccinated. Under a stamping out with no emergency vaccination scenario, the loss to producers and consumers from an FMD outbreak was projected to be approximately $190 billion with an estimated additional $12 billion in government costs. The most optimistic median economic impact, a $56 billion loss to producers and consumers and $1.1 billion in government costs, was predicted to occur under a scenario with the large vaccination zone and vaccination capacity. Consumers and producers would experience additional losses of about $30 billion under an aggressive vaccination strategy if stamping out or a less aggressive vaccination strategy could effectively and rapidly contain the disease outbreak. Researchers noted that decision criteria to be used by animal health officials to distinguish outbreaks that can be contained rapidly by stamping out from outbreaks that are expected to be larger and longer lasting and require emergency vaccination would be valuable (Schroeder et al., 2013).

The size of the vaccination zone was projected to be more important than the vaccination trigger. Losses to producers and consumers declined by an estimated $70 billion (48%) when the vaccination zone was increased from 10 km to 50 km and by $15 billion (10%) when vaccination capacity increased. Whether animals are vaccinated to live or die, the vaccination trigger, and very low vaccination capacity has limited economic impact in this research. Further evaluation of vaccination zone sizes and capacities was determined to be needed and valuable (Schroeder et al., 2013).

Ex-ante and ex-post animal disease response strategy

Elbakidze and McCarl (2006) evaluated the economic impacts of pre-event preparedness versus post-event response strategies related to a large-scale animal disease outbreak in an attempt to identify the optimal tradeoff between preparation costs and occasional event damages. Decision makers are faced with the choice of investing in pre-event actions or doing nothing. At the time of an outbreak, they face decisions about the level of investment in their response efforts (Elbakidze & McCarl, 2006).

Decisions can be divided into six categories defining actions and activities: anticipation, prevention, detection, installation, response, and recovery. Vaccination can be included in prevention as a pre-event action or response as a post-event action. Response activities also include slaughter and carcass disposal. Some of these actions are irreversible, meaning once implemented these actions cannot be reversed and other strategies may in turn no longer be considered feasible. Others are conditional and can only be implemented if another step has already been taken. Some costs are fixed and others are variable in an outbreak. Most previous studies focused on post-event decision making, rather than pre-event decision making. In this case, focus was on the economic benefit of periodic animal health testing and results indicated investment would increase as probability of an outbreak increased and such investment would substantially reduce the economic effect of a disease outbreak (Elbakidze & McCarl, 2006).

Researchers at Texas A&M University found "carcass disposal generates a tremendous operational concern in the face of which society would try to minimize the loss from both disease management, facility investment cost and the adverse external costs induced by carcass disposal processes" (Jin et al., 2006, p. 2). They hypothesized that buying time for carcass disposal might be beneficial. A two-period and a multi-period model were used to study vaccination as a support strategy for slaughter and disposal in a disease outbreak. They modeled vaccination-to-slaughter as an alternative to slaughter policy combined with strict movement bans and optimized the number of animals to be slaughtered and vaccinated in each period. Cost and capacity of disposal, cost of slaughter and vaccination, incident size, disease spread by vaccinated and non-vaccinated livestock, and the assumption that all animals would eventually be slaughtered were factored into the model to minimize costs (Jin et al., 2006).

Results indicated a vaccination protocol gains time to reduce the flow of carcasses to slaughter and disposal while controlling the disease and, therefore, decreases slaughter and disposal cost. As the marginal cost of vaccination declines, the outbreak size increases, the disease is more contagious and spreads more rapidly, and vaccine efficacy increases, so vaccination becomes more cost effective. In addition, researchers assumed environmental costs decrease if the time pressure is removed from carcass disposal. Such an approach indicated policymakers could choose a response strategy with lower costs and less negative environmental effects. If policymakers preferred a vaccination alternative, researchers noted the ability to provide vaccines in a timely manner and negotiate trade barriers and policies are issues that need further discussion (Jin et al., 2005). Results indicate a new optimal disease control management system should be considered that establishes a "tradeoff between disease management costs and carcass disposal costs" (Jin et al., 2005, p. 4).

Research comparing ex-ante strategies of prevention and preparedness to ex-post strategies of response and recovery lend credence to the consideration of vaccination. Ex-ante strategies reduce the probability of a significant effect from an outbreak, but require investment in capability and infrastructure. Ex-post strategies are designed to limit spread of disease and reduce consequences through implementation of contingency plans based on diagnosis, disinfection, slaughter, and disposal. The goal in either case is to return to pre-event conditions as quickly as possible. The optimal balance between ex-ante and ex-post strategies depends on probabilities, event severity, cost, and strategy effectiveness. Ex-ante investment in animal disease proves more effective as the probability of disease outbreak increases, the disease spreads more quickly and is more contagious, the ex-post response is more costly, the damages are more consequential, and the target more valuable. Ex-ante activities are also more desirable when they are less costly, more effective, have greater co-benefits, and when the public is more risk averse (Jin et al., 2009). Industry leaders and policymakers need to consider if the long-term expenses tied to investment in disease control strategies is worth the economic payoff in the case of a disease outbreak (Swallow, 2012).

An exercise example

In Operation Palo Duro, a tabletop exercise addressing an FMD outbreak in the Texas Panhandle, vaccination was considered. USDA players activated the NAFMDVB on the first day. Texas animal health officials were notified they would receive 350,000 doses in one week and an additional million doses after an additional week. A request from exercise players to vaccinate rather than depopulate animals that were not showing clinical signs but were located on infected premised was denied by the policy group. The policy implemented was vaccinate-to-kill, but was actually vaccinate-to-slaughter. Beef cattle in feedlots were determined to be allowed to live until normal slaughter would occur, but dairy cattle were to be slaughtered as soon as feasible. A 60-day withdrawal period was established before vaccinated animals could be slaughtered. Farmers and ranchers were allowed to vaccinate their own animals under regulatory oversight. While a vaccination strategy was developed following the NAFMDVB decision tree, exercise participants noted additional strategic and operational concerns needed to be considered. The receipt, staging, storage, and distribution of vaccination were all identified as areas in need of further discussion. Expectations were that vaccination distribution would occur rapidly and players were surprised by the limitations on how quickly vaccine can be produced, the limited number of vaccines Texas would receive, and the time it would take for vaccines to be distributed. Players also noted the policy team should have more completely discussed and weighed the impact of trade restrictions versus disease eradication speed when selecting the vaccination policy approach (Giovachino et al., 2007).

Other Disease Examples

While the focus of the vaccination section has been dedicated to a discussion on vaccination as a response strategy to FMD, the use of vaccination as a control measure for avian influenza and classical swine fever are discussed in the next sections in a more limited manner.

Avian influenza

Historically vaccination has not been considered a viable response tool to AI and stamping out has been the preferred response strategy. Stamping out, the classical approach to HPAI control has been successful in countries such as Canada, the Netherlands, and Mexico. However, it has not proved effective in Egypt, Indonesia, China, Vietnam and Bangladesh (Sims, 2013). Typically, vaccination has not been used unless surveillance, biosecurity, depopulation, and movement restrictions have not been implemented effectively to control the disease outbreak (Berg et al., 2008). Cost, animal welfare issues in remote locations and poor countries, movement or sale of birds ahead of culling, and farmer resistance have been identified as the biggest challenges related to mass depopulation as a disease control method. Early detection, effective disease reporting, and surveillance systems are important to the success of stamping out in high density areas (Sims, 2013).

Due to HPAI, tens of millions of birds have died or been depopulated causing significant economic losses and creating animal welfare and ethical concerns (Capua & Marangon, 2007). Vaccination of poultry against HPAI can increase infection resistance, protect poultry from clinical disease, and reduce shedding if poultry becomes infected (Sims, 2013). However, AI vaccine research has not developed at the same rate as it has for other animal diseases (Capua & Marangon, 2007). Vaccination may not be effective alone as an AI disease control strategy, but has the potential to be used effectively with other control measures, such as biosecurity, surveillance, movement control, education, quarantines, and culling of infected birds. Vaccination-to-live and vaccination-to-kill approaches can be used as part of a vaccination strategy. The technical feasibility of vaccination, necessary funding, the types of species under consideration for vaccination, the impact on trade, market shocks, types of stakeholders involved and the availability of an effective, safe, and well-matched vaccine should all be considered in the decision to vaccinate (NAHEMS, 2011e).

Disease characteristics

Influenza viruses are segmented, negative strand RNA viruses and can be identified as types A, B, or C, and only A viruses can cause natural infections in birds. Type A viruses can be divided into subtypes of H and N, dependent on the antigenic characteristics of surface glycoproteins haemagglutinin and neuraminidase, respectively. Sixteen H subtypes (H1–H16) and nine N subtypes (N1–N9) have been identified. Those viruses that can infect poultry can be divided into two groups based on disease severity. HPAI is caused by a very virulent virus, results in mortality in some susceptible species, such as chickens, at levels as high as 100%, and is limited to strains belonging to the H5 and H7 subtypes. The impact on wild birds and waterfowl and their role as reservoirs of infection is more variable and less predictable. Viruses belonging to all subtypes (H1–H16) of a less virulent nature can cause low pathogenic avian influenza (LPAI), a localized infection resulting in a mild disease consisting primarily of respiratory disease, depression, and egg production issues. Researchers have concluded that HPAI viruses emerge from H5 and H7 LPAI by mutation or recombination after viruses have moved to poultry, however such mutation is unpredictable. Thus, not only are HPAI control strategies important, but LPAI outbreaks of the H5 and H7 subtypes in domestic populations must also be controlled effectively because they are potential precursors to HPAI (Capua & Marangon, 2007).

Strains of AI viruses change continuously, which is typically referred to as antigenic drift and can cause one virus to result in a number of variants. Incubation can last from a few hours to week. Shedding can begin within one to two days after infection. Backyard flocks can serve as disease reservoirs and can contribute to disease transmission. The AI virus can be shed in feces or respiratory secretions and transmitted via fecal-oral or aerosol methods. Vaccination can reduce virus shedding and decrease susceptibility of the vaccinated population to infection (NAHEMS, 2011e).

Vaccines can be inactivated, whole virus vaccines or recombinant vectored vaccines based on the H subtype. A vaccine with heterologous N subtype antibodies can be effective if the H subtype matches the outbreak strain. Otherwise, H and N subtype vaccines are not cross protective with other H and N subtype disease strains (NAHEMS, 2011e).

Previous use of vaccination

There have been 32 HPAI outbreaks since 1959, and 27 have been eradicated by stamping out without vaccination (Swayne, Spackman, & Pantin-Jackwood, 2013). The largest outbreak has been the H5N1 HPAI outbreak that began in China and spread to more than 60 countries or regions. While in many regions within this outbreak stamping out was successful, vaccination was used as an additional control strategy to reduce the clinical infection and help rural economies. Vaccine has been used to help control HPAI in the countries of Mexico, Pakistan, Hong Kong, Indonesia, China, Russia, Egypt, the Netherlands, France, and Vietnam. LPAI outbreaks that occurred before 2006 were not previously listed with OIE. LPAI became an OIE-listed disease because of its potential to mutate into an HPAI virus, as experienced in the US, Mexico, Italy, Chile, and Canada. Vaccines have been used in outbreaks of H5 and H7 LPAI in the US, Italy, Mexico, Guatemala, and El Salvador (Swayne, Pavade, Hamilton, Vallat, & Miyagishima, 2011).

Mexico first used vaccine against H5N2 HPAI in 1995, which lead to disease eradication and nationwide freedom from HPAI in December 1995. The H5N2 LPAI virus that served as its precursor continued, and vaccine is still used as a part of the LPAI control program. The second use of HPAI vaccine was in Pakistan against H7N3 later in 1995. The H5N1 HPAI virus initiating in China in 1996 was first detected outside the country in 2001 in Vietnam, led to large outbreaks in Indonesia and Korea in 2003, spread to an estimated 63 countries, and accounts for the greatest historical use of HPAI vaccine. Overall, from 2002 to 2010, 113 billion doses of HPAI vaccine were used in 15 countries. Approximately 10 billion doses were used to fight LPAI in six countries with the biggest users in order of doses being Mexico, El Salvador, Guatemala, and Italy (Swayne et al., 2011).

An outbreak of AI H7N3 in the Los Altos region of the Mexican state of Jalisco in 2012 was brought under control through the use of vaccination. The outbreak occurred in the country's primary egg production state that is home to 55% of the egg supply and more than 60 million layers. More than 22 million hens were lost in Jalisco leading to a loss of 15% of Mexico's egg production. Cooperative efforts between government, industry, and academia led to rapid disease identification and vaccine production. Once the seed virus was ready, four laboratories, one government, and three private companies produced vaccines and had 90 million doses available within a month (each bird requires two doses). Significant funds were contributed by the Mexican Poultry Association for vaccine production startup costs. The vaccine was only approved for the Los Altos region, which was also quarantined, and the vaccination response was seen as temporary. The region would not be declared disease free until the last vaccinated layer ended egg production and was culled (Wright, 2012).

Vaccination programs for HPAI were also effective in outbreaks in Italy and Southeast Asia (Egbendewe-Mondozo, Elbakidze, McCarl, Ward, & Cary, 2013). Starting in 1997, a number of H5 and H7 LPAI outbreaks occurred in areas of Italy with high poultry concentration. An HPAI outbreak emerged after the LPAI version circulated for 9 months in 1998. Initially all infected farms were depopulated, and vaccination programs were put in place over the following decade. In one case in Italy, however, an H7 virus spread extensively regardless of the use of vaccine (NAHEMS, 2011e). In Italy, development of a Differentiating Infected from Vaccinated Animals (DIVA) vaccination allowed for the use of a vaccination protocol without mass preemptive depopulation in eradicating two epidemics of LPAI (H7N1 and H7N3) in 2007 - 2008. It was used successfully with other restrictive measures and intense monitoring (Capua & Marangon, 2007).

In some parts of Asia and the Middle East, vaccination is a traditional part of disease control programs. Hong Kong has been dealing with HPAI since the 1990s. While success in other countries has varied and H5N1 viruses are endemic in a number of countries with poultry vaccination programs, Hong Kong has successfully eradicated numerous H5N1 HPAI outbreaks using stamping out with or without vaccination (NAHEMS, 2011e). In one case in Hong Kong, a DIVA strategy was used to stop the spread of HPAI to neighboring farms (Capua & Marangon, 2007).

China has used vaccination as a part of their official H5N1 control strategy since 2003 and mandatory vaccination of domestic poultry began in 2005. H5N1 HPAI continues to circulate in China. In Vietnam, vaccination reduced the reported number of AI outbreaks and human cases, but both continue at a less significant rate. Vaccination in Indonesia and Egypt has been less successful. The intensive surveillance and biosecurity necessary for a successful vaccination program may not be feasible in countries without the necessary resources and infrastructure to maintain these aspects of disease control (NAHEMS, 2011e).

In the US, AI vaccine has been used for years in some LPAI outbreaks (Breytenbach, 2007), but not in all cases. Vaccination has not been used in the US against HPAI because stamping out has proved effective (Capua & Alexander, 2008; NAHEMS, 2011c). Vaccine was used successfully to combat LPAI in Minnesota and Utah turkey farms in the 1990s, in California as a part of a voluntary control program in 2002, and in Connecticut in at a large commercial layer operation in 2003. In the Connecticut case, the projected benefit-cost ratio of vaccination to mass depopulation was 10:1, not including the business and social costs of depopulating 3.5 million layers. While the USDA approved vaccine usage, approval would have been withdrawn if trade restrictions were imposed. An inactivated H5 vaccine is licensed in the US for emergency vaccination purposes, but vaccines are expensive and do not offer cross protection between the 16 serotypes of AI (CFSPH, 2013c).

Economic and epidemiological research

In a survey of countries that had previously reported an AI outbreak but not used AI vaccines and would not plan to in future outbreaks, 24% indicated they do not use vaccination as a control measure because stamping out has been effective at eradication, 22% indicated vaccination does not prevent infection and creates clinically silent shedders, 17% mentioned the difficulty of differentiating naturally infected birds from vaccinated birds, 16% identified high costs of vaccine and vaccination, and 14% mentioned trade restrictions. When the countries that have vaccinated were surveyed on why they had used or planned to use vaccination, 29% indicated stamping out was not an adequate control measure, 24% mentioned the widespread nature of the outbreaks, 13% noted the high risk of disease spread, and 9% indicated the importance of protecting valuable birds (Swayne et al., 2011).

In a companion study to research on FMD and CSF completed by Wageningen UR, the Netherlands research team evaluated the impact of control strategies on HPAI. The EU minimal control strategy requires the depopulation of infected farms, regulation of transport, implementation of protection and surveillance zones, and tracing of dangerous contacts. An epidemiological model is used to compare the EU control strategy and four alternative response strategies, including preemptive culling in 1-, 3-, and 10-km rings around infected farms and emergency vaccination within 3 km. Culling and vaccination capacity, premature slaughter on broiler farms, combination approaches, vaccination coverage, and hobby farm strategy were also considered. The EU strategy was not predicted to be effective at halting an HPAI outbreak in densely or moderately populated areas, but was estimated to be sufficient in sparsely populated areas. Although projected to lead to more infected farms, preemptive culling was estimated to reduce the epidemic duration. Emergency vaccination was expected to minimize the epidemic's effects but does not shorten it. If culling capacity is limited to 20 farms per day, infected farms could be culled within one day of detection of infection. But, expanding the radius for preemptive culling from 3 to 10 km was predicted to be ineffective due to the same limit on culling capacity. Preemptive culling in an inner ring combined with vaccination strategies in an outer ring was estimated to be no more effective than culling only (Backer et al., 2011).

Economic analysis included costs related to compensation for culled poultry and welfare slaughter, depopulation, tracing, screening, vaccination, surveillance, and monitoring vaccination efficacy. Culling around infected farms within 1 or 3 km is estimated to be optimal for eradicating HPAI from an economic perspective. Vaccination within 3 km led to estimated lower costs than the EU minimal strategy or culling within 10 km, but it was predicted to lead to larger and longer disease outbreaks. Backer et al. (2011) determined the optimal policy choice for responding to HPAI is between preemptive culling and vaccination. The decision has large financial and economic implications and socioethical consequences because the choice is between accepting larger animal death loss versus extended trade restrictions.

Epidemiological models and ex-ante economic analysis can also be used to help develop contingency plans for responding to an HPAI outbreak. The goals of a study by Longworth, Mourits, and Saatkamp (2012a & 2012b) was to provide an economic rationale for epidemiological models, a transparent description of the parameters in a spatially based epidemiological model for analyzing HPAI control strategies in the Netherlands, and a discussion on the validity and future use of the model. The model is intended to provide science-based information to decision makers to help them make rational and informed choices for disease control. Overall financial and economic effects included direct costs (disease control, culling, compensation, vaccination, surveillance, and organizational costs), direct consequential costs (originated from derived control measures, production losses, restocking loss, and business loss), indirect consequential costs (market distortion and price effects), and aftermath costs (price changes due to massive restocking, production under capacity, and attempting to regain market share) (Longworth et al., 2012a).

InterSpread Plus (ISP), a spatially based stochastic and dynamic simulation model, was the modeling framework used to evaluate eight HPAI disease control strategies in three regions (high-, medium-, and low-density poultry regions) of the Netherlands. In addition to costs, the model looked at the number of infected premises and the duration of the outbreak. The baseline strategy was based on the EU strategy including depopulation of infected farms, 0-3-km protection zones and 0-10-km surveillance zone around infected farms, tracing of contacts, screening within the protection zone, and movement restrictions on live poultry, eggs, manure, and persons. Additional strategies considered were a 72-hr movement standstill, preemptive culling within 1 km, preemptive culling within 2 km, vaccination within 3 km, vaccination within 10 km, and preemptive culling within 1 km combined with vaccination outside the depopulation zone and within 3 km. In addition, a preventive vaccination strategy is applied to high-density and medium-density areas not affected by HPAI with preemptive culling within the infected areas. Results indicated the baseline EU minimal strategy was not the best option. Preemptive culling within 2 km was estimated to outperform culling within 1 km on disease spread, duration, and economics. Both combinations of culling and vaccination were predicted to result in lower economic costs, shorter duration of disease, and fewer infected farms than the vaccination-only scenarios. When comparing the two combination strategies with the 2-km culling strategy, the culling strategy provides better estimated results. In high-density and medium-density areas, the combination of vaccination and depopulation was predicted to be competitive with culling only. In low-density areas, preemptive culling only was the preferred option based on the estimated outcomes. However, in any of these cases, if depopulation capacity needs could not be met, costs were predicted to increase and it would likely be less than optimal. In addition, the images and actions of culling would potentially result in socioethical concerns, but it does result in fewer estimated farms being depopulated. It also predicted to result in fewer trade distortions. Authors are also working on efforts to mitigate the economic impact by lowering indirect consequential and aftermath costs (Longworth et al., 2012b).

The economic effectiveness of vaccination in responding to HPAI was evaluated by simulating an outbreak in the Texas poultry sector. AI strains are classified as low pathogenic and highly pathogenic, which includes H5 and H7 subtypes. Current U.S. guidelines for dealing with HPAI depend on flock sampling, movement controls, and depopulation, but the OIE has also suggested vaccination as a possible response. Vaccination may reduce the number of birds depopulated and slow disease spread. Vaccine using dead microorganisms is preferred to those containing live virus. An integrated model was developed allowing for simultaneous consideration of economic and epidemic factors. The goals of the research were to help producers and policymakers develop response plans (Egbendewe-Mondozo et al., 2013).

Two control strategies were compared, one based on traditional guidelines and one including vaccination. Low, medium, and high flock density were examined and the model included chicken, egg, and turkey product markets with broiler, small layer, large layer, turkey, and barnyard flock production facilities. The findings indicate vaccination is most effective in high-density regions and its effectiveness declines as flock density decreases. In high-density regions, the length of the outbreak was estimated to be reduced from 43 days to 34 days with vaccination. Vaccination created fewer predicted benefits in low- and medium-density regions. While the estimated reduction in duration of the outbreak reduced projected costs when vaccination was used, the actual cost of vaccination and relevant administrative costs was predicted to offset the savings. The policymakers' risk aversion is critical to determining the best response strategy in a situation. Traditional response methods were preferred in high-density regions if a policymaker was more risk neutral. In other cases, for a policymaker with a higher aversion to risk, vaccination was preferred. Researchers determined flock density and the risk preferences of decision makers are key to determining if vaccination should be used. They noted the lack of quantitative information about policymakers' risk preferences affects their ability to make specific policy suggestions. The study only examined the poultry sector, but effects would also be seen in commodity markets, tourism, restaurants, and other industries impacted by poultry production (Egbendewe-Mondozo et al., 2013).

Sims (2013) considered various AI intervention strategies with a focus on stamping out and vaccination. The use of multifaceted response approaches in the past makes it challenging to conclude a causative effect from a single response measure. The same measures may be applied in one situation successfully but may be applied in other regions where AI becomes endemic. It is also unlikely any single measure will prove successful in controlling an AI outbreak. The manner in which the measure is applied can also be a critical factor. A whole chain approach was also recommended, meaning that how birds are raised and sold may strongly influence the duration and severity of disease outbreaks (Sims, 2013).

Considerations and challenges

Emergency vaccination for AI is now considered by some a viable option to stop disease spread (Capua & Marangon, 2007). Vaccination in poultry increases resistance to viruses, protects against clinical signs and potentially death, reduces shedding levels, improves transmission dynamics, protects against changing virus, and can be used in combination with depopulation to help control AI (Benson et al., 2009; Berg et al., 2008). AI viruses may still result in infection and disease replication without clinical signs (Capua & Alexander, 2008). Vaccination is not effective as the only control measure, but can be powerful if used with other control measures such as culling and biosecurity protocols (Alphin et al., 2010; Capua & Marangon, 2007; Sims, 2013).

Vaccination of poultry can help reduce the risk of transmission to humans by decreasing the quantity of circulating virus. Vaccine can also be used to protect valuable birds or those with high risk of infection. Emergency vaccination plans need to be in place before an outbreak occurs. Some studies indicate emergency vaccination has limited benefits or would not be necessary to stop disease spread, but how the vaccination program is managed will make a critical difference. The most critical factors are timing, quality, number of doses applied, concurrent diseases, species, and if vaccination actually occurs. Biosecurity, communication, movement control, and disinfection protocols can all be important as well (Sims, 2013).

Vaccination can provide an alternative to mass depopulation and disposal in an AI outbreak. The effectiveness of a disease control program incorporating vaccination depends on variables such as density of poultry flocks, level of biosecurity, industry integration, and characteristics of the virus strain. Vaccine availability, capability to administer quickly and adequately, and other practical and logistical concerns must be considered when determining if vaccination should be used. Compartmentalization rather than zoning may work better in an AI outbreak because the size and dimension of the vaccination zone will be impacted by transmission rate, disease spread during the high-risk period, and functional interconnections between zones (Capua & Marangon, 2007).

There are limitations related to the use of vaccination in AI disease control. It will not totally prevent infection, so infection could be masked and birds could spread the disease without showing disease symptoms potentially resulting in a longer outbreak. Vaccination may create a false sense of security and create a lax application of biosecurity measures leading to greater disease spread if infection does exist. The influenza virus can mutate rapidly and it is possible vaccination may actually promote mutation (Berg et al., 2008).

Another concern is the time it takes for immunity to develop. It takes a minimum of 7 to 10 days for the onset of an immune response, and more than two weeks may be required before vaccinated poultry have protective antibody levels. Decisions must be made quickly and vaccines must be immediately available (Capua & Marangon, 2007).

An AI vaccination system may need to include the capability to detect field exposure within the vaccinated flock in order to be effective. When conventional inactivated vaccines are used, the testing of unvaccinated sentinels can serve the purpose of detecting field exposure but such a process is likely to be impractical. Other systems are in development that can detect if a vaccinated bird has been exposed to a field virus through the creation of certain antibodies. A DIVA vaccine for LPAI H7 subtypes has proved successful in eradication and allows detection of field exposure. Antibodies amongst subtypes (e.g. H7) are cross-protective and can be used to ensure against clinical infection, create disease resistance, and reduce shedding from one variation to the other (i.e. a vaccine containing H7N1 can be used against H7N3) (Capua & Marangon, 2007).

Recombinant vaccines have been developed that protect chickens against exotic Newcastle disease (END) and AI. In addition, one allows differentiation between vaccinated and naturally infected animals (CIDRAP, 2006). An egg-injected vaccine for AI has been developed that could potentially reduce the spread of HPAI in large poultry operations. It provides a high-degree of protection if the strain has been determined and used in formulation (Hoerr, 2007).

While new vaccines and vaccine types are under development, future research and development of next generation vaccines and field studies needs expanded. Cost-effective and efficient AI vaccines are needed that can be applied in emergency mass depopulation efforts through methods such as spray or drinking water and that provide strong local immunity (Berg et al., 2008).

Prophylactic vaccination is an innovative concept that could be used to create a level of protective immunity that can be boosted if a field virus or emergency situation occurs. Such an approach could allow for fewer animals to be depopulated, limit disease spread in an emergency, improve animal welfare, and reduce the severity of economic losses from an emergency disease situation. It does not have to be considered permanent state but could be used in regions with higher density poultry production that are more at risk for an AI outbreak (Capua & Marangon, 2007).

Regardless of the successes that have occurred in controlling AI, legislative and scientific uncertainties over issues such as time until onset of immunity, vaccine efficacy, and ability to differentiate vaccinated birds from naturally infected birds make governments reluctant to consider vaccination, primarily because of the international trade implications (Capua & Marangon, 2007). In the case of LPAI, concerns also exist over the vaccine's ability to mask disease symptoms and hide an early warning of a mutation to HPAI (Breytenbach, 2007). Most vaccine failures are a result of the vaccination plan and process (Swayne et al., 2013). Cause and effect relationships between control measures and disease control are immersed in uncertainty and subject to knowledge gaps making it difficult to understand the effectiveness of vaccination in AI disease control (Sims, 2013). Vaccination may best be seen as a strategy to help maximize the effectiveness of other control measures, rather than as an exclusive method of disease control (Capua & Alexander, 2008).

Classical swine fever vaccination

Vaccination has had limited use as a control measure with classical swine fever (CSF) but has the potential to decrease virus circulation and reduce the economic and epidemiological impact of the disease outbreak. Vaccine may be used in a vaccinate-to-live, vaccinate-to-kill, or a vaccinate-to-slaughter approach. Vaccination can be applied in a number of manners, prophylactic (routine), emergency (protective or suppressive), targeted, ring, barrier, or blanket vaccination.

Disease characteristics

CSF is a small-enveloped, single-stranded RNA virus. There is only one serotype, but variability has been shown to exist. All species of domestic, feral, and wild pigs are susceptible. Viral shedding can occur before clinical signs appear and continue through the course of clinical and subclinical disease. Transmission can occur by oral or oronasal routes through direct and indirect contact; saliva, lacrimal secretion, blood, urine, feces, and semen; feeding uncooked contaminated garbage; genital transmission or artificial insemination; fomites; and airborne passage. Incubation lasts from 2-14 days, depending on disease virulence, infection route, and dosage. CSF virus can survive in the environment and in pork products for months, adding to its ease of transmissibility (NAHEMS, 2012b).

While CSF was eradicated in the US in 1976 and is not present in Canada, New Zealand, Australia, and many regions of western and central Europe, it remains endemic in many other regions of the world (NAHEMS, 2012b).

There is no inactivated whole virus vaccines deemed effective or available for use. Live attenuated virus and modified live virus vaccines are the most typical vaccines for CSF vaccination. Live-attenuated virus vaccines do not allow for differentiation of vaccinated animals from naturally infected animals, but a modified-marker vaccine creates antibodies that are distinguishable. Because there is only one serotype, vaccine matching is not required (NAHEMS, 2012b).

Previous use of vaccination

In outbreaks in the Netherlands, England, and Belgium, vaccination was not used, but has been used in Brazil, Bulgaria, Israel, Korea, Mexico, Romania, and the US (NAHEMS, 2012b).

Prior to 1990, vaccine was used extensively in Brazil. At that time, the country was divided into different regions based on presence of CSF. In the region where CSF was endemic, vaccine was mandatory, and vaccine was prohibited in the CSF-free areas. By 1998, due to success of the disease control program, vaccine was prohibited throughout Brazil. Brazil was and is currently divided into two regions, one free of CSF and one where CSF was endemic. Between 2001 and 2009, a number of CSF outbreaks occurred and they were contained by disinfection, quarantine, and stamping-out. These measures were not effective at controlling outbreaks in 2009 and vaccine was approved for use in the CSF-endemic region. Approximately 90,000 pigs were vaccinated (NAHEMS, 2012b).

In Bulgaria, CSF was identified in 2000. Emergency vaccination was approved in 2006 with the intent to eradicate CSF. In 2008, a vaccination program including wild boar was initiated, but in 2009, CSF was still found in the wild boar population. Germany experienced a large number of CSF outbreaks in the 1990s and the EC approved the use of vaccines in 2002. The Netherlands had been CSF free for 10 years before an outbreak occurred in 1997. Over the next year, 11 million pigs were destroyed and vaccination was not used. In Romania, from 1974-2001, vaccination was mandatory. Vaccination was prohibited beginning in 2002 and 38 cases were diagnosed that year. In the following year, the number of cases continuously increased. After 1,393 cases were identified in 2006, Romania received approval to vaccinate and the vaccination program began the following year. In 2009, four million pigs were vaccinated. Vaccination was discontinued in 2010 except for the vaccination of wild boar within 20 km of the borders. In Great Britain, vaccine can be used in coordination with other control measures such as stamping out and disinfection, but the decision was made not to use vaccine in a 2000 CSF outbreak and 75,000 pigs were culled (NAHEMS, 2012b).

A CSF outbreak occurred in Israel during 2009 in domestic pig and wild boar populations. Vaccination was not used in 2009 although it was considered an acceptable alternative for disease control, 500 doses were used in 2010. In Korea, CSF was first diagnosed in 1908 and became endemic by 1947. Cases decreased starting in 1967 due to the use of vaccine, but full eradication strategy was not initiated until 1996. The strategy involved increasing vaccine usage and culling of infected animals with the intent of decreasing the number of outbreaks, followed by implementing mandatory vaccination, and resulting in CSF-free status without vaccination. In 2001, disease-free status was achieved and vaccination was prohibited. In 2002, CSF was again diagnosed, eventually resulting in the implementation of a national vaccination policy (NAHEMS, 2012b). Mexico was divided into three regions in 1996, a CSF-free zone and an eradication region where vaccination was prohibited and an infected area where vaccination was mandatory. The first outbreak in the eradication zone since the regionalization occurred in 1998, and a marker vaccine was used to prevent disease spread. Researchers found it to be successful in reducing clinical signs and limiting new outbreaks. An outbreak occurred in 1999 in the disease-free region and was eradicated with quarantine, stamping-out, and movement controls; vaccine was not used. CSF outbreaks occurred regularly in the eradication and infected zones by 2000, and vaccination was used in disease control. The country was then divided into two zones, disease free and endemic. From 2002-2004, Mexico had 15 outbreaks, two in 2005, zero in 2006-2008, four in 2009, and none in 2010-2011. In 2009, animals were destroyed and vaccination was not used (NAHEMS, 2012b).

In the US, vaccines were used to control CSF in the late 1800s and continued to be used in the 1900s. Safer vaccines became available in the 1950s leading to the prohibition of the use of virulent hog cholera virus in 29 states by 1959. An eradication program was approved in 1961. Vaccine usage began to be phased out in 1969 when the USDA prohibited interstate movement of CSF modified live virus vaccine with the goals of the elimination of all vaccine usage by 1970. Quarantine and depopulation were used more aggressively and by 1975 all states reported to be in the final program phase of protection against reinfection. In 1978, the US was declared CSF free (NAHEMS, 2012b).

Economic and epidemiological research

Mangen, Nielen, and Burrell (2002) used four inter-linked models and a spreadsheet to model epidemiological and economic consequences of a CSF outbreak and control strategies in the Netherlands with a focus on livestock population density. InterCSF, a spatial, dynamic stochastic epidemiological model, was used to estimate daily disease spread and incorporate various disease control measures. EpiPigFlow, a deterministic farm-level model, aggregated daily production figures. EpiCosts, a sector-level, partial-equilibrium model estimated market and trade effects. DUPIMA, a deterministic farm-level model, was used to calculate control costs based on response measures implemented. The spreadsheet was used to calculate economic welfare changes (Mangen et al., 2002; Mangen, Burrell, & Mourits, 2004).

Sparsely and densely livestock populated areas were compared under four control strategies and two trade assumptions. The EU directive of stamping out infected herds, tracing all contacts, and imposing quarantines was the baseline control measure. The other three control measures compared were preventive depopulation within 750-1,000 m of the infect herd, the addition of emergency vaccination-to-cull, and emergency vaccination-to-live with intra-community trade allowed after quarantines expired. The EU control baseline was assessed to be enough of a control measure if outbreak began in a sparsely populated area but additional measures were found to be necessary if the outbreak began in densely populated area. The economic impact of preemptive culling compared to emergency vaccination depended on whether the trade ban was applied to only quarantine zones or the whole country. If trade continues outside the quarantine zone, then emergency vaccination-to-live was estimated to be the most economically successful but increases risk of larger disease spread and greater economic losses if trade ban is comprehensive. Therefore, the researchers concluded preventive slaughter was the most economically rational if CSF occurred in a densely populated area (Mangen et al., 2002).

Mangen et al. (2004) used the same suite of models to discuss disease control measure selection based on the epidemiological and economic effects of the 1997-98 CSF outbreak in the Netherlands. Researchers assumed policymakers used multicriterion approaches to make disease control policy decisions with an emphasis on epidemiological indicators, public expenditures, producers' costs, and economy-wide welfare impacts. Thus, they attempted to quantify and integrate all decision factors to allow for the comparison of different control strategies (Mangen et al., 2004).

Backer, Hagenaars, van Roermund, and de Jong (2009) studied the Dutch contingency plan policy preference of emergency vaccination over mass depopulation in a CSF outbreak. A stochastic model incorporating within-herd dynamics based on virus transmission and the effect of marker vaccination on individual animals was used for strategy comparison. This individual-level model was then combined with farm-level and national level models. This multilevel approach allowed for evaluating the effect of vaccination of individual animals on a national epidemic in regard to control strategies. The EU minimal strategy of restricted zones, 72-hr livestock transportation standstill, culling of infected herds, and contact tracing was compared to preemptive culling within 1 km and emergency marker vaccination in rings with radii of 1 km, 2 km, and 5 km (Backer, Hagenaars, et al., 2009).

The number of herds infected, culled, and vaccinated and the duration of the outbreak influenced the socioeconomic effect of an outbreak. The animal welfare perspective was also influenced by the duration of the outbreak and the number of infected herds. All models assumed vaccinated meat could be sold within the EU according to EC requirements. The EU minimal strategy was the least effective and resulted in the largest and longest disease outbreaks. When comparing depopulation and vaccination within 1 km only, preemptive culling is more effective. When vaccination was extended to 2 km, results were similar to culling within 1 km. From an epidemiological perspective, the 5-km vaccination strategy resulted in the smallest and shortest outbreak. Vaccination allowed for fewer animals to be destroyed. The duration of the epidemic from first detection on infection to substantiation of disease absence through screening was the most critical factor to animal welfare and economics. When considering welfare and economics, overall results showed that vaccination was the preferred control strategy with a sufficient ring radius to minimize outbreak duration (Backer, Hagenaars, et al., 2009).

Mourits, von Asseldonk, and Huirne (2010) used multicriteria decision making to compare contagious animal disease control strategies in the EU with specific focus on epidemiology, economics, and social ethics. The goal of EU animal disease control strategy is to achieve "a high level of animal health and animal welfare without compromising the functioning of the internal market" (Mourits et al., 2010, p. 203).

While the analysis was intended for use with numerous diseases, they specifically analyzed control strategies related to CSF. The EU compulsory measures of depopulation and disposal of pigs in a defined zone, surveillance zones, and movement restrictions served as a baseline. Alternatives considered included preemptive slaughter within a predefined radius, suppressive vaccination (vaccination-to-kill) within a predefined radius, and protective vaccination (vaccination-to-live) within a predefined radius. Strategies were applied in six regions defined by herd density, average herd size, piglet production per sow, revenue prices, feed prices, and production costs (Mourits et al., 2010).

The epidemiological indicators included in the analysis were duration of the epidemic, number of infected herds, size of the infected region, number of animals destroyed, and number of herds destroyed. The economic indicators considered were direct costs and farm losses, consequential revenue losses due to idle production in the region, losses in related industries such as slaughterhouses and processing plants, organization and control costs, exports within the EU, and exports outside of the EU. The social-ethical indicators identified were efficacy, social and psychological impact, macroeconomic impact in export interests, impact on related commerce and commercially interested parties, animal health, and animal welfare. To establish the decision context, European chief veterinary officers were asked to identify the most important criteria. The individual animal health officials differed in their opinions of most important criteria to affect decision making on control strategies. They found the epidemiological criteria to be most important with an average relative weight of 52%. The economic and social-ethical criteria received weights of 30% and 18%, respectively. The two most important epidemiological factors were duration of the epidemic and number of infected herds. Consequential farm losses and export restrictions were considered the two most important economic factors, and efficacy and socioeconomic impact were considered the two most important social-ethical indicators. In the survey of officials, some factors were eliminated because of their low rankings, including number of non-farm animals destroyed, consequential farm losses outside the affected region, losses to non-related industries such as tourism, tax payer contribution to solution, tourism social-ethical impacts, health and welfare of non-farm animals, human health impacts, consistent government policy, impact on animals' natural lifecycle, and exclusion of animals products from human consumption. Researchers also assumed a risk-averse approach (Mourits et al., 2010).

The EU baseline was not sufficient in disease control for high-density regions in the epidemiological model and was not considered in further analysis. In these regions, suppressive vaccination was the dominant strategy from an economic perspective. In low- and medium-density regions, the EU baseline was the best economic alternative. In regard to the social-ethical perspective, protective vaccination was the dominant strategy in four regions and the EU baseline was dominant in the other two. In four of the six regions, protective vaccination was the preferred control method, while the EU baseline and preemptive culling were each preferred in one region. When considering total dominance over all factors, the EU baseline strategy was preferred in three regions, all of which had average herd sizes of more than 900 head and had moderate population density. In the remaining moderately dense region, protective vaccination was the dominant control strategy. Preemptive slaughter was the preferred strategy in the two high density exporting regions, with protective vaccination a close second. Because vaccinated animals were required to be culled, suppressive vaccination always dominated from an epidemiological view due to low scores on number of destroyed herds and animals, and it was the least successful strategy in overall dominance for all regions. These results indicated strong consideration needs to be given to region-specific control strategies (Mourits et al., 2010).

Policy Considerations and Implications

"Complex decisions made under time pressure and uncertainty" such as the decision to vaccinate must be based on sound evidence (NZFMG, 2011, p. 32). The benefits and limitations of vaccination programs must be clearly understood by policy and decision makers. Previous cases where vaccination was unnecessary, such as the 2007 U.K. FMD outbreak, or cases where vaccination did not result in the desired outcome, such as the 2010 Japan FMD outbreak, provide lessons for decision makers. In New Zealand, industry and government are working together to draft a revised FMD vaccination policy based on evidence available (NZFMG, 2011).

Analysis based on sound science and lessons from recent outbreaks will be critical as decision makers utilize decision making criteria and analytical tools to develop animal disease policy (Hagerman et al., 2012). Better decision-support tools are critical to making response decisions (Paton et al., 2009). Logical decision processes that consider the scientific, economic, political, and practical considerations unique to individual outbreaks are necessary. Decisions cannot be entirely science based, and the goal should be to eliminate the disease and the negative economic impacts (DeHaven, 2003). "The decision to use, or not to use, a vaccine in the face of a foreign animal disease outbreak can be complex and have far-reaching socio-economic consequences. Incorrect decisions or delays occurring during the actual outbreak can be costly" (DeHaven, 2003, p. 282).

Decision makers must determine how important it is to stop disease spread immediately and the most cost-effective method for stopping disease spread. The industry's ability to return to disease-free status will likely drive these considerations (DeOtte & DeOtte, 2009). "…government policies on how to respond to FMD are not related in any way to the seriousness of the illness in an animal or herd; they do not depend on animal health, welfare, pain or suffering. They are purely financial…" (Breeze, 2004, p. 253).

The decision to invest in vaccination and implement vaccination protocols needs to happen in the planning stages to create the least economic disruption (McLeod & Rushton, 2007). Adequate vaccine stocks along with criteria for vaccine usage and dispersal must already exist if vaccination is to be considered as a response mechanism in an FAD outbreak (Hugh-Jones & Brown, 2006).

Before deciding to vaccinate, a number of factors should be considered including, but not limited to:

- Technical feasibility of vaccination;
- Funding availability of full-scale vaccination program;
- Accessibility of a safe, well-matched, sufficiently potent vaccine;
- Number of times vaccine will need administered;
- Adequate supply of the vaccine identified for full-scale deployment;

- Availability of DIVA tests;
- Logistics of vaccine administration;
- Adequate number of trained personnel; and
- Resources and technology needed for related activities, including identification, traceability, movement permitting, and serological surveillance (NAHEMS, 2011d).

The epidemiology of the outbreak, such as the disease and disease strain, the length of time since outbreak began, geographic disease distribution, species, number of animals affected, geographic and environmental impacts on disease spread, and wildlife and feral populations at risk have to be taken into consideration. Pros and cons of vaccination should be weighed accordingly, including trade and export impacts, market shocks due to shifts in consumer confidence, marketability of products from vaccinated animals, existence of genetically irreplaceable stock, vulnerability of endangered species, extent of outbreak, disruption of tourism and other activities, impact on local economies, and "types of stakeholders affected (e.g. small-scale operators with limited safety nets vs. large-scale operators)" (NAHEMS, 2011d, p. 60). Virus identification needs to be initiated within the first 24 hr of the outbreak even if the decision has not yet been made to vaccinate (Zack, 2013).

The scientific and technical considerations related to vaccination will not be the only issues considered when deciding to use vaccination as a response strategy. "Political and economic decisions that take into account matters beyond technical advice on disease control can also influence the selection of control measures…" (Sims, 2013, p. 16).

It is clear animal disease control will be costly in actual expenses, livestock culled, and welfare loss. Risk management evaluation can play an important role in policy development. Multiple metrics need to be considered because it is possible one metric may suggest one policy while examination of another metric may support a contradictory approach (Hagerman et al., 2012).

No control measure is perfect, so any successful disease control strategy must involve multiple components. These choices depend on the epidemiological situation, access to financial resources, and the need to recover disease-free status for trade purposes. For a country that is disease-free and does not practice routine vaccination, the primary strategy should be the elimination of disease and interruption of contact between infected and susceptible animals allowing for a quick return to disease-free status (Leon, 2012).

Chapter 5 - The Role and Methods of Policy Analysis

Policymakers have the responsibility to reach conclusions and act on behalf of society based on the information available and the best assumptions at the time when faced with decisions (Doering, 1994).

If there is no conflict, disagreement, or controversy, there is no public policy decision to be made. Public policy issues can be characterized as involving problems that require group decisions and are influenced by value judgments, being of broad interest and concern, dealing with controversial matters, and tending to be identified as problems by decision makers (Barrows, 1983; Beaulieu, 2000; Flinchbaugh, 1988).

Policymakers are often faced with difficult choices among several alternatives to solve a policy problem. Rarely is the choice between action and inaction. Alternatives need to be narrowed and ranked. The goal of policy analysis is to help decision makers make policy choices effectively, ethically, and intelligently. A policy choice is one with an outcome critical enough it deserves debate and analysis. In turn, policy analysis allows for the use of reason and evidence to compare policy alternatives, evaluate tradeoffs, and select the best policy choice (Bingham & Ethridge, 1982; McRae & Wilde, 1979).

Government policy depends on leadership, organization, and analysis. Structured policy analysis is designed to reduce uncertainty about the consequences of alternatives and provide data to facilitate and guide decision makers' processes and choices (Quigley & Scotchmer, 1989). "Policy analysis is an integrative and adaptive process with respect to available knowledge and data" (Farrell, 1976, p. 768). Lynn (1999) referred to policy analysis as the "craft of governance" based on "intuition, argument, and ethical promptings" (p. 411).

Decision making is about achieving set objectives through the allocation of resources, and decision analysis methods are designed to provide decision makers with structure as they evaluate alternatives, uncertainties, and outcomes. A decision maker's approach to risk will likely influence their decision process as well (Spradlin, 1997).

Any decision making process requires consideration of tradeoffs. Public policy tradeoffs are challenging and require continuous evaluation. Policymakers must evaluate choices, implement the optimal selection, and then use new information, values, and goals to tweak policy approaches (Lindblom, 1959; Maness, 2007). As Earl Butz (1989) noted, "The very essence of democratic government is a trade-off among competing interests to reach consensus in legislation or in regulation to maximize the common good" (p. 1195). Any decision support tool needs to provide guidance on how to make tradeoffs when benefits for one group of stakeholders conflict with benefits for another group (Holland, 2005).

Policy choices cannot be based on singular discipline science alone; they must include ethical or philosophical consideration as well as intuitive and nonscientific knowledge. Policy deserving of analysis typically falls into a realm of action and, instead of drawing from just one discipline, combines several disciplines. Typically, values will be in conflict and tradeoffs must occur for a resolution. Consequences need to be considered in determining the policy's effectiveness. Imagination plays a role in policy analysis, because new ideas or solutions may be possible. However, at the same time, practicality of what can be accomplished in a political environment is also necessary. It may also be necessary to distinguish between desirability (the most preferred option) and political feasibility (what can be enacted). The value of the policy is the combination of both. At times, desirability and feasibility may be in conflict. Analysis must look at all that is possible compared to what is practical. Creativity and political feasibility may be contradictory, but are both required for policy analysis (McRae & Wilde, 1979).

Public policy is governmental decision making between choices, levels, combinations, and potentially controversial alternatives with a focus on finding the optimal solution that maximizes benefits and minimizes costs (maximizing net benefits). This concept is approached differently depending on if the alternatives have a logical order. If the alternatives do not have an inherent order, policy making is also influenced by the existence or lack of contingent probabilities. In the case of no probabilities, policy goals need to be weighted relative to each other to develop a comparison and make an optimal selection between alternatives (Nagel & Neef, 1978).

Policymakers often see themselves as decision makers, but few make decisions completely independently. They use decision processes comprised of rational choices based on evidence, compromise, and balance between competing resources (Trostle, Bronfman, & Langer, 1999). Public policy is intended to improve efficiency or equity as a result of the decision process. An efficient policy decision maximizes benefits over costs, while equitable policy focuses on equal distribution of benefits (NCEDR, 2002). Analysis provides the organization of knowledge in an orderly manner allowing for the clarification of options (Trostle et al., 1999).

Knowledge and capability are critical. Effective policy must consider both (Premashthira, 2012; Paton et al., 2009).

Analysis of a policy decision dealing with a complex problem is critical to quality decisions, which is influenced by the process of how the decision is made in addition to the outcome itself. Quality decisions start with defining the appropriate frame and solving the right problem, identifying all alternatives by being creative, having all possible information, knowing the highest ranked values, using logical reasoning, and committing to action (Shachter, 2008b).

Attributes of Decision Makers and Decision Making

Decision makers formulate questions and seek the necessary information to make timely, quality decisions in a process matching their personal preferences and style. They must balance the desire to make decisions in the best public interest with the need to find consensus among conflicting options within the given time frame and limited resources available. Information can either be pushed on policymakers or pulled in by them. Decision makers typically fall in three categories: those who gather information from lots of sources but apply selective filters to avoid information overload, those who place tight filters on incoming information and are largely influenced by experience and instinct, and those who immerse themselves in all available information and data in order to be as well informed as possible. The style of decisions makers can vary as some are slow learners and others quicker and more intuitive, some are deliberate in their decision process and others more volatile or dynamic decision makers, and some are more rational and others more irrational decision makers (Teitelbaum, 2005).

Decision makers are required to make decisions when critical information, time, and resources are unknown or constrained (Hagerman et al., 2012). It is unlikely a decision maker will have time to personally collect and assimilate data, and they are often forced to make decisions under significant uncertainty. It is also unlikely they can devote all of their time to any single issue so decisions are always competing with other issues also deserving consideration. Time constraints and resources are almost always limited which affects the decision makers' access to complete and timely information. Their goal is often to reduce uncertainty, and information can serve that purpose. Successful policymakers link knowledge with action in order to select the best policy, but this becomes increasingly difficult as the complexity of the issue increases (Teitelbaum, 2005).

Complex decisions can be analyzed by considering eight elements: problem, objectives, alternative courses of action, consequences, tradeoffs between conflicting objectives, uncertainty, risk tolerance, and linked decisions with influential factors (Hammond, Keeney, & Raiffa, 1999). Decision makers attempt to simplify complex decisions. Alex Mintz (2004) assumes they use a two-stage, poliheuristic decision process. Poliheuristic theory defines "domestic politics as 'the essence of decision'" (p. 7). In the first stage, policymakers reject unacceptable alternatives and narrow the policy choices by using cognitive shortcuts, and in the second stage, they select the choice that maximizes benefits and minimizes costs from amongst the remaining alternatives.

Methods of Policy Making

Policymaking is a political process based on political power and legal authority exercised by executive, legislative, and judicial entities at local, state, national, and international levels and made in the context of political interaction (Dunn, 2012; Holland, 2005).

Charles Lindblom (1959), in his well-known paper "The Science of 'Muddling Through,'" described two methods of policy formulation and decision. He referred to the method he considered the most frequently taught and discussed as the Rational-Comprehensive Method or the Root method. This method involves five steps: clarification of values or objectives distinct from and a prerequisite to analysis of policy choices, formulation of policy through a means-end analysis where ends are identified and means to achieve said ends is pursued, policy is tested to determine whether it is the most appropriate means to desired ends, all relevant and important factors are analyzed, and theory serves as a critical foundation for analysis. It is also called the Root method because analysis starts anew each time from the ground up. The second method he described is the Successive Limited Comparison or the Branch approach. The method consists of five steps: value goals and analysis are intertwined and not distinct from each other; no distinction is made between means and ends so means-end analysis is limited; policy is tested by various analysts agreeing on policy choices; analysis is limited because some possible outcomes, policy alternatives, and affected values are neglected; and a succession of comparisons between policy choices eliminates dependence on theory. It is called the Branch approach because it builds on the current situation step-by-step in small degrees (Lindblom, 1959).

While the Root method is familiar, easy to understand, and often seen as the best method, it is difficult to apply in complex policy decisions. So, policymakers often have to use the Branch approach which is far less studied in public policy analysis. The definition of values as described in the Root method is highly challenging because a complex problem will have many critical, conflicting values or objectives and stakeholders and decision makers are unlikely to be able to agree on how they are ranked. Even if an overarching objective can be agreed to, the subobjectives may be controversial among stakeholders or contradictory with each other. When it is not possible to rank values or objectives, policymakers must move forward to make policy decisions with different combinations of values. Therefore, evaluation and analysis are intertwined as policies to achieve objectives and the actual objectives and values are selected simultaneously. This approach can potentially allow agreement to exist on the right policy even if disagreement occurred on values selection. The Root method calls for a comprehensive inclusion of all important factors, but that is likely not feasible with a complex policy issue because human intellectual capacity and available information are both limited, so the process must be simplified. The Branch method simplifies complex problems by studying only the marginal and incremental differences between policy alternatives from each other and status quo. While excluding important factors is not ideal, it may be necessary to evaluate the alternatives. In the Branch method, policy is not made all at once, but is a successive approximation of desired objectives that adjusts through incremental policy change as objectives adjust. The difference between these two methods is the difference between theory and practice. The difference explains why theorists do not think policymakers (practitioners) take their advice and why policymakers do not find theoretical problem solving useful in their decision process (Lindblom, 1959).

House (1993) summarized, based on the work of Mary Ellen Wolfe, five models of policy making. Their findings are included in Table 5-1.

Table 5-1 *Five Models of Policy Making*

Model	Focus	Use	Limitations
Kings and kingmakers	Power lies with the influencers	Describes the role of leaders and reveals hidden powerbrokers who influence public policy	May overstate role of influencers, underestimates roles of groups and multidimensional aspects of policy development, powerbrokers hard to identify
Clusters Iron Triangle	Power lies with groups	Describes central role of organized groups and allows for incrementalism	May overstate group role and understate role of public officials and institution, may overlook environmental factors
Rational-comprehensive	Decisions are made rationally and comprehensively	Describes a rational, scientific decision making process	May be unrealistic, may overlook role of groups and influencers, exaggerates the time, resources, and information available to the decision maker
Muddling through	Decisions are made incrementally	Highlights how officials make decisions	May overlook role of influencers, systematic stages in the process, and possibility of innovative policy changes
Stages in the decision making process	Regularly occurring steps in the policy making process	Describes the process or system, multiple decision points, and fragmentation of power	May overlook changes in social and political environment, actual content in the process may be overlooked

Note. Adapted from House (1993).

History of Policy Analysis

At the turn of the 20th century, the progressive movement focused on reforming American government to be more focused on public interest and less influenced by big business and corrupt political machines. The goal was to make government more business-like and utilize scientific methods and techniques in the policy process. Progressives attempted to deal with the social, economic, and political impact of science's expanding role in society (Nelson, 1987).

Woodrow Wilson, a progressive, defined policy as divided into two categories, politics (general policy and social values choices) and administration (administrative and instrumental decisions). Progressives believed scientific advancement would lead to objective administrative policy and technical decisions instead of subjective political choices (Leman & Nelson, 1981; Nelson, 1987).

As administrative discretion became more prominent in the 1920s and 1930s and administrators started to take on policy making authority, the role of the policy analyst began to emerge and the concept of policy analysis was founded. Starting at that point and leading into the 1960s, "these efforts evolved into a movement to institute analytically grounded, decision-oriented policy analysis, planning, and program evaluation as routine functions of the public executive and as instruments of political leadership" (Lynn, 1999, p. 413).

The progressive approach was basically eliminated from the policy process after World War II because the government failed to meet the progressive ideal and policy was driven by interest group competition and political bargaining. In 1959, Lindblom published his works describing policy making as the "science of muddling through" and John Kenneth Galbraith in 1956 called politics a system of "countervailing powers" (Nelson, 1987, p. 55). By the late 1960s, analysts and economists argued that values influenced all parts of the decision process and expert independence from politics was not typically maintained (Nelson, 1987). Analysts, such as Dwight Waldo and Laurence Tribe, argued science and politics could not be divided, value judgments were inherent in the analysis, and analysis is influenced by the values of their sponsoring entity (Leman & Nelson, 1981).

During the 1960s and 1970s, a link was forged between policy analysis and policy making. If policymakers needed assistance, they would turn to analysts for support and information. This positivist knowledge-for-action approach focused on the brokerage of research to those charged with making decisions. The number of policy analysts grew significantly during this time. As Aaron Wildavsky noted, policy analysts became bilingual, skilled in the languages of science and policy, and "spoke truth to power" in a language policymakers could understand (qtd. in Lynn, 1999, p. 413). This movement drew substantial criticism from those who argued that analysis overemphasized assumptions, neglected reality, and ignored the need to balance interests of stakeholders. Critics in the 1980s and 1990s continued to express frustration with the popularity of policy analysis and argued analysts were trying to make decisions for policymakers. Charles Lindblom, as an example, called for more cooperative inquiry providing information to policymakers such as critiques and synthesis of issues but not an optimal solution to the question (Lynn, 1999). Others have argued that policy analysis is more a craft than a science, and analysts are more craftsman than scientists. Intuition, judgment, entrepreneurship, interpretative skills, and ability to provide a big picture approach are just as important, if not more so, than rigor, technical skills, and large amounts of data and information (Lynn, 1999; Nelson, 1987).

Controversy and discourse continue to exist about the role of policy analysis and the training provided to policy analysts. Those scholars referred to as postpositivists have argued policy analysis has become too focused on ineffectual advice, has an elitist approach, and is blind to political realities. While some with this attitude would take a drastic approach of dismantling all policy analysis and the institutions that provide it, a more moderate view calls for a more qualitative and participatory approach to policy analysis that is integrated with the democratic process. They do not believe facts and values can be considered independently and see the positivist attitude that policy is fact based alone as outdated and ineffective. Peter deLeon noted that values, ideology, and beliefs are all necessary parts of the policy analysis process. This thought process remains one that traditional policy analysts do not consider worthy of their concern (Lynn, 1999).

According to Lynn (1999), policy analysis should continue to improve public policy by providing information to policymakers while remaining uninfluenced by interest in the outcome and adding to the policy discourse while respecting the democratic process and exhibiting intellectual integrity. Policy analysis will remain both pragmatic and crafty (Lynn, 1999).

Defining Policy Analysis

Policy analysis is the use of reason and evidence to identify and evaluate policy choices from among multiple alternatives with the intent to address a policy problem by creating, estimating, and communicating relevant knowledge (Dunn, 2012; McRae & Wilde, 1979). The goal of policy analysis should be to improve policymaking by providing information useful to the policy process and to assist decision makers in choosing a course of action from complex alternatives under uncertain conditions (Dunn, 2012).

According to Knutson, Penn, Flinchbaugh, and Outlaw (2007) there are four questions that need to be addressed in any policy analysis.

- What is?
- What can be?
- What will be?
- What should be?

Policy analysis should provide the answers to the first three questions with objective statements of facts that identify the situation, address alternatives, and forecast potential consequences. It is then the policymakers' decision based on the information provided and their value judgments about what should be (Knutson et al., 2007).

Policy analysis includes the definition of common elements:

- Problem to be addressed,
- Criterion for choice,
- Alternatives, models, and decisions to made,
- Political feasibility, and
- Cycle of analysis (McRae & Wilde, 1979).

Analysis begins with a clear statement of the problem being analyzed. Different stakeholders may have different definitions of the problem, so a careful examination of the true issue is necessary to define or redefine the problem and keep it targeted (McRae & Wilde, 1979). Accurate problem identification and structuring is critical because the biggest factor leading to policy failure is due to the wrong problem being addressed. Problems need to be addressed from multiple perspectives because different decision makers have different preferences and values. Dunn's integrated framework is a problem centered policy analysis where the problem serves as the focus and policy actions, outcomes, and performance are all evaluated relative to the central problem (Dunn, 2012). The goals, objectives, and expectations of all stakeholders must be considered in problem and alternative identification, and the limitations on time and scope must be taken into account (Dunn, 2012; McRae & Wilde, 1979).

The goal of policy analysis can be seen as taking the steps necessary to choose the best policy. However, different stakeholders may have different views of best. Different people have different values and disvalues, as well as varied priorities and views on what is important. Analysis must create an overarching values criterion and identify opportunities for tradeoffs.

Most people are concerned with the ends or goals beyond the policy and want to know if different alternatives produce certain results. People may support the same policy approach for completely different reasons, and significant effort may be necessary to get people to agree on the deductive criteria (McRae & Wilde, 1979). McRae and Wilde (1979) refer to these as ethical criteria and note they must be clear, consistent, and general enough to compare amongst alternatives. It is not effective to just list criteria in order of priority, which is often referred to as the *naïve priorities method*. This approach is unclear, lacks precision, and provides no measurement of the intervals between the priorities (McRae & Wilde, 1979).

Policy analysis provides a framework for a structured review of dealing with policy complexities (NCEDR, 2002). Policy analysis and education is more of an art than a science (Adams & Hairston, 1995; Flinchbaugh, 2003). It is about "creating policies from a shifting palette of social, political, legal, economic, and environmental concerns" (Adams & Hairston, 1995, p.1).

Policy analysis should be focused on establishing fact and destroying myth while respecting values (Flinchbaugh, 2003). Once a problem is identified and defined, facts, myths, and values become interwoven within the policy process. Facts are the result of observation, discovery, research, and statistics. Myths, widely held incorrect beliefs, are treated as fact unless disproved by facts. Values reflect each person's principles, beliefs, and priorities. It is the interaction of these three areas that shapes policy and the policy development process. In the analysis process, alternative policy approaches are identified, analyzed, and documented, and then the political process creates a policy solution (Knutson et al., 2007). A graphical representation of this relationship can be seen in Figure 5-1.

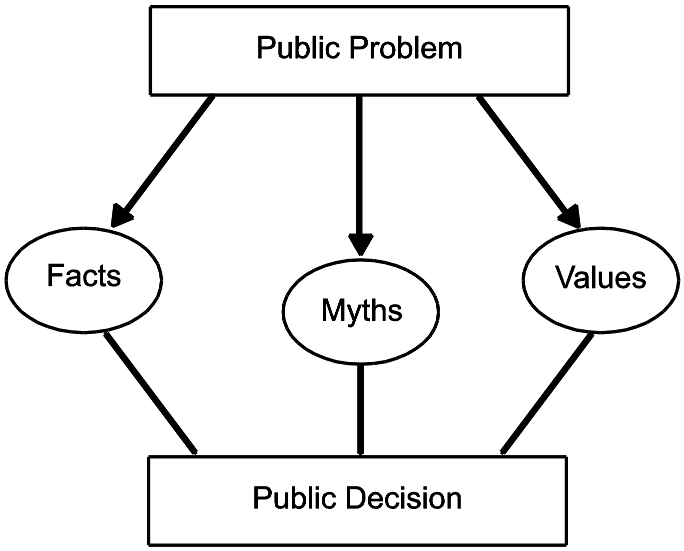

Figure 5-1 How public policy decisions are made (Flinchbaugh, 2003, p. 2).

Tools can be used to merge analysis, planning, and budgetary allocation and can complement the advocacy process (Lynn, 1999).

Techniques designed to address the comparison of policy alternatives must:

- Compare advantages and disadvantages when alternatives affect a multitude of widely different concerns,
- Incorporate long-term impacts,
- Assess the impact of uncertainty regarding possible outcomes, and
- Assess social distribution of costs and benefits (Bingham & Ethridge, 1982).

When considering different alternatives, it is common to ask which criteria make people better or worse off. Economists use the concept of welfare economics to calculate social welfare of different alternatives. One approach is to pursue a utilitarian solution to create the greatest good for the greatest number. Another approach is to compare the status quo to various alternatives in search of the Pareto optimal solution where no additional change can be made without harming someone else in the process (McRae & Wilde, 1979). A potential Pareto improvement indicates those who benefit from the policy change gain more than those who lose from the policy change and could technically choose to compensate the losers in the scenario. This results in an overall gain in social welfare (NCEDR, 2002; Shachter, 2008a). The Kaldor-Hicks criteria offer another possible approach and solution where total gains must exceed total losses. This asserts a policy is efficient and that overall welfare would be at its maximum if those who are better off have enough gain to hypothetically compensate those who suffered losses (even if the compensation does not actually occur) (McRae & Wilde, 1979).

The decision making process follows four steps: identify the real world problem, model potential alternatives, analyze the results, and implement a solution. The context of the situation largely influences the appropriate decision strategy and is determined by the level of uncertainty, the ability to quantify costs and benefits, number of criteria, and the number of participants who have decision making power. A strategic conflict can arise when different decision makers addressing the same situation have different preferences or priorities. Most analysis suits the single objective and single decision maker context, but multiple objective and multiple decision maker situations may be better suited with different analytical approaches, such as game theory (Xin, 2006).

Types of Analysis

Traditional versus interpretive analysis

The traditional view of policy analysis identifies decision making as a rational choice where decision makers establish goals and select policy alternatives that maximize utility and systematic thinking solves problems. This approach assumes public interest is defined by aggregating individual interests and that the marketplace satisfies preferences. Analysis is seen as a useful problem solving tool reducing uncertainty and providing an objective, ideally conclusive solution. The public is seen as inattentive and politically unsophisticated, and their interests can best be explained by experts. The process itself is built on incremental change achieved in linear stages. Simply put, traditional policy analysis sees it as a tool for problem solving and selecting between competing policies (Shulock, 1999).

The interpretative view approaches policy analysis as having ambiguous goals with uncertain means and decisions focused on process and organization rather that projecting consequences. It provides a retrospective rationality and assumes debate and discourse along with a collective social struggle over issue interpretations that lead to learning. Information is inherently inconclusive, reflects values, and creates a framework for understanding issues. The determination of cause and effect is not a goal. Citizens are believed to be attentive and capable of engaging with policymakers. The process is nonlinear and dynamic. The politics of ideas lead to a constant battle over agenda, interpretation of issues, and jurisdiction. Interpretative policy analysis is an instrument of the democratic process used by policymakers, special interests, and citizens to define issues, determine goals, justify actions, and symbolize rational decision making (Shulock, 1999).

Dan Durning and public policy specialists have called for a blend of analysis that calls for greater participation of analysts with those affected by policy and sees information sharing and policy advice as a joint responsibility of stakeholders and analysts (Shulock, 1999). However, Shulock (1999) believes significant overhaul of the policy process is unnecessary. It already involves discourse, blends ideas into political thought, and influences policy outcomes. The problem lies with policymakers, analysts, and the public who need to have an accurate view of what policy analysis can be. "Policy analysis has changed, right along with the policy process, to become the provider of ideas and frames, to help sustain the discourse that shapes citizen preferences, and to provide the appearance of rationality in an increasingly complex political environment" (Shulock, 1999, p. 240). Policy analysis can contribute to informed discourse, provide ideas, and raise the level of the debate, but it cannot provide ready-made, comprehensive, conclusive solutions to policy problems (Shulock, 1999).

Normative versus positive approach

Policy can be analyzed from a positive or descriptive approach in which the reasons behind policy changes are evaluated and future policy changes are predicted. Normative analysis refers to a proactive analysis of how policy should be reformed (Scrimgeour & Pasour, 1996) or "defining what we ought to do" (Cahn, 2002, p. 6). An empirical policy approach is focused on identification of facts and a valuative approach addresses the worth or value of alternatives. While normative process is designed to solve a problem, a descriptive approach such as empirical or valuative is designed to create an understanding of the problem (Dunn, 2012). The normative process is typically how policy analysts want decisions to be made rather than in a traditional political process. Such policy development methods allow for transparency and defensibility (Shachter, 2008b). Without transparency in the policy development process, stakeholders are unlikely to understand, support, or have confidence in the policy decision or its anticipated outcomes (Giovannini, 2007).

Prospective and retrospective analysis

Dunn (2012) identifies three forms of policy analysis. Prospective analysis addresses policy choice prior to implementation and attempts to predict what will happen. Retrospective policy analysis instead evaluates policy decisions after implementation. Dunn proposes an integrated framework that is multidisciplinary in nature and combines a retrospective and prospective approach to analyze the consequences of policy alternatives (Dunn, 2012).

Political philosophy versus procedural policy

Erven Long (1953) examined agricultural policy debates and discussed the differential between underlying philosophies driving policy direction versus day-to-day policy decisions. Goals to be addressed, values to be served, and basic policy assumptions held by involved parties need to be considered when identifying the appropriate philosophical approach to a policy question. The clarity of the philosophy behind policy is critical to accurate guidance of daily procedural policy decisions. To serve a purpose and have meaning, policy analysis must start with an understanding of the philosophical questions at hand and appraise all options and their aligned consequences while avoiding drastic simplifications and generalizations related to the overarching philosophical approach (Long, 1953).

Additional Influences on Policy Decisions

A number of additional factors may influence policy decisions and how they are made. A few of those factors are discussed in the following sections.

Role of stakeholders, special interests, and the public

Analysis depends on appropriately specifying the question. Stakeholders need to be engaged in planning, execution, and evaluation and their objectives need to be considered in the development of evaluation methods and frameworks. Identifying the objectives of multiple stakeholders becomes more important as the goals of one stakeholder group conflicts with the goals of others (Rushton, Thornton, & Otte, 1999).

Any policy process involving different interests will be challenging because all interests will be affected in a positive or negative manner. Representatives of those special interests will desire to influence the decision process and policy development. Negotiation, maneuvering, bargaining, and compromise will be necessary to reach an acceptable outcome (Pielke, 2002).

The public should play an active role in risk assessment and be engaged in the policy development and decision making process. In addition, risk communication needs to be a two-way channel and related strategies need to be incorporated into the policy development process (Hueston, 2007).

Public risk

When evaluating policy choices, risk assessment and public reaction to risk play a factor. However, it is more difficult to evaluate public risks than private risks because public risks are broadly distributed, remote, and outside an individual's control and understanding. These types of risks are typically underestimated and consequences are usually misjudged. Incentives for individual or group action tend to be minimal. This is especially true in the case of a low-probability, high-consequence risk. Even though economic incentives might exist, it is less likely action will be taken such as the case with many collective action situations (May, 2001).

Self-interest

The behavior of any decision maker is still influenced by traditional individual motivations. Public choice theory is based on the concept, although not exclusively, that all individuals and their actions within a political process are affected by self-interest and wealth maximization. A broader approach includes the idea of the *economic man* as one that extends self-interest to include concern over the welfare of others. If decision makers are acting in this manner, then *what is, is efficient* should apply and all decisions should be the best policy choices under the exiting circumstances. However, the political and regulatory process is not perfectly coordinated and such balance is rarely automatically achieved. Uncertainty abounds and information is limited so even when policymakers want to act in the best interest of everyone involved, the consequences of policy alternatives is often unclear (Scrimgeour & Pasour, 1996).

Tools for Analysis

To select a policy alternative, decision makers need to consider society's preferences, determine how to weigh the diversity of opinions represented, forecast the impact of policy alternatives, and select the best choice. Even if they had a clear understanding of preferences, comparing alternatives requires time and capabilities that decision makers typically do not have. In addition, by the time a decision is made, societal preferences may have changed. Tools have been designed to assist policymakers based on the impact of policy choices, related time frames, budgetary impacts, and the role of public involvement (Maness, 2007).

Any tool used for economic analysis or other methods of alternative policy evaluation need to consider costs, benefits, and distribution of costs and benefits while taking into account the role of voters and public opinion, interest groups, agency bureaucrats, politicians, and the constitutional, statutory, and regulatory framework in which polices are developed (Scrimgeour & Pasour, 1996). The choice for a model is often a balance of getting the desired output and application of a feasible model based on data, time, risk, space, resources, and capabilities (Rich, Miller, & Winter-Nelson, 2005a; Rich, Winter-Nelson, & Miller, 2005b).

Analysis provides an advantageous, systematic approach to policy decisions. It allows results to be reproduced, reasoning to be checked, assumptions to be identified, key factual issues and interpretations to be isolated, and the debate to be focused (Quigley & Scotchmer, 1989). In some cases, analysts see their role as providing information to the decision maker in order to help them make a decision. As described by Longworth et al. (2012a), analysis tools are designed "to provide decision-makers with science-based information to enable them to make informed and rational choices between decision alternatives" (p. 2). In contrast, some public policy specialists identify their role as actually providing the solution to the decision maker. "Decision tools are utilized to model and analyze the problem to find a suitable solution to solve the problem" (Xin, 2006, p. 1).

Models, which are simplified representatives of or substitutes for more complex real-world systems, can serve as a useful resource to decision makers. They are often intended to study how a scenario will develop in response to various interventions and explain system behavior to non-experts. The complexity can vary from a simple deterministic mathematical model to a spatially explicit stochastic simulation. A deterministic model describes average effects and uses average data throughout the system and is designed to gain understanding and improve knowledge. Stochastic models are based on a variable range of data, behaviors, and patterns and provide a range of effects with confidence intervals (Garner et al., 2007; Green & Medley, 2002; Taylor, 2003).

It is as much an art as a science to determine the appropriate level of complexity in a model. The addition of more factors may add to the complexity without improving the model's resourcefulness. Additional parameters should not be included if evidence is not clear it will improve the model's predictive capabilities (Garner et al., 2007; Green & Medley, 2002; Taylor, 2003). The decision of what to include in the model can be considered subjective and is influenced by knowledge and data (Taylor, 2003). The appropriate model depends on the situation, the level of data available, ability to quantify the critical elements, and a spatial or non-spatial approach. Models need to be fitted to the specific purpose, verified, and validated (Garner et al., 2007). The validity, accuracy, availability, and completeness of data will determine if the model can be effective. Few models are universal, and most are developed for a targeted purpose and may not be transferable to other situations (Taylor, 2003). They serve as just one tool and should not be used independently from additional information, experimental studies, and relevant data (Garner et al., 2007).

There are a number of different policy tools that can be applied to policy analysis. A sampling of those methods is described in the following sections.

Quantitative approaches

Quantitative analysis allows for a clear comparison of alternatives. Complex policy decisions incorporate measurement, time, uncertainty, and distribution.

Cost-benefit analysis

The most common systematic policy analytic tool is cost-benefit analysis (CBA) (Bingham & Ethridge, 1982; McRae & Wilde, 1979; Quigley & Scotchmer, 1989). Advantages and disadvantages of different alternatives is the basis of all assessments, and values are estimated representing the costs and benefits of society. CBA frameworks are typically designed to help society determine the acceptability of alternatives. Costs and benefits can be economic, environmental, social, or biological. However, the definition of these costs and benefits is not always straightforward, data requirements are significant, and the quantification and valuation in economic terms can be difficult (Rushton et al., 1999).

CBA estimates all costs and benefits, is consistent, and works effectively when all criteria can be assigned a monetary estimate. This method does not always meet the moral values of all parties if agreement does not exist on the appropriate values to assign. Multiple iterations may be required to create consensus on the monetary values. Those who do not agree with the methods or values are not likely to support the policy recommendations. The controversy over CBA is typically linked to a discussion of equity and fairness, although the monetary weighting is, in itself, an exercise in value assessment. McRae and Wilde (1979) note CBA is a clear and consistent system used extensively in policy analysis, and analysts and decision makers need to understand the reasoning even if they disagree with the assumptions (Bingham & Ethridge, 1982).

CBA allows the decision maker to determine potential Pareto optimal solutions and understand magnitude of gains and losses (NCEDR, 2002). The process attempts to operationalize and measure all gains and losses and assumes society is better off if benefits outweigh the costs. It is typically difficult to measure all social costs and benefits, but careful analysis can compensate for imperfect measurement of social values. Each alternative is compared to the status quo and the choice of no action. Opportunity cost is used to quantify the values forgone by the selection of each alternative (Bingham & Ethridge, 1982; McRae & Wilde, 1979).

CBA measures economic efficiency, but some situations may require more than an assessment of efficiency and it cannot measure the multidimensional issues such as ethical, equity, and social issues. CBA can inform public policy, but it is one-dimensional and cannot make the decisions (NCEDR, 2002). Although CBA has been applied to agriculture and natural resource issues for decades, a consensus does not exist on monetary valuation methods, data is limited, valuations from one scenario are typically not transferrable to another, and valuations are often not accepted by public or policymakers (Stoorvogel, Antle, Crissman, & Bowen, 2001). CBA is only capable of estimating the effects of an isolated impact and does not explicitly model linkages across scales or sectors. One variation on CBA is partial budgeting which assesses only additional or marginal costs and benefits (Rushton et al., 1999). A policy analysis matrix (PAM), which is a system of partial budgets identifying costs and revenues by market segment, can be used with a CBA to evaluate linkages between sectors. If spillovers into other sectors are extensive or changes are expected in land or labor markets due to impacts from a demand shock, then CBA and PAM are likely not appropriate. Price effects are also typically not included in a traditional CBA analysis (Rich et al., 2005b). Regardless, Quigley and Scotchmer (1989) argue that all public decisions should be made using some variation of CBA.

Input-output tables

An input-output (I-O) table can specify economic transactions through the flow of inputs and outputs between sectors of the economy and model interregional flows of critical economic linkages. A social accounting matrix (SAM) can extend the results by adding factors related to production, institution, capital, and rest-of-world (ROW) impacts. Individual commodities on the domestic level can also be assessed. A SAM can also show flows of incomes and spending to and from different household and income groups, government income from taxes, and public expenditures. Savings and investments across the economy can be shown with a capital account and a ROW account will indicate the economy-wide global influences. Exogenous shocks on sector performance can be analyzed using an I-O table in conjunction with an SAM with the use of multipliers. A CBA can be used to generate short-run costs as an input into an I-O model. While an I-O can be a useful tool for policy analysis, limitations exist. Production assumes no substitution between inputs and constant returns to scale, specifications known as Leontief technology. It also assumes fixed prices and perfectly elastic supply while all changes are due to demand shifts, and they are not designed for medium- or long-term impact analysis (Rich et al., 2005b).

Partial equilibrium model

Functional supply and demand relationships for specific commodities at a set time and place can be defined in a partial equilibrium model. Market-wide impacts of a shock on prices, quantities, and welfare is measured, and models can be single sector or multimarket, which creates linkages and identifies impacts between related markets. The data required to develop a full functioning model is substantial. Partial equilibrium models can be used in conjunction with a CBA (Rich et al., 2005b).

Computable general equilibrium models

A computable general equilibrium (CGE) model represents the entire economy and can measure impacts across sectors, types of households, and different employment groups. The strengths of I/O models and multimarket partial equilibrium models can be combined in a CGE model. Price changes, reallocation of labor and capital, and long-term impacts can be evaluated. Such a thorough model, however, is highly complex, expensive to develop, and is challenging to interpret. They are often aggregated in such a way as to simplify the construction while providing less useful results if specific questions need to be addressed. CGE models can be combined with a CBA to provide more specific results (Rich et al., 2005b).

Optimization mathematical programming

Dynamic optimization models can be used to minimize negative costs or maximize positive outcomes when comparing multiple alternatives and allowing dynamic situational changes (Kobayashi et al., 2007b). All possible activities are considered while resource use and production are constrained within the model. The intent is to identify an optimal solution that maximizes the given objective. Accurate data is necessary for effective and trustworthy model optimization. Shadow prices, the incremental change due to a change in the constraint, can also be generated to aid the evaluation process. The focus can be on a single goal or multiple priorities which leads to multicriteria decision making (Rushton et al., 1999).

Linear programming is designed to find an optimal solution through maximization or minimization and can better deal with long-term impacts than CBA. It does not allow for price effects to be modeled and does not consider inter-sector linkages, but does allow for evaluation of changes in behavior (Rich et al., 2005a). Dynamic programming focuses on the identification of an optimal solution through a sequence of decisions. Policymakers do not usually have a simple objective function, so dynamic programming analysis is designed to deal with multiple and sometimes competing objectives. Multiple objective programming can be useful to decision makers because numerous what-if scenarios can be compared and compromise can be found between objectives. These methods can face technical limitations and depend on the correct specification of the problem and specific objectives (Rushton et al., 1999).

Economic surplus

Economic effects of change can be evaluated with an economic surplus method based on a production function applied to study the effect of changes on supply functions. The steps include determining expected technological changes, evaluating the impact of those changes on the supply curve, estimating the supply shift and its associated new market equilibrium, and measuring the resulting changes in welfare. Substantial data is required and concerns exist about the need for value judgments and the relevance of results to policy concerns (Rushton et al., 1999).

Simulation modeling

A simulation model is a mathematical, computer-based tool that simulates real world occurrences based on input data. It is highly effective for dynamic relationships with multiple subsystems and interactions. Simulation models offer significant flexibility and can be structured in multiple ways. Simulation is a suitable alternative when experimentation is not feasible, but it can be costly and time consuming. Limited available data requires the simplification of assumptions, which compromises the model's integrity, validity, and purposeful use (Rushton et al., 1999). Simulation models can aid decision makers though development and comparison of policy alternatives. If there are multiple levels and alternatives to evaluate, the options and scenarios that need to be considered may be difficult to model and compare and a more efficient process may be required (Kobayashi et al., 2007b).

Risk analysis

When uncertainty exists, risk analysis can be a helpful decision making tool. For each policy alternative, numerical values of the probabilities and consequences are estimated and used to compare impacts of each alternative. Risk is communicated to stakeholders and decision makers. Evaluations are typically quantitative, but could also be developed in a qualitatively. Risk analysis can be seen as "technically sound and socially responsible" (Giovannini, 2007, p. 257) when used to support decision making at all levels and has been increasingly used for studying issues related to food safety, national security, natural disasters, and international trade and health (Giovannini, 2007).

When alternatives are considered under uncertainty, their outcome may not be as expected. The decision maker's risk tolerance is influenced by their risk attitude and the scale of the risk. The risk attitude of the decision maker will determine how they interpret results from analysis and will influence their policy decision. A decision maker who is risk neutral will focus on expected values of policy choices and select a policy alternative with an average lower cost, while a risk-averse decision maker will focus on minimizing the chance of negative consequences. A risk-seeking decision maker will be influenced by the upside of the consequences. This knowledge may impact a researcher's process of sharing data and information (Hueston, 2007; Ge, Mourits, Kristensen, & Huirne, 2008).

When a policy choice is made ex ante with high uncertainty, the risk of underreacting or overreacting exists. The decision maker's risk attitude will play a critical role in the selection of policy alternatives in static analysis. If predicted risk can change over time, a risk-averse choice may become a risk-taking choice if the situation changes from pessimistic to optimistic (Ge et al., 2010).

If the decision maker understands the probability distribution and uses it in the decision process, their risk preferences will be expressed related to distribution of adverse consequences. Risk-neutral and risk-averse decision making can be represented by the breakeven risk aversion coefficient (BRAC). BRAC analysis, typically with constant absolute risk aversion (CARA), can identify the risk aversion coefficient where the decision makers preferences changes from one alternative to another (Hagerman et al., 2012).

There are four components of risk analysis, including hazard identification, risk assessment, risk management, and risk communication. One component within risk management is option evaluation, which can be used to identify, select, and evaluate the efficacy and feasibility of alternative strategies to reduce adverse consequences. It serves as a bridge between risk assessment and risk management (Giovannini, 2007).

Risk assessment is used to evaluate the related quantitative estimates and the role risk plays in decision making. Typically, the components of a risk are defined quantitatively with the intent to compare alternatives across predetermined criteria. Risk assessment can also be semiquantitative or qualitative depending on the situation being assessed. Results can serve as decision support for policymakers. Risk assessment has been used more recently for environmental policy analysis. The use of risk assessment in decision making in this area indicates a positivist perspective in which risks to the environment and public health can be compared with feasibility, cost, resource availability, etc. The precautionary perspective emphasizes the need to give more consideration to uncertainties and can be further influenced if the public does not trust the information being used or the decision process (Cowell, Fairman, & Lofstedt, 2002).

While it can be considered objective and scientific, some concerns do exist with risk assessment as a stand-alone decision tool. A few of those concerns include the role values may play in the process, the sense of certainty created by the quantitative results when uncertainties exist, the difficulty non-experts have interpreting results, the delays in action created by uncertainty, and the challenges of obtaining necessary data (Cowell et al., 2002).

Expected utility theory

Expected utility theory can be used for analyzing policies involving risk. Utility functions are used to quantify preferences. Biases in probability judgment can occur due to conjunction fallacy (e.g. if it plausible, it is probable), optimism (it will not happen to me), and availability (versus frequency). Judgments may also be incorrect when risks from low probability events are ignored. Mental accounting, reframing, endowment effects, reluctance to make tradeoffs, inclusion of additional attributes, regret theory, ambiguity, status quo bias, emotional dimensions of risk, intertemporal risks, and other aspects of prospect theory can influence judgments and violate expected utility. Contingent weighting, lexicographic choice, and threshold comparison are rules that can be applied to simplify expected utility theory. Traditional policy tools designed to deal with low probability risks, such as economic incentives, compensation, benefit sharing, regulations, and standards, interfere with public choice and expected utility. Risk and uncertainty continue to influence choice and must be considered in the decision process (Camerer & Kunreuther, 1989).

Robust decision making

Robust decision making (RDM) runs models on a large number of varying sets of assumptions to determine how policies perform in different settings. RDM avoids the predict-then-act framework by completing multiple runs of the analysis backwards starting with the plan under consideration. The process starts with policymakers defining the goals, uncertainties, and choices under consideration, and then computer models generate a large database of runs indicating the performance of the policy in the future. Analysts can provide results in statistical and visualized forms to decision makers to help them see how their plans will perform under certain conditions and scenarios. The scenarios are used to identify ways to address vulnerabilities and options are evaluated using tradeoff analysis. RDM combines the best features of scenario analysis and probabilistic risk analysis. Two ways RDM has been used are with water management decisions and terrorism insurance. RDM uses a deliberation with analysis approach and is intended to improve decision making under deep uncertainty (RAND, 2013). It allows a change in the question being answered from “what will the future bring?” to “what steps can we take today to most assuredly shape the future to our liking?” (RAND, 2013, p.5).

Predictive analysis

There are an increasing number of policy issues requiring social change and innovation. Policy analysis needs to account for these characteristics and be able to compare alternatives. One approach is predictive analysis. Statistics, modeling, and data analysis are used to evaluate current and historical facts to predict future or unknown events. By capturing historical relationships, risks can be assessed to guide decision making and models can forecast results of decisions (McRae & Wilde, 1979).

Sensitivity analysis

Because economic decision processes are rarely precise, it is typical to evaluate changes in specific estimates on expected values using sensitivity analysis. All values are held constant except for the factor being considered (Rushton et al., 1999).

Qualitative approaches

Alternatives-consequences approach

J. Carroll Bottum and J. Byron (Heavy) Kohlmeyer, agricultural policy economists at Purdue University, developed the alternatives-consequences approach to public policy education in the 1930s. This approach is considered a milestone in public policy analysis, empowers education in the face of controversy rather than prescription or advocacy, is still applicable today, and is comprised of five steps:

- Define the issue as a problem to be solved,
- Develop and list the alternative solutions,
- State the consequences of each alternative,
- Educate and interact, and
- Move on to work on something else, leaving to policymakers to make the decision (Barrows, 1983; Barrows, 1993; Bottum, 1975; Flinchbaugh, 2003; House, 1993).

The alternatives-consequence approach creates a framework for linking research and problem-solving processes to real-world problems, requires equal consideration of multiple alternatives, involves interaction with stakeholders and decision makers, and creates an opportunity for rational consideration of policy choices by decision makers (Barrows, 1983; House, 1993). Philosophically, it is about teaching people how to think rather than thinking for them. The choice itself is left to the political process (Barrows, 1983). This approach is significantly different from analysis completed by “penning pithy policy prescriptions from the safety of one’s office” (House, 1993, p. 28).

Listing consequences and allowing for application of quantitative weights to each one works well when alternatives are specific (McRae & Wilde, 1979). Assessing consequences rather than pros and cons is important to maintain objectivity (Adams & Hairston, 1995). Objectivity is essential but should be seen as a goal to reach for and not an absolute condition. Pure objectivity is impossible, but working to be objective is not. The alternatives-consequences approach provides a tool for objective analysis of the problem, alternatives, and consequences (Barrows, 1983; Flinchbaugh, 2003; House, 1993).

An alternative model, which can be referred to as the Consequences-Alternatives Model, is based on the idea that all stakeholders are interested in the same consequence or goal and the analysis then focuses on helping determine which policy alternative best meets that goal (Barrows, 1983; Barrows, 1993).

Value contribution method

The Value Contribution (VC) method begins with the prioritization of objectives. Confusion may exist over which objectives are higher priorities, so the VC method calls for the specification of objectives and priorities before alternatives are identified. If goals are agreed upon initially, it is more likely policymakers will select a policy approach that best meets those priorities. Priorities can be set through numeric scaling or ranking. Objectives may need to be disaggregated in order to prioritize and then aggregated again for policymaker consideration (Campbell & Nichols, 1977).

The value contribution method is based on the concept that the policy objectives need to be prioritized for alternatives to be compared. Priorities need to reflect community needs and the expected benefit of each alternative. By setting priorities, decisions can be made about which objectives can be detailed in action plans, alternatives, and consequences. The value contribution method is based on identifying desired objectives to be prioritized, goals to be achieved by meeting objectives, the relative value contribution of different objectives in reaching the same goal, the relative worth or value of desired achievements, and the gap between current and desired levels of achievement of each objective. The priority of an objective is the product of its value when fully achieved times the discrepancy gap between current and desired levels of achievement. The value contribution method provides a rational, objective approach to combine subjective value judgments (Campbell & Nichols, 1977).

Cost-benefit analysis qualitative framework

In some cases, costs and benefits related to policy alternatives may be a challenge to quantify, place in a certain range, or reduce into one CBA due to limits on available data. In those cases, a comparative matrix may be useful in the decision process when comparing alternatives. Implicit tradeoffs between costs and benefits for one stakeholder may create an externality for another. Thus, the outcome of a CBA or economic analysis may be necessary but insufficient in evaluating the impact of policy alternatives and the actual overall societal effect. A combination of economic analysis and qualitative assessments can be used to address this shortcoming. A finite list of policy alternatives must first be identified and explained in detail, and costs and benefits related to each of these choices should be identified for each stakeholder with the current situation as a baseline. A qualitative framework may consist of a table with color coding to indicate increased benefit/decreased cost, increased cost/decreased benefit, neutral offset of cost and benefit, and economic analysis results indicating impacts on costs and benefits. This process can be further improved by creating scenario frameworks allowing for better long-term planning and more accurate conclusions on outputs and parameters (Bitko, 2007).

Cost-effectiveness

There are issues deserving of analysis in which the costs and benefits are not well suited for monetary evaluation. In some cases, it is not possible to measure all benefits so analysis must come with qualifications. One alternative to the benefit-cost ratio is the cost-effectiveness ratio where beneficial outcomes are compared to the costs. Cost-effectiveness ratios serve as tests of efficiency and systematic comparisons of positive and negative effects of specified alternatives. Cost effectiveness does not require that all outcomes be valued in the same unit and allows alternatives to be ranked in terms of magnitude (Bingham & Ethridge, 1982; McRae & Wilde, 1979).

Cost-effectiveness analysis is based on the idea there is a specific desirable outcome or benefit to achieve and multiple alternative pathways. The analysis is designed to be comparative and identify the cheapest or most efficient choice to achieve the desired benefit. A cost-effectiveness approach allows costs to be compared while maximizing benefits that are measured by some scale of measurement other than monetary value. It still allows for optimization by focusing on benefits gained at the most effective cost. It is possible the least expensive option is not the best policy choice and other social and political factors need to be considered (Sewell & Marczak, 2008; Shachter, 2008a).

All cost analysis tools face limitations because they can be overly simplistic, there is no standard way to assign monetary values to some qualitative factors, market costs do not always reflect actual social costs, some costs or values may be more or less important than others, and there may be multiple competing goals requiring prioritization (Sewell & Marczak, 2008).

Decision analysis

Decision analysis is most concerned with uncertainty where desirable outcomes are well established, but it is unclear which alternative best delivers those outcomes. In these cases, probabilities of each outcome must be estimated (Bingham & Ethridge, 1982; McRae & Wilde, 1979). The evaluation is based on events the decision maker can control, the probability of certain events, and the value of outcomes. By identifying policy alternatives and assessing values and probabilities to potential outcomes, complex problems and related actions can be evaluated. It typically involves the construction of pay-off tables or decision trees. The decision trees provide the advantage of chronologically depicting events and outlining sequential decisions (Rushton et al., 1999). Decision analysis and CBA are often used jointly. When alternatives have more than one possible outcome, a CBA can be used to assess the relative value of each and decision analysis may be used to determine which alternative is best (Bingham & Ethridge, 1982; McRae & Wilde, 1979).

Multicriteria decision making analysis

Multicriteria analysis attempts to provide support to decision makers when there are multiple conflicting criteria and a finite set of policy alternatives. Objectives are defined, criteria are arranged, alternatives are selected, and consequences (direct measurements of alternatives in meeting criteria) are measured. The goal is to identify the conflicts and find a compromise solution. Results can select the best alternative, sort alternatives into homogenous groups, rank alternatives from best to worst, or describe the impact of each alternative (Xin, 2006). Multicriteria decision making evaluates alternatives on their ability to meet predetermined objectives using measurable criteria. It allows for complex problems to be broken down into manageable components for consideration, requires active stakeholder participation, and emphasizes the stakeholders' opinions in the establishment of objectives and criteria and the associated weighting of relative importance (Mourits et al., 2010). The general steps in multicriteria decision making are: "(1) establishment of decision context, (2) identification of alternatives to be appraised, (3) identification of criteria, (4) scoring of alternatives, (5) weighting of criteria, (6) calculation of overall value, (7) examination of results by ranking alternatives, and (8) performance of sensitivity analysis" (Mourits et al., 2010, p. 202).

One form of multicriteria analysis is strategic policy analysis involving multiple decision makers who have different goals and the ability to influence the potential outcomes through their decisions. Non-cooperative game theory is one model alternative based on economics and Bayesian decision analysis. However, timing of actions is critical in the modeling process which is often difficult to determine. Utilities are also difficult to measure and mixed strategies are problematic to interpret. Another option for analyzing strategic conflicts is the graph model for conflict resolution. This process analyzes the decision in terms of decision makers, states, transitions, options, and preferences to identify possible resolutions based on certain stability definitions. Other models include multi-attribute utility theory, outranking, metagame analysis, conflict analysis, and theory of moves (Xin, 2006).

Another form of multicriteria decision analysis is the analytic hierarchy process which includes consideration of both quantitative and qualitative factors in a mathematical decision making model. Complex decisions are reduced to one-on-one comparisons, and then results are synthesized. A hierarchy structure is developed based on a criteria-subcriteria-alternatives framework. Single properties of alternatives are compared allowing the decision makers to use clear rationale to make the best selection. The analytic network process replaces hierarchies with networks and allows for interactions within and between clusters of decision elements. This method is especially applicable when risk and uncertainty exist (Xin, 2006).

The multilevel hierarchic Markov decision process (MLHMP) is a dynamic multistage decision making model. It is designed to create a connection between the static approaches of decision making typically seen in research with the dynamic decisions made in reality. It builds on the real options approach, which is based on irreversible choices under uncertainty. It allows for flexibility in decision making by keeping options open in the face of uncertainty. Real options theory has been used primarily with investment decisions and flexibility and allows for options thinking in any complex situation. Real options theory focuses on the logic of strategic opportunism. Investments in different time frames and returns to policy alternatives can be compared (Ge et al., 2008).

MLHMP stacks Markov decisions into a hierarchical structure based on levels of decisions modeled. The process can be used to model and optimize decisions in a situation framed in uncertainty, and is suitable for strategic, tactical, and operational decisions in systems with long-term impacts. States, actions, decision stages, and time horizons are defined at every hierarchical level, and an optimal action in each state is determined. The decision model "formulates the scientific form of the decision problem" (Ge et al., 2010, p. 168) based on data provided to select an optimal strategy. The optimization of the MLHMP model results in optimal policy choices being identified with decision rules for each state at each stage in the decision process. The model offers distinct advantages in the structure, formulation, and solutions of complex decision problems consisting of interdependent decisions across time frames and can be useful in practical decision making. The perceived complexity of the multilevel, multistage process can be seen as a disadvantage. User-friendly look-up tables or policy guidelines with respect to application of policy choices could simplify the process and make it more relevant (Ge et al., 2010).

Tradeoff analysis

Tradeoff analysis is based on knowing what is being managed for and if those things are being achieved. To determine these questions, criteria and indicators must be identified. Criteria need to be strategic, operational, scientific, and reflect values and critical considerations of stakeholders. Indicators are tactical and should be measureable, operable, credible, and relevant to criteria. They must determine if criteria are being met and progress is being made. Multicriteria tradeoff analysis may use experts to rank criteria to narrow the potential list to one that is manageable for consideration. While this approach is highly transparent and simple, concerns may exist over expert reliability and priorities especially when facing complex situations. Several methods have been developed to determine stakeholder values and preferences through different weighting techniques (Maness, 2007). When ranking alternatives, it is also a challenge to develop one common unit of analysis and determine what weighting to use (Stoorvogel et al., 2001). Once preferences are determined, multiobjective linear programming and goal programming can be used to model planning choices using a multicriteria approach (Maness, 2007). Tradeoffs can also be characterized between different objectives based on the concept of Pareto optimality where no further improvement can be made without causing harm elsewhere (NCEDR, 2002; Sekine, Campos-Nanez, Harrald, & Abeledo, 2006). Tradeoff analysis has been used in agricultural and environmental policy analysis with decision tools integrating disciplinary data at the field scale using GIS, agronomic production models, econometric models, and environmental process models. The use of a tradeoff assessment allows for the design and organization of multidisciplinary research with competing objectives. Public stakeholders, policymakers, and scientists identify critical concerns. Simulations are used to aggregate outcomes from the modeling tools and thus to analyze economic, environmental, and public health tradeoffs (Antle, Stoorvogel, Crissman, & Bowen, 2000; Stoorvogel et al., 2001).

Feasibility analysis

Any policy decision needs to consider the feasibility of policy alternatives to determine if the options can be implemented. In dealing with a foreign animal disease (FAD), a number of policy alternatives may be considered that are simply not viable. Feasibility should be evaluated in at least four areas:

- Administrative (Operational) Feasibility. Can the alternative actually be implemented and used?
- Technical Feasibility. Are the resources and technology available?
- Economic Feasibility. What are the costs and who pays? Are the benefits worth the costs?
- Political Feasibility. Does the political will exist to implement the policy alternative?

Any policy alternative that is not feasible in any of these areas is unlikely to ever be implemented or considered a successful alternative. Feasibility should be addressed early in the analysis process and can be provided to decision makers in the form of a feasibility analysis matrix (Giorgini, 2003).

Fault tree analysis

Fault trees are a logical and hierarchical risk assessment tool used to identify pathways from an undesirable incident leading to an undesired final event, such as ineffective animal disease control, by identifying all combination of consequences and causes interconnected to intermediate events along the pathways. Researchers in Switzerland and Japan identified a need for new epidemiological tools to complete a risk assessment of disease control responses and developed a general FMD fault tree to help decision makers find more effective disease control activities and identify optimal strategies. They identified a lack of rapid, effective, and complete FAD control as the final failure and looked at cause-effect relationships of response strategies and legislative changes occurring after an initial FMD outbreak. The situation worsened within the tree if inaccurate epidemiological assumptions were made, ineffective communication occurred between stakeholders, or inadequate policies were implemented. Examples included overestimating culling capacity, insufficient information about number of animals to be vaccinated, poor vaccine quality, and overestimation of the amount of disposal resources available. A total of seven intermediate and 68 basic events were built into the fault tree. Different events were not weighted or prioritized. The fault tree can be used for retrospective analysis to determine what led to a negative outcome, the basis of review and update of existing contingency plans, and prospective development of an event map for use in an actual event. Probabilities of each event and priorities on each branch would add to the usefulness of the fault tree and allow for a qualitative and quantitative assessment of control strategies (Isoda, Kadohira, Sekiguchi, Schuppers, & Stark, 2013).

Limitations of policy analysis

Political scientists have struggled with remaining relevant to decision makers and many have come to the realization that analysis remains only one factor in the policy decision process. Costs of analysis, lack of practical application, poor predictive theory, and a failure to address political doctrine are downfalls of political science work. New frameworks of policy analysis continue to be considered but fail to meet the needs of policymakers who do not trust that results can be accurate, useful, and actionable (Miller, 1989).

Limited usefulness to decision makers

Regardless of the amount of effort and progress accomplished in the field of policy analysis, there are substantial indications that policymakers do not often use policy analysis for making policy decisions or for choosing amongst alternatives (Shulock, 1999). Policymakers are typically not provided the breadth and depth of information they need to make decisions and justify political action with traditional policy analysis tools. Analysis focused on economic efficiency as sole justification is seen by some decision makers as inadequate. While economic efficiency is critical to overall social value, it may not include all relevant information necessary for policy evaluation (Holland, 2005). Some decision makers see quantitative methods and tools as counterproductive or as distractions when dealing with fast-paced, transformative, and challenging policy decisions. They know it is possible predictions will be wrong, so they are likely to ignore analytical help (RAND, 2013).

While some discussion of policy analysis and its decreased use by decision makers calls for changes in analysis and a new approach to evaluation, others have laid the problem on policymakers and changes in the political process and do not believe analysis needs to be adapted. In addition, experience is often valued as more important than research (Trostle et al., 1999). As Shulock notes, today's policy world "favors anecdotes over substance, pessimism over the incrementalist's optimism, passion over reason, and media sound bites over reasoned political discourse" (1999, p. 239).

A report from the House of Commons Environment Sub-Committee notes that policymakers should avoid the use of computer models as prescriptive answers and not allow results to be developed in an isolated technocratic process and then used to force a decision on skeptical stakeholders (Cowell et al., 2002). "A model constitutes a theory, and a predictive model is therefore only a theoretical projection" (Kitching, Thrusfield, et al., 2006, p. 298). No simulation, regardless of its complexity, is exactly like real life (Kao, 2002).

As originally noted by George Box, models are typically wrong, but some may be useful in the decision process (Green & Medley, 2002; Taylor, 2003). While Green & Medley (2002) considered how wrong a model must be before it is no longer useful and how useful it must be to advise policy, Taylor (2003) wondered how valid it must be to be useful to decision makers. It may be more important to determine if the model is useful and if policymakers can be confident in its results because of its relationship to real systems and real decision processes than to determine its validity. It may be more important to validate the use of a model rather than the model itself (Taylor, 2003).

Data and time limitations

While models are intended to reduce uncertainty, decrease risk, maximize credibility, and create confidence for the end user, quantity and quality data limitations are one of the greatest challenges to the ability of policy analysis tools to meet those expectations. As Longworth et al.

noted, “the risk of garbage in garbage out exists, and uncertainty can never be ruled out completely” (Longworth et al., 2012b, p. 3).

Tools or models need quality data and useful results to serve a purpose in the decision making process; specifically, the model’s ability to reliably predict the outcomes of policy alternatives to assist policymakers. Even if the model accurately reflects the impact of policy choices, the results are only as good as the original data. As Heller noted, analysis provides “a marvelous array of pretend tools which would perform wonders if ever a set of facts should turn up in the right form” (Farrell, 1976, p. 791).

One of the greatest challenges in dealing with policy is timing. If a choice needs to be made and useful information does not exist, lacks quality, contradicts other information, or is insufficient, the policymaker still must make a decision. Therefore, scientists must think ahead and determine what policymakers will need, learn how to deal with uncertainty, and have relevant information available (Meffe & Viederman, 1995). Policy researchers, such as congressional aides, have indicated that for information to be useful in policy development it must be available on demand as important issues surface. Timely delivery of information addressing policy questions is critical for the information to be helpful (Boone, Tucker, & McClaskey, 2002); “The burden, unfortunately, is on scientists to provide relevant, timely, and meaningful information to policymakers” (Meffe & Viederman, 1995, p. 328).

Political realities

The decision styles of policymakers are different from the type of evidence and information provided by analysis. In the most basic comparison, it comes down to reason versus politics. A rational approach indicates decisions are made from purposeful and logical deliberation while the political model indicates decisions are made by debating alternatives with no more emphasis placed on scientific evidence than previous experience. A third model, intuitional approach, is not based on processing information, but is based on feel, instinct, and ideology. Often intuition becomes the primary source of influence over the decision maker when policy analysis tools appear to be no more credible or reliable than gut feeling (Miller, 1989). In addition, policy analysis needs to pay attention to political feasibility in the evaluation process (Szostak, 2005).

Low-probability, high consequence events

For policy analysis to serve its purpose, it is necessary to accurately define the objectives, outcomes, and values of stakeholders from the beginning. This can be exceptionally challenging in low probability, high consequence events with a wide range of impacted stakeholders (Cowell et al., 2002). In these cases, there is generally disagreement on the probabilities and potential consequences, which leads to unrealistic expectations and misunderstandings about risk. Most analysis tools assume stable understanding and risk preference of the situation, which makes it more difficult to apply them to low probability-high consequence events. If the probabilities of risks are not estimated effectively and there is incomplete information, a classic market failure can occur as does with externalities and public goods (Camerer & Kunreuther, 1989).

More questions than answers

Policy analysis is frequently based on scenarios with assumptions which makes results seem meaningless and typically creates as many questions as answers. These shortcomings in policy analysis make the role of the decision makers more difficult rather than simpler (Miller, 1989). While traditionalists see analysis as a tool to help decision makers select from policy alternatives, others see it as a contribution to the discussion and not a problem-solving tool (Shulock, 1999). Conflicting, imperfect information and demands from multiple perspectives surround policymakers. They want answers, not more problems or questions (Meffe & Viederman, 1995). Policy analysis may be more effective at showing the challenge of selected problems and the difficulty in making a decision than simplifying the decision process (Lynn, 1999). Scientists and economists can be seen as "better at asking the right question than finding the right answer" (Leman & Nelson, 1981, p. 99). Policymakers often expect rapid, unequivocal research that leads to clear, final answers and do not want the predictable response of "more research is needed" (Trostle et al., 1999, p. 103)

Communication and influence

If the work of policy analysts and educators is going to prove useful, it must reach decision makers and serve a purpose when it does so. The Kings-Kingmakers model, depicted in Figure 5-2, has been considered most useful by some policy analysts and educators in reaching policymakers but requires analysts and educators "to get out of the ivory tower and 'break bread'" (Flinchbaugh, 2003, p. 2). The order of influence as depicted in the triangle indicates the importance of a small group of influential individuals and organizations, known as kingmakers that operate behind the policy stage to influence policy decisions. Kings are typically visible leaders and elected officials. Actives represent civically-engaged individuals and interested individuals that stay informed on relevant topics. The apathetic groups represent those not engaged. All levels of influence need to be considered in the policy development process (Knutson et al., 2007).

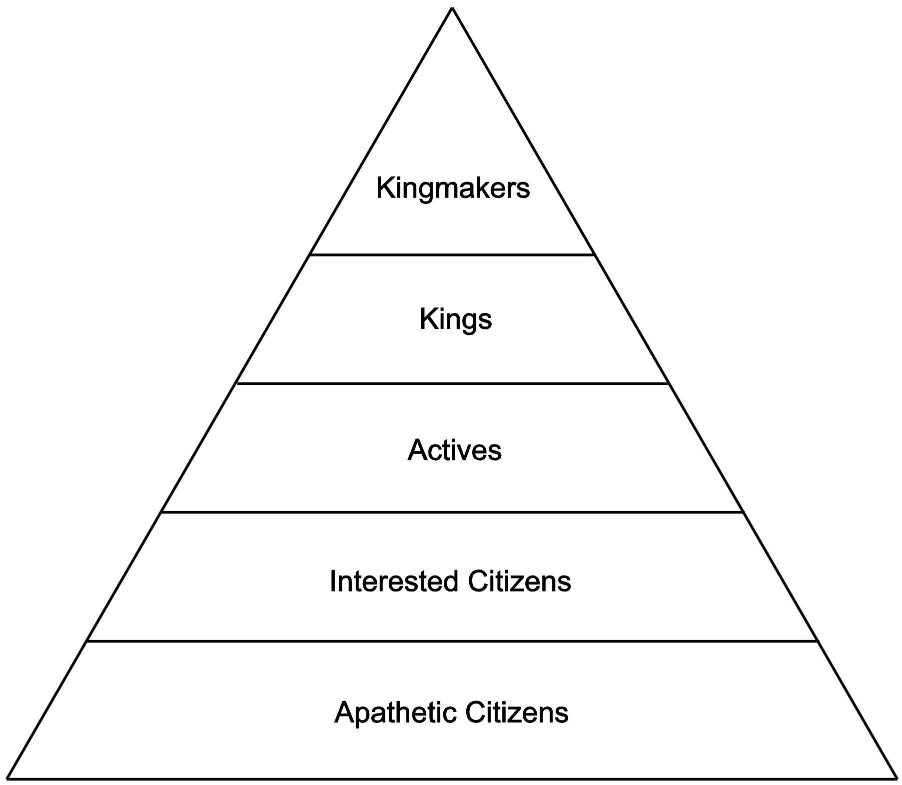

Figure 5-2 Community influence triangle. (Flinchbaugh, 2003, p. 2).

Only one part of the process

Policy analysis is a social science and it cannot achieve the rigor of other scientific areas. While the application of science to policy leads to data collection, the rigorous evaluation of alternatives, and defined reasons for action, it does not account for values, human interests, and political context which are necessary in the policy making process (Lynn, 1999). Political analysis is not an end in itself; it is a means to an end of improving how policies are made (Bottum, 1975; Lynn, 1999).

As Tildesley et al. (2007) noted in defense of their model, "our model will be of value as a decision tool, it should only ever be used – as with any model – as one of the various sources of information available to policy makers" (p. E13).

While models are seen as invaluable decision support, they "cannot provide complete and unequivocal answers to a decision making problem" (Taylor, 2003, p. 6). They can be used to explore options and issues, but decision making criteria will be based on factors not covered in a model. Decision makers need to understand model results will likely be imprecise and depend on assumptions made to deal with uncertainties. They are not an end in themselves, but help provide greater understanding (Taylor, 2003).

The greatest gain from mathematical models is the understanding that is created (Green & Medley, 2002). "Many modelers live with the mantra that all models are incomplete, are partial representations of reality, are therefore wrong in some (possibly important) respects, are largely about ideas, understanding and integration of complexity, are but one of the tools in the scientific armory, and last and essential, if they are to be applied on practical matters, they must first be shown to be better than existing ways of solving those problems" (Thornley & France, 2009, p. 140).

Need for a framework

Models must be used with caution in the decision process. Policymakers cannot depend on models and should be prepared to consider model results as one factor in the decision process. "Decision makers require some sort of framework within which model results can be combined with other quantitative and qualitative criteria to guide the decision" (Taylor, 2003, p. 81).

Policymakers and the public need to understand the problem, identify the alternatives, and weigh the consequences. Long- and short-term impacts, public and private costs and benefits, and clarification of who pays and who loses must be considered (Bottum, 1975). Policy analysis needs to provide evaluation of the means and ends of a policy choice with an equitable consideration of the means that make it possible for an end to be achieved as well as the end itself (Holland, 2005). A decision-making framework is needed that is designed by competent scholars to incorporate this information, other relevant research from multiple disciplines, and the bits and pieces that make up policy information and analysis (Bottum, 1975).

Science, Economics, Research, and Policy

Policy is influenced by many forces, including scientific and economic research. Informed choices, rational policy selection, and considered decisions result from the bridging of research and policy. When research is not considered, policy is more heavily influenced by vested interests. However, scientists and economists providing research information to policymakers could also be considered vested interests. Research can influence policy with three approaches:

- Rational approach (knowledge driven and problem solving),
- Strategic approach (political and tactical), and
- Enlightenment or diffusion approach (interactive and intellectual) (Trostle et al., 1999).

Challenges

The application of scientific information to policy decisions is not often successful. Often the scientific information is provided in a manner or volume difficult for the policymaker to comprehend, is not available, or deals with only one or a few of the scientific, economic, legal, or social issues being considered (Adams & Hairston, 1995). The problems related to influencing policy with research are well-known, yet potential solutions are rare. Unrealistic expectations, a lack of definitional clarity, and poor comprehension are challenges related to linking research with policy. Guidance provided to policymakers should be less focused on policy content variables and more on the decision makers' identities and qualities (motivation, agendas, leadership strengths, experience, training, prestige, and power), the processes of change and application (communication, interest group influence, actions, and outcomes), and the context of policy development (political and economic stability, level of centralization, and roles of government branches) (Trostle et al., 1999).

Many policymakers do not have scientific backgrounds or expertise, but are faced with science-related policy issues. Scientists need to provide accurate information to help decision makers consider policy alternatives while understanding science alone may not determine the decision (Nath, 2008). In the case of agricultural economics where alternatives are typically weighed in terms of consequences, research can serve as an analytic, educational, or decision making resource (Butz, 1989). Science gets translated into risk and risk gets translated into some type of policy action. Scientists need to develop sound risk-based scientific models to guide policy development (Institute of Medicine of the National Academies, 2006).

Risk attitude

A decision maker's risk attitude will influence policy decisions (Spradlin, 1997). Risk cannot typically be eliminated by a policy choice, but policy choice can attempt to lower risk at the least cost. Policymakers must blend science and reality to make a value judgment on acceptable levels of risk for the given scenario (Adams & Hairston, 1995). A more risk averse decision maker will attempt to reduce potential negative outcomes in all cases, but a more risk neutral decision maker will likely consider the approach that averages the lowest negative outcome. A risk-taking policy approach may focus on the strategy that leads to the most positive outcome even if it is less probable (Bergevoet et al., 2009). Risk serves as the basis for decision making in regard to preventative and preparatory measures (Rushton & Upton, 2006) and determining the acceptable level of risk is political judgment to be made by the decision maker (Giovannini, 2007).

Science and policy relationship

In 1921, Charles Merriam called for the cross-fertilization of science and politics, but attempts to blend the disciplines did not really get attention by analysts until the 1950s and 1960s (McCool, 1995).

Science has traditionally been politicized in public policy debates. Political advocates, legal experts, and special interest representatives increasingly use alleged scientific facts and acclaimed scientists to argue for their opinion or positions. The contribution of science to sound policy development has been diminished and is in danger of being compromised (Pielke, 2002); "The connection between science and policy is nothing less than the connection between science and society itself" (Lynn, 1999, p. 423).

There is an increasingly tense relationship and conflict between science and policy. Scientific problem solving is empirical, rational, and methods are highly prescribed. Policy making is normative, assumes multiple interests, is not empirically justified, and is embedded in an irrational system. Often policy is developed with little scientific or technical expertise but significant influence from special interest. On the other hand, regulations and rules are often developed by bureaucrats and agency administrators who access scientific and technical information but engage the public on a limited basis. Policymakers often have science advisors, staff scientists work with agency decision makers, and science advisory panels may review policies and regulations and provide feedback. While these methods create discussion between scientists and decision makers, no framework exists that equally integrates "science based rationalism and interest based democracy" (Cahn, 2002, p. 7).

Science is made up of many scientific subgroups and in itself is not monolithic. Many scientists believe "science alone provides a sufficient basis for decision-making, in that a problem is identified, various hypotheses are tested, remedial policies suggested and implemented – then the situation improves" (Pielke, 2002, p. 367). However, this approach ignores political reality and may, in fact, lead science to being more political rather than making policy more scientific (Pielke, 2002). Instead of scientific data driving policy and perhaps not asking the correct questions, there is a need for "policy-driven science" (Breeze, 2006, p. 273) where policymakers develop visionary goals and scientific tools are applied to meet those goals (Breeze, 2006).

Researchers cannot complete scientific work and assume someone is using the information to make good decisions. If results do not lead to effective policy, it accomplishes very little; "The challenge is for science to inform policy to change individual and institutional behavior" (Meffe & Viederman, 1995).

It is important to understand "…how essential a close collaboration and a mutual understanding and agreement between scientists and policymakers are. An open, progressive policy making process stimulates research and science in developing targeted, risk-based and cost-efficient survey methodologies" (Reist, Jemmi, & Stark, 2012, p. 182). The development of strong working relationships between policymakers, industry leadership, implementing agencies, technical experts, and researchers early in the process allows for a better understanding of knowledge gaps, the development of solutions that best meet existing needs, and their more rapid, effective implementation of policy choices (Reist et al., 2012).

The attempt to combine science, policy, and advocacy can be described as a shared interest iron triangle with policymakers, special interests, and scientists in each corner. In this relationship, science is a traditional tool of debate and political maneuvering. Thus, a clear definition needs to exist between political analysis and political advocacy. Advocacy tends to try to limit policy alternatives to one or very few choices, while analysis provides a range of alternatives and choices defined with associated consequences determined by scientific research. Advocates will continue to use science to support their arguments, and scientists must understand the repercussions of letting advocacy blend with scientific information until neither can stand alone. Scientists need to determine how to provide input in a usable format through independent authorities to expand policy alternatives. The goals of such efforts should be to reduce political stalemates and create a more realistic understanding of the role science can play in policy development (Pielke, 2002); "Policy efficacy can be improved to the extent the paradigmatic conflict between science based assessment and interest based policy making can be resolved" (Cahn, 2002, p.3).

Scientists want public policy to be scientifically rational, but do not believe it to be. While there is great opportunity for science to influence policy, the process itself is not scientifically rational. Scientists have experienced culture shock when exposed to the policy process and are surprised by the pace of activity, number of issues being considered simultaneously, and the reality that decisions must be made with incomplete information (Doering, 1994).

"In an ideal world, biologists would experiment, observe, tell policymakers what to do, and it would be done. But our world is far from ideal, and policy-making does not work that way" (Meffe & Viederman, 1995, p. 328). In order to have influence on public policy, scientists must understand it is a political process balancing different players and different goals. Instead of complaining about the political process, scientists need to adjust to the existing system. Scientists are also citizens and have every right and responsibility to influence policy. The science-policy relationship will never be symmetric because policymakers will continue to make decisions without scientific input. Scientists must incorporate broader information from multiple perspectives to better influence policy. Science is only one potential input into the policy process, and scientists must listen to policymakers if they expect the opposite to occur. They must also go where policymakers are – they are not readers of journals and they do not attend research conferences. Scientists must provide information policymakers want and need, not what interests them (Meffe & Viederman, 1995).

Education, science, and politics all serve different social purposes in public policy. Education is about developing the decision maker and requires interaction between learners, leaders, content, and context. Science is about developing the information and differentiating myth from fact. Politics is about developing public policy potentially through communication, compromise, and agreement. As Larry Libby noted, when referring to public policy analysis and education, "Our goal is to facilitate orderly change, minimize conflict, and generally inform people. It is not our goal to preserve farmland, preserve farmers, preserve wetlands, increase the supply of cheap housing or expand the tax base. We may vote on these issues at some point, but continued credibility as analysts and educators requires that we merely catalyze a decision process" (House, 1993, p. 29, Libby, 1991, p. 107-108).

Economic considerations

Economists want their work to influence public policy, but do not often think about how their work can do so effectively. They typically see themselves as distinct from politics, values, subjectivity, and normative elements. If they limit themselves to this role, they can become irrelevant and excluded from the policy process. They are advocates for efficiency, which is in itself a value-laden objective, and cannot be purely objective because economics, like other sciences, imposes its own premises and paradigms (Nelson, 1987). Policy is about choosing between competing values and economic analysis fails to help decision makers select between them. Equity may be seen as more important than efficiency and values may need to be weighted to reconcile with policymakers' preferences (Leman & Nelson, 1981). "While all disciplines of a university may contribute research results necessary to policy formulation, economics is the pivotal discipline" (Bottum, 1975, p. 764).

Some stakeholders in policy debates see economists as the enemy. Environmentalists are offended by the concept of a cost-benefit analysis of an environmental policy issue (Nelson, 1987); "Within the field, policy analysts trained as political scientists have jousted with policy analysts trained as economists" (Lynn, 1999, p. 411).

In some cases, natural resource and environmental professionals do not believe natural resource and water issues are a good fit for economic analysis because they are so politically charged. The Bureau of Land Management has noted because it is "morally, ethically, and professionally right to institute management practices that stop erosion, grow better vegetation, and improve rangeland condition and trend. We should not have to economically justify these management practices" (Leman & Nelson, 1981, p. 98). Economists can serve a valuable role in policy debates and, like other scientists, provide a different view or perspective to policy selection. If economists will consider values and understand political priorities, many believe economists can provide guidance to policymakers on technical and scientific matters and help make the process more efficient and effective. Once economists define the impacts of policy alternatives, policymakers can weigh the options against values and priorities (Nelson, 1987). Theories related to natural resource issues can be directly related to animal health issues.

Rulemaking

Cahn (2002) called for a model of science-based policy where decisions are influenced by stakeholder debate but limited to predetermined alternatives constrained by scientific and economic efficacy. While most research on policy analysis and influence on decision making have been done related to legislative bodies or head executive positions, little exists related to administrative-level policy influence which is where a majority of day-to-day policy decisions are made. This model extends beyond negotiated rulemaking where consensus decisions are reviewed by a scientific panel to a process of bringing a consensus-based stakeholder group and a science advisory panel together to create a better policy that is based on technical expertise and science-based evaluation (Cahn, 2002).

Communication between policymakers and scientists

Clear communication between policymakers and researchers is critical because the vocabulary of each is often different and understanding may be lost. If each player wants to be seen as the most influential contributor to the decision, "mutual intellectual disdain" may exist (Trostle et al., 1999, p. 107). While research is only one input in decision making, it can serve a critical role in the policy process with effective communication and collaboration between policymakers and researchers. When policy formulation and research process can overlap and not be limited to functioning independently, opportunities exist to make better policy decisions (Trostle et al., 1999).

Values and policy

A general belief exists among some scientists that research should be value free. However, policymaking is about maximizing a set goal and the selection of the factor being optimized incorporates value judgments. Policy optimization is based on achieving goals, and goals represent and result from underlying values. Policymakers, like researchers, need to be objective and value free in execution and keep their personal values from influencing the evaluation and decision process. Policy analysis also needs to be sensitive to account for changes in optimal policy choices when goals change (Nagel & Neef, 1978).

Policy analysis includes economics, statistical inference, political science, social psychology, and sociology. The language used is not neutral and serves as an indicator of values. Analysis is about resource scarcity, opportunity cost, validity, stakeholders, organizational culture, goal displacement, cognitive dissonance, and efficiency (Lynn, 1999). Policy analysis tends to ignore ethical considerations and public policy programs tend to fail at teaching future analysts how to incorporate value decisions (Szostak, 2005). Science is influenced by ethical and methodological value judgments (Kuhn, 1977). Scientific analysis is often in conflict with values-driven choices (Coates, Heid, & Munger, 1994); "There is little sense in yearning for a bygone era when science was construed as 'value-free'" (Pielke, 2002, p. 368).

Values influence what individuals believe ought to be or should be and determine how they view problems and the policy strategies that can address those problems (Beaulieu, 2000). Science cannot independently determine the best policy choice because it cannot provide a value judgment that prioritizes goals or interests of one stakeholder over another. But values may drive what areas researchers choose to work on or develop expertise in and providing information even if intended to be unbiased can shift the political balance on the given issue. Even an objective, unbiased, non-advocacy approach to public policy analysis or education likely is not politically neutral (Barrows, 1983).

Ethical analysis is typically described in three broad terms: consequentialism (evaluate acts in regard to their consequences), deontological (evaluate in regard to rules), and virtue or process-based approach (in regard to a set of virtues). Intuition and tradition can also be used as ethical evaluations. Ideologies within politics can also be aligned with ethical analysis methods: pragmatic liberals are consequentialists, classical liberals are deontological, socialists focus on virtue, populists align with intuition, and conservatives value tradition (Szostak, 2005).

Some scientists see any involvement in policy as advocacy, a conflict with their commitment to scientific objectivity and a violation of the public's trust. All analysis is subjective because values influence objectives, model selection, data sources, etc. Meffe and Viederman (1995) argue values are constantly present even if they are not explicitly expressed or admitted. Values and biases become clear and focused in the policy process and by the individuals involved (Meffe & Viederman, 1995).

Agricultural Policy

Agriculture policy stems from the industry's social, political, and economic interdependence, diversity, and irreversible role in international affairs and must be considered as an integral part of national and global policy arenas. As the effect of agricultural policy has expanded, the potential conflicts have grown between traditional agricultural and food interests and special interest areas such as environmental protection, urban development, food safety, and international trade policy. As the government role in agriculture is defined, questions arise about who loses and who gains, the impact on societal welfare, the measurement of net costs and benefits, and compensation for policy losers. All of these concerns and conflicts lead to an evaluation of policy tradeoffs within a complex political, social, and economic policy matrix. Societal goals and priorities must be at the center of the analysis, not just a consideration of the impact on the agriculture. While agriculture policy analysis in narrowly defined areas is well recognized, the evaluation of long-term, complex, controversial agriculture policy issues is more challenging (Farrell, 1976).

Application to agriculture and animal health emergencies

Protecting animal health is strongly related to food safety and is critical to "public health, consumer confidence, and profitability of animal agriculture" (Goodwin, Clark, Thilmany, & Hamm, 2006, p. 189). Animal health and food safety are components of national security and central to the national economy. As public goods, they require public intervention and collaborative industry approaches rather than individual farmer and rancher actions; "The challenge is to develop and implement policies that most effectively protect a safe and secure food supply and a competitive livestock and poultry sector in North America, given increasing concentration and intensification of animal agriculture" (Goodwin et al., 2006, p. 190).

Policies and efforts supporting animal disease research, surveillance system development, animal identification and tracking, and vaccine research can help reduce the impact of an animal disease outbreak. Implementation gaps, poor communication, and ineffective information sharing exist among federal and state agencies and organizations with responsibilities for food safety and animal health (Goodwin et al., 2006). This is especially true in dealing with an FAD outbreak; “Decision making on highly contagious livestock disease control is a multi-stakeholder and multi-criteria process, usually focused on a variety of decision alternatives” (Longworth et al., 2012b, p. 13).

The same characteristics that make environmental policy complex can also be applied to agriculture emergency decision making, including “incomplete information, uncertainty, systemwide change, trans-frontier impacts, current causes that have far reaching future effects, irreversibilities, and possibilities of catastrophic change” (NCEDR, 2002, p. 1).

In regard to developing policy to address intentional and emergency threats against agriculture, the *4Rs* approach applies: reduction of the threat and its impact, readiness of operational systems and capabilities to deal with an emergency, response to the emergency, and recovery efforts following the incident. The values the policy and response system is designed to protect must be clearly identified as well as the expectations, responsibilities, procedures, and decision making process (Ministry of Agriculture and Forestry [MAF], 2008). When policymakers select control strategies, they must reflect animal health, economic, and social concerns, and can be categorized as epidemiological effectiveness, economic efficiency, and social welfare (Ge et al., 2008). There is a need for more research on the management issues of an animal disease outbreak and a better understanding of policy alternatives faced by animal health officials (Pritchett, Thilmany, & Johnson, 2005).

Complexities of dealing with FAD

In FAD response policy, threats and risks need to be assessed, prevention contingency plans and strategies need to be developed, surveillance methods need to be improved, gaps in regulatory powers need to be addressed, cooperative efforts need to be established, and coordination and decision making needs to be improved to make a rapid, effective response possible (Texas Agricultural and Natural Resources Summit Initiative, 2002); “A major challenge of FMD prevention in the US is to design an appropriate prevention and control plan which effectively partners capable officials with livestock stakeholders” (Premashthira, 2012, p. 8).

Developing optimal animal disease control strategies is a complex problem. Policymakers must make choices with limited information amidst a dynamic process where optimal solutions change as circumstances evolve (Kobayashi et al., 2007b). Policymakers may be tempted to act rashly or hastily when complete information is unavailable. They may not understand that within an animal health framework there will always be information they do not know. The chaos and complexity of animal health disease decision making represents a fairly new understanding that full truth cannot always be achieved in scientific arenas. The potential volume of information makes full knowledge impractical and may more likely create noise rather than provide strategic signals for action. Complex policy issues indicate that while patterns may appear and be identified, they cannot be consistently predicted in a complex domain. In a chaotic domain, cause and effect cannot be easily identified. In these cases, predictive strategies do not lead to effective responses (Ackerman, 2006).

Control and eradication costs, along with production losses, have been the focus of most impact assessments of animal disease emergencies. Future analysis needs to consider assessing changes of national and international trade regulations due to the response of domestic and global consumers. In addition, the management of an animal health disaster will require control measures influenced by environmental protection issues, food supply and safety concerns, and international trade rules (Rushton & Upton, 2006).

Policy processes and decisions regarding the threat of a disease outbreak need to balance the adequate preparation without exaggerating the chances and impacts of the threat. A policy built on paranoia or overreaction, especially if an intentional disease introduction is involved, will create greater security concerns. Developing measures that address intentional and unintentional disease outbreaks will help deter terrorists and criminals while assuring farmers, ranchers, and consumers that the industry and agency is prepared without appearing to be fear-mongering (Lawson, 2000; Pearson, 2006).

While decision making is often discussed in literature, minimal discussion has been devoted to how decisions are actually made in dealing with an animal disease outbreak. Multiple decisions over a period of time will influence the end result of the outbreak, and this decision making process is not limited to a single step at a set time (Ge et al., 2008). Decision makers need to consider a number of issues, including export markets, American confidence in the food supply, reassurance of the human health threat/non-threat, indemnity costs, costs of control strategies (vaccination, depopulation, and disposal), psychological impacts of animal destruction, and cleaning and disinfection costs (DeOtte & DeOtte, 2009).

Making a decision and selecting a strategy

Many times decisions related to animal health, especially at the national level, have been influenced by gut feelings, common sense, political pressure, and the effective lobbying of special interests. However, there is an increased desire for policy decisions to be more transparent, accountable, and based on a structured framework for priority assessment. Developing frameworks is exceptionally challenging due to the number and variety of animal disease problems. There are also multiple control options for FADs and multiple methods for applying those options which results in decision criteria that are constantly changing instead of quantifiable absolutes (Perry et al., 2001).

In many cases, in an animal disease emergency, the economic value of avoidable losses is a more appropriate comparison than total losses when evaluating control strategies. A number of economic models have been used to quantify the total value of losses related to animal disease or the value of avoidable losses related to a specific control strategy. With significant effort, more epidemiological information about production and disease spread has been translated into economic functions. It is unlikely a single framework for animal disease priority assessment can be defined and implemented, so decision makers will likely be limited to well-defined disease constraints, control strategy alternatives, and other decision criteria determined necessary by the decision maker (Perry et al., 2001).

Some of the factors that will determine the effectiveness of a control strategy will differ in each outbreak, so a response policy cannot be static. A generic explanation of the economic impact of any one response is unlikely to be accurate in all cases. In each scenario, the benefits of one response strategy may be distributed to one group of stakeholders while others carry the costs (Giovannini, 2007; Horst et al., 1999). In addition, the distribution of costs and benefits from disease response will likely be influenced by "political ideologies and choices" (Horst et al., 1999, p. 376).

Perry et al. (2001) identified four steps for selecting an animal disease control strategy that is appropriate, technically feasible, and economically efficient as:

- Scenario development – construction of a framework identifying realistic control alternatives and their associated consequences,
- Quantification of alternative strategies – accurate quantification of components and costs of each control alternative and their associated outcomes,

- Development of decision criteria – key criteria on which the strategy will be evaluated, and
- *Ex post* evaluation of the decision making process – assessment of how the scenarios, data, analysis, and information prepared were used by the decision makers (Perry et al., 2001).

Each of these steps has its own challenges. Scenario development requires the best information on disease incidence and spread, impacts of control strategies, logistics, resource availability, and that national policies and aspirations are considered and all alternatives evaluated be deemed realistic in the light of this information. Eradication strategies need to be given special consideration as control alternatives. The quantification of alternatives creates a significant challenge as inadequate data typically make it difficult to provide decision makers with high quality, credible information. There is little information on decision criteria. Biological efficacy and economic criteria, such as benefit-cost ratio, net present value, and internal rate of return, are the most commonly discussed criteria. However, a number of other issues such as effect on employment, distribution of benefits, impact on other sectors, public health, etc., need to be considered and may make a tool such as CBA based on economic indicators alone useless. The tools and information need to be appropriate for the policymaker to use in making decisions, but typically the usefulness of tools is not evaluated (Perry et al., 2001).

In the UK, Deirdre Hutton (2002) called for a new approach to government decision making in dealing with an animal disease emergency that restores consumer confidence, keeps leaders from hiding behind scientific advisors, and includes consumer interests in public policy making. Consumers should be engaged in framing the scientific questions, scientists should remain independent, and decision makers must apply political value judgments to the uncertainties and risks highlighted in scientific analysis. In general, decision making needs to be more open and transparent, the public must be continuously involved in the policy process, the precautionary principle should be used judiciously, and social and economic factors need to be considered in addition to scientific concerns (Hutton, 2002).

In another assessment of FMD control strategies in the UK, researchers at the University of Reading developed a decision analysis tool made up of four matrices, a flow chart, and a spreadsheet. Four initial matrices were developed related to epidemic characteristics and ability to control the disease (virus type, species impacted, disease confinement, and likely speed of control), export issues for different livestock and livestock products (stability, competitiveness, value, related jobs, trade balance, and national market), livestock systems demographics and relationships (numbers, density, breed, systems, slaughter, and links to other sectors), and importance of livestock sector to the rural economy, jobs, business environment, and community stability. These four information matrices were then combined into one overall control strategy matrix designed to assess the control strategies and their impact on the epidemic, exports, jobs, and the rural economy. A flow chart is then implemented that incorporates information from the four initial matrices and the control strategy matrix along with results from economic and epidemiological models. A spreadsheet model is then used to calculate direct costs of different control and eradication strategies. The goal was to develop a more flexible decision analysis tool that can be modified to meet the needs of specific users in specific scenarios (Rushton, Taylor, Wilsmore, Shaw, & James, 2002).

Maness (2007) found in dealing with natural resource policy analysis that public beliefs and values must strongly influence policy decisions, the decision makers must be continuously educated, and no optimal solution typically exists with the information available. There should be less focus on values and more on consensus of policy goals and use of continual evaluation of indicators.

McReynolds (2013) noted the need for well-informed decisions to be made in determining the best disease control strategy. In an FAD outbreak, conflicting interests from various stakeholders will complicate the decision maker’s job. For example, in some cases, economic interests may be paramount while others may prioritize animal welfare over economics (Mourits et al., 2010).

Animal health agencies cannot handle all components of a response; emergency management, logistics, economics, legal, and communications experts must all play a role. The response must represent the whole of government and industry combined (Garner et al., 2002). Regulatory agencies with expertise in animal health, agriculture industry economics, and livestock production can be replaced if appropriate policy approaches are not implemented. In the 2001 U.K. FMD outbreak, the Ministry of Agriculture, Fisheries, and Food (MAFF) (currently known as the Department of Environment, Food, and Rural Affairs [DEFRA]) lost their authority over control strategy policy decisions to the Cabinet Office Briefing Room

(COBRA) which was advised by the Science Group and the Scientific Advisor to the Government (Kitching, Thrusfield, et al., 2006).

Emergency animal disease dilemmas are not just scientific and technical issues; they are economic, political, and social issues. Decisions on response strategies need to consider all these aspects. As an example, long-term consumer confidence in the agriculture industry can be gained, maintained, or lost based on the response (Willis, Evans, Clifford, O'Neil, & Murray, 2007).

An FAD outbreak leaves a decision maker with a true dilemma; all choices lead to unattractive results. In one case, a full stamping-out strategy leads to mass destruction and disposal with the intent to reduce the economic costs of the outbreak, and, in the second case, the response strategy may allow a larger disease spread and longer trade restrictions but reduces the need for animal destruction (Hueston, 2007).

Animal health policy framework needs

The animal health policy framework must be flexible and include information from research, medical, public health, environmental, and policy experts. The many decision makers with responsibilities in the animal health arena need to better define their roles and better coordinate their actions. For disease response to be more effective current systems need to be restructured and a culture change is required. Scientifically based mathematical, epidemiological, and risk analysis models can help identify optimal strategies and result in science-based decision making and policy. However, the development and collection of high-quality scientific and economic data is necessary for models to be effective and accurate (Institute of Medicine of the National Academies, 2006).

In developing an analysis framework, it first needs to be determined if the focus is on the disease itself or the control of the disease. If the question to be answered is about control strategies, the responses considered should be socially acceptable and technically feasible. It is also important to understand from whose perspective the analysis is being completed and at what level. It is likely that a compromise will need to be made in the selection of method between an epidemiologically and economically thorough method with one the decision makers can understand. Analysis of animal disease policy dilemmas needs to "inform decision making, and thus needs to be strongly focused on what is achievable, what is practical, and what is acceptable" (Rushton et al., 1999, p. 338).

Uncertainty needs to be integrated into policy strategies and responses rather than just assuming it can be minimized or eliminated. A "…greater weight [needs] to be placed on robust, broad and holistic approaches to animal and public health instead of specific fixes to the particular threat (or disease) that is currently most prominent in the minds of public or policy-makers" (Ackerman, 2006, p. 357). Animal disease control policy is likely based on a compromise between large-scale disease response and logistic and economic feasibility (Garner et al., 2007; Tildesley et al., 2006). "Decision makers are faced with many difficult choices with respect to the design of U.S. FMD control policy. Thus, these decision makers will increasingly seek analytical tools and decision criteria based on sound science, as well as lessons learned from recent outbreaks" (Hagerman et al., 2012, p. 119).

Decision makers need to identify clear goals. To determine if a control strategy is successful, it is important to define success. Depending on their perspective, stakeholders can define success as achieving disease-free status as quickly as possible, confining the disease to a defined and limited region, to minimize loss of the domestic animal population, to minimize financial costs, and to minimize resistance and criticism from the public or the agricultural industry (Tildesley et al., 2012).

Use of models in dealing with FAD

Models can be a useful tool and play an important role in developing and evaluating control polices in an animal disease outbreak by inferring values of parameters and behavior that cannot be tested by experimental methods (Kao, 2002). When used in animal disease situations, models are designed to represent the behavior of biological process and their consequences. Often the models are designed to gain better understanding of processes to make the model more realistic. While a significant number of models have been developed, more complex quantitative theory will not necessarily overcome the limited knowledge of the biological processes and cause-effect relationships (Pfeiffer, 2004). Models are often static, short-run, or non-spatial, but animal disease and livestock production cycles evolve across time, space, and risk level (Rich & Winter-Nelson, 2007). Typically, epidemiological models are used in regard to animal disease outbreaks to predict duration, prevalence, and focus of the epidemic or identify potential control measures (Kitching, Hutber, & Thrusfield, 2005). Scientists need to be cautious with interpretation and outputs if models are used in dealing with or preparing for an actual disease outbreak because then they are no longer theoretical and will actually affect the livelihood of individuals, industries, and national economies (Pfeiffer, 2004).

Modeling what-if scenarios can help identify strategies that reduce the number of animals to be destroyed or other negative consequences. It is most helpful when used retrospectively to analyze previous outbreaks and determine response strategies, resource use, and risk assessments before an outbreak. Decision makers can use model results to help identify and evaluate control strategy options and to gain insight into policy choices, such as when emergency vaccination becomes economically viable in a scenario. Models should never be used in isolation when dealing with an animal disease outbreak, and all assumptions made and limitations encountered in modeling should be disclosed. While models can be a useful tool in supporting policy development, they receive little attention and have little influence outside the scientific arena. The primary concern about model use relates to the actual complexity of reality compared to model simplicity (Garner et al., 2007; Ward et al., 2009).

U.K. FMD example

The use of models for predictive purposes to guide tactical decisions during an outbreak needs to be cautioned based on recent experiences with model use in the 2001 U.K. FMD outbreak. This situation created controversy about the validity of models and the role they can play in dealing with an animal disease outbreak (Garner et al., 2007; Kao, 2002; Kitching, Thrusfield, et al., 2006; Ward et al., 2009). Since modeling was used during the U.K. FMD outbreak to help guide the decision making process, its role has been scrutinized (Thornley & France, 2009) and created significant disagreement between modelers and veterinarians (Pfeiffer, 2004). Models were developed in the midst of the disease outbreak and used to make policy decisions in meetings with the Science Group, specifically to implement the contiguous culling policy (Kitching, 2004; Taylor, 2003). Multiple mathematical models were used, ranging from computationally complex but conceptually straightforward models to mathematically simple models that were conceptually challenging and abstract. Deterministic differential equation, stochastic spatial, and more detailed Monte Carlo simulation (InterSpread) models were used (Kao, 2002). It is believed to be the first time mathematical models were used to make decisions on FMD control (Green & Medley, 2002). The use of models was not called for in contingency plans, and their use was in an ad hoc manner (Kitching, Thrusfield, et al., 2006). For example, Ferguson et al. (2001) published model results during the outbreak and concluded, "…extensive culling is sadly the only option for controlling the current British epidemic" (p. 1160).

Anderson (2002) noted little information was available on how the decision to implement the contiguous culling policy was made. Past event analysis indicated such an approach may not have been necessary. This indicates the models were either invalid or used inappropriately. At the time, animal health officials argued the models were wrong, and some have argued policymakers were influenced by the scientific and mathematical truth of a model when little other evidence was available to them at the time (Taylor, 2003). Kao (2002) did not find value in attempts to identify quantitative prediction estimates of alternative policy responses, and the use of models as a tactical advice resource has also been questioned (Green & Medley, 2002; Taylor, 2003). Better methods are needed to guide decisions in future outbreaks (Taylor, 2003); "The perception is that on this occasion modelling failed to deliver the goods, and indeed, misled the decision takers into less-than-optimal decisions, causing much consequent distress. Nevertheless, it would be a pity if this perceived failure contributed to a more general skepticism about the value of models, whether of global climate, of ecosystems, and of animal and human disease" (Thornley & France, 2009, p. 139).

In a U.K. FMD post-outbreak study, the Royal Society (2002) still found quantitative models to be an essential tool for the development and evaluation of control strategies as a part of contingency planning. Substantial data needs to be collected and made available to researchers if models are to be useful. They will have limited predictive value, but are more dependable with sufficient data in dealing with livestock disease than human disease. The pragmatic value of models can be evaluated by the ability to measure the effectiveness of control measures and estimate outbreak costs (Royal Society, 2002).

In the 2007 FMD outbreak in the UK, models were used only as a tool to predict disease spread. In place of the cost-benefit model approach to advise policymakers, a more qualitative method was used. Expert opinion from the livestock and meat industry, risk assessment information, and research on economic and trade impacts of different control strategies were provided to the DEFRA Animal Disease Policy Group who then used the qualitative concepts to make response decisions. They tended to place greater emphasis in their discussion on disease control and seemed to have a limited understanding of trade and economic impacts. Some have called for the use of a more comprehensive cost-benefit analysis tool rather than a more qualitative approach (Anderson, 2008).

DEFRA emphasized scientific input in updating their contingency plans after the 2001 FMD outbreak. One of the key lessons learned had been to use science as a basis for policy decisions, and, in 2007, scientific guidance was critical to the decision process. But, their typical response was basically "'we are following the science'" (Anderson, 2008, p. 84). If the public and industry are to be confident science is driving policy decisions, greater openness and transparency are required (Anderson, 2008).

Future use of models

Taylor (2003) concluded models can be used for retrospective evaluation of disease outbreaks and response strategies, resource planning by exploring resource needs for strategies in hypothetical situations, contingency planning by comparing response strategies in hypothetical situations, training through use of virtual models and realistic scenarios, surveillance targeting to identify priority targets based on risk assessment, and tactical decision support on a limited basis. They can also be used to evaluate effectiveness of control and surveillance strategies (Garner et al., 2007).

Models are best used in the absence of animal disease crises in conjunction with retrospective evaluation of actual disease outbreaks and hypothetical scenario modeling to develop *a priori* response guidelines for decision makers. During an outbreak, predictive modeling should be limited to monitoring and making minor strategy adjustments and should defer to veterinary intelligence to influence tactical decisions (Kitching, Thrusfield, et al., 2006; Taylor, 2003).

Green and Medley (2002) note results from modeling FMD control strategies are not "hampered by logistic, economic, or political considerations" (p. 203). Quantitative data may not be relevant but the knowledge can help decision makers. For example, results may indicate the radius of the cull zone needs to be wider than the radius of infection spread. Results can be more helpful when costs are considered or efforts are made to optimize outcomes based on control strategy. For example, nearly all models indicate the faster the disease is brought under control regardless of strategy the less costly the outbreak will be and a delay of just a few days can substantially increase costs, thus indicating preparation is worth the expense. These results provide insight for policymakers to minimize transmission quickly and reliably by reducing the number of susceptible animals (vaccination, culling, or quarantine/stop movement) and removing infectious animals (culling or quarantine) (Green & Medley, 2002).

Keeling (2005) identified three primary roles for modeling in animal disease response policy development. Models can be used:

- As a predictive tool based on current situations and available information,
- To extrapolate probable dynamics for one scenario based on the known dynamics from another set of parameters, and
- To test outbreak scenarios and control strategies for a simulated animal disease outbreak (Keeling, 2005).

The types of models used in animal health include qualitative and quantitative risk models that consider the introduction of disease to animal populations through risk pathways, analytical models that explore relationships between disease incidence and risk factors, disease spread models, population dynamic models, economic models, and specialized disease models (Taylor, 2003).

Economic models

Typically, economic questions arise regarding the impacts of animal disease. Questions surround the costs to farmers, ranchers, and government; price changes and the effect on farmers, ranchers, and consumers; international trade; national welfare; and employment in the agriculture and related sectors. The priorities placed on these issues will influence the types of models that should be considered for analysis (Rich et al., 2005a). To assess the economic impact of animal disease, analysis must provide the ability to compare and measure results from alternatives (Rushton et al., 1999). To weigh disease prevention and control strategies, policymakers need an accurate analysis of losses (Pritchett et al., 2005). The economic models used to study animal disease outbreaks differ by the type and impact of disease, including disease spread characteristics, species affected, impact on markets, or policy strategies. Common models include CBA, I/O analysis, CGE models, linear programming, partial equilibrium models, and multimarket models. Traditionally, impacts on government, production, markets and prices, food security, human health, environment, employment, and financial cost are examined (Hagerman et al., 2012; Pritchett et al., 2005; Rich et al., 2005a; Rich et al., 2005b).

Economics is about decision making. When applied to animal health, the framework is designed to optimize animal health management decisions. Economics can provide a rational basis for resource allocation and policy development in responding to an animal disease outbreak emergency (Garner et al., 2002). Decision makers need a complete understanding of the economic consequences of an FAD to determine effective policy. Most decision makers do not understand the impacts on consumers and producers, who bears the costs, and who wins and who loses. The accurate costs of implementing control strategies need to be available and considered along with welfare impact in selecting optimal disease control strategies, and policymakers should consider the point where marginal benefit equals marginal cost (Nogueira et al., 2011).

Economic analysis tools have become more important in animal disease prevention, control, management, and recovery, and economic-based decision criteria are likely to be considered a priority by policymakers (Schoenbaum & Disney, 2003). There is an increased appreciation of the importance and value of economic analysis as a tool to influence animal disease control policy, and CBA serves as a common analytical framework (Barasa et al., 2008; Rushton et al., 1999). Such a quantitative approach assumes public policymakers and private decision managers need to understand the possible outcomes of disease control options in monetary terms (Barasa et al., 2008).

CBA has been used a number of times for evaluating the impact of FAD and the potential control strategies. Researchers have frequently combined CBA with epidemiological models of disease spread. It is highly effective at estimating disease impact on a farm or herd, but not as effective when scaled up to determine regional or national effects. In addition, CBA also has limitations in estimating impacts across the economy or in long-term impact analysis. In some cases, the shortcomings of CBA can be addressed by combining it with additional analysis tools. Partial equilibrium models allow for shifts in supply and demand from a disease outbreak to be modeled and have been used to measure consumer and producer surplus from FAD response strategies. The combination of CBA and partial equilibrium can provide better modeling of price impacts, but the scope of analysis of links between agricultural and nonagricultural economic sectors is limited (Rich et al., 2005b). Multimarket models are used extensively in agricultural and environmental policy and could be used to assess national or aggregate disease impacts. I/O models can be used to analyze exogenous disease shocks on industry sectors and to evaluate the impacts of changes in demand due to data from an epidemiological model or exogenous shock.

Price changes cannot be assessed in an I/O model, so these models are less useful for estimating long-term effects of a disease outbreak (Rich et al., 2005a). CGE models have been used to assess FMD mitigation strategies and the impact of FMD outbreaks, but epidemiological factors have been provided exogenously rather than in conjunction with an epidemiological model as typically used with CBA, I/O, and partial equilibrium models (Rich et al., 2005b). They can provide policymakers insight into broad, national impacts of an FAD outbreak on income, trade, employment, and all economic sectors. However, limited data, poor information about immediate impacts, and obscure results may reduce the usefulness to policymakers (Rich et al., 2005a). The primary use of CGE models has been on measuring the economic impact of the disease rather than in analysis of response strategy (Rich et al., 2005b). The dynamic nature of livestock inventories and production cycles is not addressed in I/O, partial equilibrium, and CGE models, and it takes longer to reach new market equilibrium than the year typically modeled in an I/O model (Zhao et al., 2006).

In the case of an animal disease emergency, disease incidence is not predictable. Partial budgeting tends to be a better economic analysis tool than CBA. Decision analysis may be more appropriate than CBA and partial budgeting (Rushton et al., 1999). Risk plays a critical role in disease modeling. After the hazard and its characteristics are identified, epidemiological risk pathways for disease are modeled to determine predicted disease spread (Taylor, 2003). Giovannini (2007) noted risk analysis can be a valuable method for analyzing various control options in response to an animal disease emergency by quantifying their effectiveness and addressing the uncertainties. Although it has not been used extensively in animal disease control, it can be superior to other methods that have been used frequently such as CBA (Giovannini, 2007).

Decision analysis is considered by some to be the most suitable method to support decision making in an animal disease outbreak (Morris, 1999). Optimization techniques could be used to minimize disease spread, length of the outbreak, or economic loss from the disease incident. Farmer and rancher behavior changes can be considered and longer term impacts can be evaluated (Rich et al., 2005a).

Because a decision regarding the control strategy in an animal disease emergency is highly complex and requires making tradeoffs between multiple objectives, a multicriteria decision making model can be an effective tool in the decision process by providing structure to the discussion, identifying conflicting objectives and related judgments regarding tradeoffs to the attention of policymakers, developing a shared understanding and sense of purpose, and building agreement (Mourits et al., 2010).

There are a number of factors influencing decision making related to the implementation of animal disease control strategies (Perry et al., 2001). Policymakers benefit from the most comprehensive assessment that weighs losses against costs of disease mitigation (Pritchett et al., 2005). The distribution of losses, policy costs, and benefits is an important part of the information for policymakers (Paarlberg, Lee, & Seitzinger, 2003).

Epidemiological models

As quantitative epidemiology has been developed and disease modeling has improved, epidemiology has moved beyond providing technical data on disease life cycles and control strategies to disease scenario analysis, including economic impacts and consequences of animal disease and policy responses. An assumption exists that improved data and epidemiological analysis will serve as key decision support resource and result in better animal disease control policy development (Taylor, 2003). Spatial disease models allow for knowledge about infected hosts and movement patterns to be combined with quantitative factors related to infection and transmission to develop predictions about disease spread and to compare control strategies. Results can create visual mapping that conveys credibility beyond what the model can justify and may cause overconfidence in the decision makers (Riley, 2007).

Epidemiological models can be designed with different attributes and for different purposes. Analytical models are simple models designed to provide insight into epidemic data and disease observations. Predictive models project the speed and duration of the disease outbreak. Strategic evaluative models simulate a disease outbreak and can be used to compare control strategies. Economic models can also estimate the costs associated with the outbreak. Simulation models can assist decision makers in dealing with the complexity of a disease outbreak (Kostova-Vassilevska, 2004).

Epidemic models are typically based on dividing the host population into six classes: susceptible animals that are healthy but can be infected, latent animals that are infected but not infectious, subclinical animals that are infectious but not symptomatic, clinical animals that are symptomatic and infectious, recovered animals that have survived infection and are immune (either temporarily or permanently), and dead animals removed from susceptible categories

(Kostova-Vassilevska, 2004). Individual animal disease, on-farm epidemic, and inter-farm transmission factors are all influential in model development. Individual animal disease factors include species factors and in-host pathogen dynamics, such as strain variability, immunity factors, vaccine efficacy, and length of incubation, subclinical, and infectious periods. Examples of on-farm indirect and direct transmission factors are number of animals, species, transmission rates between individual animals, average number of susceptible contacts, and farm management practices. Transmission between herds and farms includes frequency and magnitude of direct contacts between farms, sale yards, and other collection points, as well as indirect contacts between locations such as vehicle and personnel travel, deliveries, road networks, weather, and geographical factors (Kostova-Vassilevska, 2004).

Control responses can be evaluated by changing the immunity status of animals within a baseline epidemic model. Variables can include the time delays of implementing control strategies, effectiveness of control strategies, or limitations on resources needed to implement strategies. As control responses are applied at various levels and simulations are run, the most effective responses can be identified by comparing gains and losses from each control measure and an optimal strategy for the affected region can be selected. Results can be used to determine total cost of the epidemic which can be helpful to decision makers. However, for a model to serve this role, substantial data that is typically unavailable is required. This is a considerable limitation unless a control response is robust enough to be the optimal solution under any data situation (Kostova-Vassilevska, 2004). This is not the case in regard to control strategies for an FAD outbreak.

A state-transition model, the typical structure of an epidemiological disease model, defines the transition from a susceptible state to an infected state, referred to as infection rate in deterministic models and infection probability in stochastic models. Models differ by the definition of infectious contacts and can be continuous or discrete. Continuous models are usually deterministic and non-spatial, and discrete models can be deterministic or stochastic and spatial or non-spatial. Models can be top down or bottom up. Top-down models are typically deterministic, based on predetermined assumptions for transmission rates and other factors identified by prefitting the model to realistic data or values, and lead to results based on these assumptions. A bottoms-up computational model is usually stochastic, divides the disease outbreak into several components, uses real data to develop attributes or parameters for actors within the model, and reaches conclusions based on averaged simulation results (Kostova-Vassilevska, 2004).

Disease models can be intra-herd or on farm models or herd-based models designed to evaluate disease spread over many herds or farms. These inter-herd models can be spatial or non-spatial. Intra-herd models are too simplistic to provide reliable disease spread estimates because contact rates within a herd or on a farm do not exist. Non-spatial herd-based models, such as the 2001 Keeling (2001) model, do not incorporate distances between farms and geographic locations and are too simplistic and of limited use because important disease transmission factors are ignored. Spatially uniform herd-based models as developed by Garner and Lack, Durand and Mahul, and Schoenbaum and Disney ignore the typical complex spatial heterogeneity between herds and farms. Spatially explicit models, such as the 2003 Bates, Thurmond, and Carpenter model or EpiMan developed by Sanson and Morris, include a number of disease transmission factors and realistic spatial distribution of farms and herds and are the best approach to measure disease transmission and assess control responses. Realistically, no existing models as they are currently constructed are robust enough for disease prediction and control in the US. An improved large-scale herd-based model including airborne transmission, road network, sensitivity analysis, and epidemic network information that provides high-speed computational efficiency is needed to address disease outbreak research in the US. It needs to be open-ended and easily modified, utilize geographic information systems, and take into account all transmission factors. If necessary data is available, a more complex, robust model can support decision makers and processes (Kostova-Vassilevska, 2004).

The three most commonly used spatial simulation models for evaluating animal disease outbreaks – AusSpread (an Australian model), InterSpread Plus (a New Zealand Monte-Carlo model), and NAADSM (a Canadian and U.S. model) – were compared. Regardless of different model building techniques, there appeared to be only a minimal number of statistically significant differences in outputs, small differences in results, overwhelmingly consistent results, and similar findings for decision makers (Garner et al., 2007).

Epidemiological and economic joint modeling

Animal health epidemiology and economics can play a unique role in policy and strategy development. The symbiotic partnership between the two disciplines provides a comparative advantage that offers additional opportunities (Perry et al., 2001). The integration of epidemiological data into economic models requires a multidisciplinary approach and can be challenging (Pritchett et al., 2005). The three questions that can typically be addressed:

- What disease comes first? (Priority),
- Which disease control strategies should be implemented? (Decision making), and
- What is the optimal method of intervention? (Disease control implementation) (Perry et al., 2001).

Mathematical modeling can evaluate the potential impacts of animal disease emergencies and epidemiological models help identify animal contacts and probable disease spread (Le Menach et al., 2005). Economic models may be paired with epidemiological models to combine disease spread predictions with potential economic impacts to help decision makers identify the best control strategies during a disease outbreak (Longworth et al., 2012a). Decision makers can utilize simulation models to evaluate policy alternatives and incorporate risk and uncertainty. But these models are only as useful as the similarity between the actual outbreak and the scenarios previously simulated. Policy evaluation continues to advance and move to the inclusion of more relevant information (Hagerman et al., 2012).

In an animal disease outbreak, practical decision making is a "sequence of decisions based on a continual stream of information" (Ge et al., 2010, p. 167). When final outcomes from epidemiological situations are used in static analysis, significant uncertainties found in chance events are taken as a given. The use of static analysis is contradictory to the actual dynamic, multistage decision process and ignores the policymakers' decision flexibility in an outbreak making it less reliable for guidance. Being able to compare scale and timing of control strategies in analysis is more realistic and would be more useful to decision makers. Without this flexibility, results create the risk of decision makers making a Type I error where underreaction occurs or a Type II error where overreaction occurs (Ge et al., 2010).

Under uncertainty, there is no guarantee the best decision will result in the best outcome (Ge et al., 2008). An epidemic-economic modeling approach provides the information necessary in a dynamic decision process and encompasses the continual uncertainty found in an animal disease outbreak. When combined with a decision model, it allows for control policies to be chosen dynamically during an outbreak rather than being pre-defined, allowing for the existence of ongoing uncertainty and knowledge gained during the epidemic. In any given state, the control strategies used will create costs within that state and influence future states.

Intertemporal tradeoffs are created as control strategies are selected at different times. Economic and epidemiological models need to interact together within the analysis process rather than being built sequentially (Ge et al., 2010).

A balanced strategy is essential to the best response, and Rushton and Upton (2006) conclude an economic decision tree analysis combined with an epidemiological model, along with a dynamic optimization model that identifies a unique solution, is the best tool to help identify a balanced strategy. However, they further note the level of uncertainty and unknowns in an animal disease emergency make optimization nearly impossible and make the value of models as a decision-making tool questionable. The value of the modeling lies in the process and not the solution (Rushton & Upton, 2006).

There remains a need for better integration of epidemiological and economic models, more complete understanding of disease dynamics and their control options, expansion of farm-level models to larger scale applications, and inclusion of factors such as environmental impacts and equity. In addition, few decision makers refer to economic impact assessments in the policy deliberation process. The use of wrong criteria, inappropriate scenarios, poor communication of outputs, and the decision makers' lack of training in epidemiology and economics can lead to assessments being of little use to policymakers (Perry et al., 2001).

Limitations of model use in the policy process

An animal disease emergency is a complex and dynamic problem. Decision makers must select a course of action based on limited information and balance tradeoffs between cost and effectiveness of various control strategies. Comprehensive measures may rapidly contain the disease but at high cost and consequence; conservative measures may allow the disease to spread and epidemic to extend, leading to larger costs in the long run even though it is less expensive in the short run. The expected epidemic and economic impacts of alternative disease control strategies need to be provided to decision makers. It is also critical to understand the dynamic nature of a disease outbreak. The decision process must also be dynamic and the optimal decision will change from one moment to another (Kobayashi et al., 2007a; Kobayashi et al., 2007b). In addition, rational economic models typically assume perfect markets and perfect information, but decision makers have minimal information about the efficacy of control alternatives (Tomassen et al., 2002).

While simulation models may be the best tool for evaluating animal disease control methods, limited data on livestock contact and limited validation of existing models will impact their usefulness in decision making as the legitimacy of any model depends on the accuracy of its data (McReynolds, 2013). The scarce availability of empirical data will make these decision processes difficult for decision makers because they will have limited information about the effect of control strategies on disease spread and economic consequences, and their selection of a less than optimal control strategy may lead to additional negative consequences (Mahul & Gohin, 1999). Additional losses can be incurred if control measure implementation is delayed due to indecision or lack of preparation. It is essential that decision makers have a decision structure in place before an outbreak because "…it is very important for animal health authorities to make the right decision immediately after the first diagnosis" (Tomassen et al., 2002).

One goal of policy analysis is to maximize social welfare by making decisions and allocating resources that optimizes social well-being. This is exceptionally difficult in agriculture-related policy evaluation because limitations exist on the ability to accurately determine the value society places on non-market natural resource and agriculture-related goods. These are complex decisions with a number of interrelated factors. It is difficult to define the public and how different opinions should be weighted. Gauging public preference is highly challenging. Even if reliable individual preferences could be collected, they cannot be combined in a way that accurately reflects society and community preferences developed through discussion and consensus, which are more valuable. Preferences and values are constantly evolving and developing and may change with how the question is posed. Analysis must attempt to deal with multiple value dimensions and measurements; deal with uncertainty about consequences; address unfamiliar evaluation contexts; balance time, effort, and accuracy; incorporate feelings and emotions; and adapt over time as values change (Maness, 2007).

Most policy simulation analysis assumes the decision maker maintains the decision made at the beginning of the disease outbreak for the entirety of the outbreak. This approach is unlikely to be realistic. In an actual disease outbreak, constant monitoring of the disease and the applied control strategies will lead to changes in policy and strategies. Decision makers would need to be able to predetermine the information they would need at any moment in the process to have the tools they need as the outbreak continued in a dynamic decision situation (Bergevoet et al., 2009). Ge noted in 2008, “The epidemic can only be understood backwards, but it must be controlled forward” (Ge et al., 2008, p. 3).

If models are to be used to impact policy decisions, research principles dictate that models need to be validated. Validation is done by testing the model against real-life data other than that which was used to create the model (Green & Medley, 2002). However, in dealing with animal disease, validation is difficult and may be nearly impossible because every FAD outbreak is different. Predictive models can serve a purpose in animal disease control policy as long as decision makers understand the assumptions made and the limitations included (Kitching, 2004).

An increased focus on the value of mathematical modeling has perhaps created a false confidence in their value, an illusion of certainty, a misperception of their importance, and a risky dependence on their outcomes, while drawing attention from the realities of animal disease control. Reliance on models that may be inappropriately constructed, based on poor or incomplete data, or cannot be validated is an abuse of mathematical modeling (Kitching, Hutber, et al., 2005; Kitching, Thrusfield, et al., 2006).

Need for Multidisciplinary Approach

Analysis with a singularity approach fails to incorporate the complexity of agricultural and animal disease related policy. Evaluation methods “must be multidisciplinary, involving technical as well as economic relations and other social sciences” (Farrell, 1976, p. 790).

Peter deLeon noted public policy was originally “grounded in the ideal of ‘the integration of knowledge across disciplines’” (Szostak, 2005, p. 853). A number of disciplines should influence policy formulation and no single discipline should dominate the decision process (Butz, 1989). Often policy-related scientific advice is provided by specialists with expertise in limited areas, such as only economics or animal health, and limited understanding about policy. This leaves the policymaker to assess the multidisciplinary impacts of their decision (Adams & Hairston, 1995). Scientists desiring to influence policy must develop an issue-driven approach rather than a discipline-driven approach. The focus should be on the problem and not a singular discipline. Disciplinary barriers must be eliminated and cooperation needs to occur across disciplines (Meffe & Viederman, 1995).

"Economics must blend with political reality, sociology, philosophy, and international diplomacy…The economist seeks to increase efficiency of resource utilization and to maximize returns; the politician tends to seek what is expedient, often from a short-time point of view; the sociologist stresses answers that focus on human values; the philosopher is concerned with what is thought to be good; and the international diplomat places a high priority on strengthening security in a peaceful environment" (Butz, 1989, p. 1995).

It is unlikely multiple individual disciplines can approach a problem independently and result in a uniform response. Blending individual inputs into a comprehensive approach is a challenging task because the objectives and methods vary amongst disciplines. Individual discipline should address policy questions independently and then blending can occur at the policy formulation level. Economists specifically should provide decision makers with policy alternatives and their consequences that can be assessed against the political, sociological, philosophical, and international goals. According to Butz (1989), applied economic work deserves greater recognition and should focus less on complicated formulas and esoteric theory and more on usable tools to address practical and societal problems. Simple data can be more influential on a policymaker than sophisticated econometrics, mathematical formulas, and empirical analyses they find difficult to understand. Tools must be easy to understand and persuasive (Nelson, 1987). Many require practitioners to have specialized training just to complete the analysis (Rich et al., 2005a). Policy-focused economists need to be aware the individuals they are attempting to educate or influence are typically not students of economics (Leman & Nelson, 1981). Collaborative approaches cannot be constrained to economic analysis alone (Maness, 2007). Though economists can help bridge a gap between the research and decision process, the final choice remains with the policymaker (Butz, 1989).

For a decision maker to address a real world, complex policy issue, it is critical to look beyond a single discipline and provide multiple perspectives and comprehensive thinking in policy development. A number of different terms are used to describe multiple discipline research and analysis, but even those terms are often defined differently.

- Interdisciplinary – the interactive synthesis or combination of two or more fields of study, disciplines, or professions that results in a new, comprehensive view.

- Cross-disciplinary – a coordinated effort incorporating two or more disciplines focused on finding a middle ground and viewing one discipline from the perspective of another.
- Multidisciplinary – an additive versus integrative approach using or relating to several disciplines at once.
- Transdisciplinary – a holistic approach designed to transcend boundaries of conventional disciplines (Choi & Pak, 2006; Gould, 2001; Salmons & Wilson, 2007).

Interdisciplinary research creates an interchange between multiple disciplines allowing for a problem to be addressed and understood from a variety of perspectives. It requires a team approach or an individual trained in multiple disciplines. This approach weaves together knowledge, approaches, and methods from several disciplines creating new solutions to a common problem. In addition to problem solving, the goal is also to create new knowledge, methods, and disciplines. Research is integrated across all disciplines into a coordinated whole rather than a compilation of research segments each focused on an individual discipline which is common in multidisciplinary research. While few problems are disciplinary in nature, an interdisciplinary approach is still challenging and requires merging of disparate approaches and thought processes (Choi & Pak, 2006; Gould, 2001; Salmons & Wilson, 2007).

Multidisciplinary research utilizes knowledge from multiple disciplines but remains within the boundaries of the individual disciplines. The disciplines themselves are not integrated; instead research results are used in a systematic additive or linear approach (Choi & Pak, 2006).

Transdisciplinary research goes beyond interdisciplinary research by cutting across disciplines through the use of a unified conceptual framework to solve a common problem. This integrative approach is designed to deconstruct academic, institutional, disciplinary, stakeholder, and government silos in order to address policy dilemmas in a holistic manner. It includes multiple levels of stakeholders, extends discipline-based concepts and approaches, and focuses research through a unified lens. Conflicts can arise in the selection of conceptual frameworks and analysis methods. Problem solving must be prioritized over discipline-specific territory protection. Participants must also display a cooperative personality and interpersonal qualities. Such a collaborative approach going beyond disciplinary boundaries is critical to dealing with complex health problems related to human-animal-environmental interfaces, such as emergency animal disease issues (Min, Allen-Scott, & Buntain, 2013).

While each of the multiple discipline approaches differ by definition and the policy recommendations included in Chapter 6 are more transdisciplinary in nature, for the purpose of this dissertation, the term multidisciplinary is used to represent all aspects of multiple discipline analysis.

To address policy issues related to animal disease emergencies, multidisciplinary collaboration amongst economists, animal health professionals, and others is needed due to the complexity of the issues and the analysis process (Rich et al., 2005a).

Knowledge about consumer and producer behavior is critical to effective use of economic and epidemiological models used for decision making in animal disease emergencies. Social and political conditions need to be considered in addition to traditional quantitative approaches. Animal health planning decision teams need individuals who are grounded in more than one disciplinary area to address multidisciplinary, cross-cutting policy, and economic concerns (McLeod & Rushton, 2007); "Experience from the global Rinderpest eradication programme highlights that effective disease control is a multifactorial process" (Shirley et al., 2011, p 116). Control strategies, such as vaccination and effective diagnostics, combined with political will and ownership by leadership of the disease situation form the pillars of disease control. The Global Rinderpest Eradication Program was successful because it included effective vaccine, reliable diagnostics, epidemiological-based targeted control, and global will to control disease (Shirley et al., 2011).

Other Considerations

Dynamic nature

An animal disease emergency is a complex and dynamic problem. Decision makers must select a course of action based on limited information and balance tradeoffs between cost and effectiveness of various control strategies. Comprehensive measures may rapidly contain the disease but at high cost and consequence; conservative measures may allow the disease to spread and epidemic to extend leading to larger costs in the long run even though it is less expensive in the short run. The expected epidemic and economic impacts of alternative disease control strategies need to be provided to decision makers. It is also critical to understand the dynamic nature of a disease outbreak. The decision process must also be dynamic and the optimal decision will change (Kobayashi et al., 2007a; Kobayashi et al., 2007b).

Economic impacts

The economic impact of animal diseases can be categorized as production effects, price and market effects, trade impacts, food security and nutrition effects, environment and public health impacts, and financial costs. In general, identification of effects is simple, but quantification of those effects is more challenging and typically involves multiperiod multiplier effects (Pritchett et al., 2005).

Animal diseases are considered an invasive species and can be modeled as renewable resources where an invasive species is introduced and alternative mitigation strategies can be examined. Bioeconomic frameworks integrating dynamic economic-epidemiological effects can be used to analyze invasive species in the livestock sector. Implementation decisions regarding invasive species policy is always about weighing gains and losses (Zhao et al., 2006).

If consumers' preferences are influenced by an animal disease outbreak, a negative demand shock is likely to occur; the shock could be temporary or permanent, be distributed across meat products equally or disproportionally, and be combined with increased purchases at lower prices in determining the change in consumer welfare (Pritchett et al., 2005).

An FAD outbreak will result in a decrease in animal productivity, a reduction in meat supply, and a probable decline in the demand for meat and meat products (Pritchett et al., 2005). Estimating changes in revenue and expenditures is not sufficient; researchers as well as policymakers need to also be concerned with economic welfare changes (Paarlberg, Lee, & Seitzinger, 2005). Welfare effects need to be broken down to determine how different industry groups and subgroups are impacted. For example, farmers and ranchers affected by the disease will suffer greater costs than those not directly impacted by the outbreak. Or, with consumers, those who forego consumption of meat from susceptible livestock will be impacted differently than those who continue to consume products. The same authors found some farmers and ranchers could gain from an outbreak if export losses and price increases are not considered (Paarlberg et al., 2003).

Understanding the economic impact is important when policy decisions are being made regarding such issues as control strategies, trade impacts, interventions, and compensation. The assumptions made regarding types and magnitude of shocks as well as parameter values and modeling of sector interactions all largely influence the model outcomes and are critical to understanding when results are interpreted (Paarlberg et al., 2005).

Externalities and public goods

Freedom from animal disease can be considered a public good, or, said another way, an animal disease outbreak is a public bad that requires government intervention and decision making (Ge et al., 2010). A public good is typically considered something that is both non-excludable and non-rival meaning that individual participants cannot be effectively excluded from use and where access by one individual does not reduce availability to others.

In addition, FADs create externalities. If one player acts or fails to act, others may suffer or benefit from their action. In the case of an outbreak, if one state, region, or nation does not protect the livestock industry in their area, others will experience negative effects. However, the opposite is true if a government chooses to protect their industry and a positive externality is created because they are less likely to become infected and transmit the disease to other regions. The presence of a positive externality reduces others' incentives to protect their livestock industry, can create economic free-riders, and could create a regional tragedy of the commons effect. In the case of an externality, public investment and policy making is necessary (Knight-Jones & Rushton, 2013).

Investment

Proper preparation for an animal disease outbreak is expensive and requires significant long-term investment. Government decision makers and industry leaders must determine if this long-term investment is worth it based on the benefits received in the case of an outbreak (Swallow, 2012). When considering investing in disease control programs, policymakers must weigh expenditures versus investment in other projects and programs. Impact assessment must compare these alternatives as well as the general economic, social, and environmental implications. The selected method of analysis must consider the appropriate point of view and compromise between methods that address disease control and the livestock system while being useful to policymakers (Rushton et al., 1999).

International cooperation

Vallat and Mallet (2006) identified the need for a global approach to FAD threats due to the global economic and social impacts these diseases can have especially on developing countries.

Disease mitigation policy decisions are complex and challenging, and investment is required in ex-ante preventative measures and ex-post response strategies. Decisions are national due to the externality and public good implications. However, animal disease is actually a transnational and global public good and therefore international cooperation in contingency planning would be beneficial. In a game theory framework, a single government agency is assumed to maximize the country's social welfare by selecting investment at a certain level in the presence of an FAD, and the framework is applied across heterogeneous countries. The decisions of trading partners and spatially adjacent countries influence the probability of disease outbreaks in other countries due to spatial spillovers. Preventative efforts in neighboring countries lower disease probability for the entire region. However when neighboring countries increase investment in preventative measures, the incentives to invest decline in other countries. Therefore, regional cooperation is critical to optimal disease prevention and control strategies (Steele, Perevodchikov, & Marsh, 2012).

Active versus passive insurance

To determine the best strategy to respond to an animal health emergency in a developed country, leaders must decide whether to focus on investment in active measures to reduce the probability of a major animal disease outbreak or to take a more passive approach with investment focused on a reactive strategy. Active insurance methods in dealing with an animal disease are those designed to reduce the disease threat, including border protection protocols, wildlife disease control strategy, surveillance measures with associated database technology, cooperative efforts to work with endemic countries to reduce chance of disease spread, established and exercised response strategies (logistics and technical aspects of management and control, socioeconomic impacts, and transparent communication), and financial investment in control, eradication, and prevention strategies (vaccine development, improvement of epidemiological and economic models, etc.). Passive insurance methods include the development of contingency funds to be used in responding to the impact of an FAD, such as insurance policies, government emergency reserves, and industry-organized funds, and the establishment of vaccine banks. The use of effective active strategies will reduce the required level of passive insurance responses (Rushton & Upton, 2006).

Role of leaders

In dealing with an animal disease outbreak, or more specifically an agroterrorism attack, leaders must go beyond well-chosen words and judicious use of force. The temptation will exist to focus only on critical management and scientific issues related to disease response (Schoch-Spana, 2004); "Neglect of civic, social, economic, and ethical-moral dimensions may ultimately jeopardize technical efforts to stem the health crisis as well as damage processes of economic and psychological recovery" (Schoch-Spana, 2004, p. 26). Decision makers will struggle with the inability to anticipate and plan for every contingency, pervasive uncertainty about the event itself and response strategies, limited resources, practical challenges of stopping disease spread, the impulse to avoid decisions or blame others, and the possibility of far-reaching, unpredictable, rapid, and long-lasting impacts. Leaders must focus on stopping disease spread, stabilizing the economy while minimizing commerce disruption, reducing fear and concern, using resources effectively, working amongst multiple jurisdictions, maintaining credibility when making decisions with limited information, and restoring social bonds and confidence of farmers, ranchers, and consumers. Decision makers must pursue these principles while creating a transparent and open atmosphere (Schoch-Spana, 2004).

For a decision maker to support and implement animal disease policy, they must first have the necessary political will which is a direct reflection of political priorities. Historically, political will has not always been strong enough to deal with an animal disease outbreak and policy decisions were not implemented effectively. Information and data showing the importance of effective policy decisions in controlling animal disease in comparison to other factors will be critical to the existence of the necessary political will. Eradication costs are expenses to the agriculture industry and government entities and are calculated as costs in determining the disease impact; they are actually transaction costs transferring money to other industries. Thus, a complete analysis has to determine if investment in agriculture or the industries to which the transfer has occurred is a better investment. This information may influence political will in regard to where the investment best serves the entire economy (Heath, 2006; Heath, 2008).

Politicians have to decide what policy choice creates the least harm and the greatest economic benefit. A tipping point is reached when the transaction costs are greater than the opportunity costs of disease control strategies. Political will and the support policymakers have for the animal agriculture industry can also be influenced by the role agriculture plays as an economic driver, employer, and contributor to national revenue. If decisions are made in a politically charged environment, decision makers will be less likely to adhere to a long-term vision and decisions may be more discriminatory, such as by siding with interest groups with more direct access to decision makers. Holistic long-term analysis determining true costs of disease control and which stakeholders benefit and which ones lose can be helpful and credible to policymakers (Heath, 2006; Heath, 2008).

Public knowledge and consumer confidence

The public's general knowledge about FAD and their potential impact is limited. Although FMD is rarely transmissible to humans, consumers in other countries have reacted negatively to the disease and reduced consumption of meat from susceptible species. U.S. consumption patterns show consumers have reduced or eliminated consumption of certain products due to perceived risks such as bovine somatotropin (BST) and genetically modified organisms (GMOs). Many consumers do not know the difference between FMD and BSE and associate human health risks from BSE with FMD (Paarlberg et al., 2003).

As Hutton (2002) notes, lack of knowledge and information are the greatest contributors to decline in consumer confidence. Shifts in consumer demand have been projected due to animal disease outbreaks (McCauley, Aula, New, Sundquist, & Miller, 1979; Schoenbaum & Disney, 2003). In one economic study, researchers found consumer education with accurate information about the impact of FMD on human health would significantly reduce outbreak costs. They assumed a 10% reduction in consumer demand for beef, pork, lamb, and mutton resulting in a loss of $7 billion in U.S. farm revenue (Paarlberg et al., 2005).

It is interesting to note a number of references are made to the impact of FMD on human health and consistency is often lacking. Mathews and Buzby (2001) acknowledged consumption of meat from infected animals is safe for human consumption, but that consuming milk or dairy products from infected animals could infect humans (Nogueira et al., 2011). Paarlberg et al. (2002) commented that the risk of disease transmission to humans via consumption of red meat and dairy products is negligible. An editorial in the British Medical Journal published during the 2001 U.K. FMD outbreak called FMD "a zoonosis, a disease transmissible to humans, but it crosses the species barrier with difficulty and with little effect" (Prempeh et al., 2001, p. 565). Ryan and Glarum (2008) note that while FMD is not considered a public health issue that over 40 cases have been identified since 1921. Human infection is rare and disease impacts are typically mild (Mathews & Buzby, 2001; Ryan & Glarum, 2008), and typically result from consuming unpasteurized milk, contact with the airborne virus, or direct contact with infected animals (Mathews & Buzby, 2001).

Contradictory information being shared with the public and a lack of clarity regarding the impact on human health could cause great concern and make the impact of an outbreak worse.

Example of an FAD Response Decision Tool – New Zealand

The New Zealand government has indicated, in regard to all biosecurity policy, that cost and benefit considerations will include all sectors of society and values to be protected, including the environment, public health and well-being, economic stability, and protection of cultural values. The principles of their biosecurity decision making process are to follow legal and international standards, analyze the issue before identifying solutions, allow decisions to be made by those best placed to make them, consult with all stakeholders, and be timely, well-informed, consistent, and transparent. Decisions are designed for benefits to outweigh costs and to improve the economic, social/cultural, health, and environmental values within the country. Options need to be evaluated on strategic fit, net benefit, feasibility, available resources, and the opportunities for and barriers to success. Uncertainty should not lead to inaction, and intervention is more critical when irreversibility exists. Risks and opportunities need to be effectively managed and outcome-based solutions are preferred over prescription-based responses. It is expected that decisions will be made promptly, take into account available information, and be based on multidisciplinary scientific advice (MAF, 2008).

Based on these principles, the New Zealand Ministry for Primary Industries (formerly known as the Ministry of Agriculture and Forestry) has adopted a "structured and consistent approach to decision making" for dealing with pest and disease response to be used in conjunction with appropriate tools and policies (Dunn et al., 2010, p. 4).

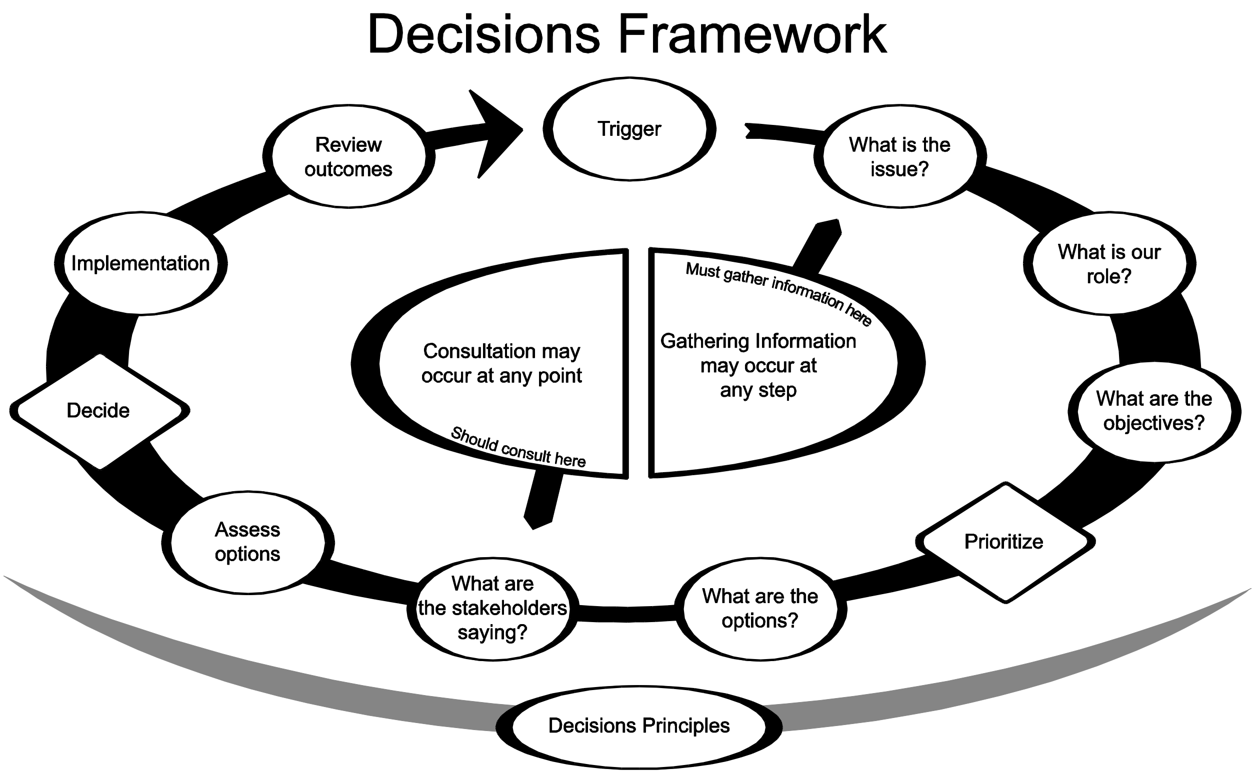

Figure 5-3 New Zealand Decision Framework: Steps and Principles (MAF, 2008, p. 40).

In testing their decision process, they found the strategy developed by high-level officials was focused on eradication and trade reinstatement. In addition, too many decisions were made at the headquarters-level versus in the field and, therefore, technical decisions took too long to implement. In general, there was a lack of urgency in making and implementing decisions (Helstrom, 2012). As noted in their evaluation, "URGENCY should be engraved on the foreheads of everyone involved" (Helstrom, 2012, p. 1).

The approach attempts to balance environmental, social, and economic concerns and involves stakeholder input. The response system divides strategic decision making and leadership from the actual response manager who receives direction from the strategic leadership team. The intent is to ensure decisions made remain objective and focused on big-picture response goals (Dunn et al., 2010). Risk-based decision making serves as the basis for the decision making system, which includes a “sequence of simple steps driving the decision-making process, facilitating consistency and acceptance of decisions” (Dunn et al., 2010, p. 5).

Summary and Next Steps

A number of models and analytical tools have been used for policy analysis. Specifically in the area of animal health emergencies, economic and epidemiology models have been used to study the impact of control strategies in dealing with an animal disease outbreak. While in many cases these models can provide information to policymakers, they do not typically provide everything the decision maker desires. The modeling process creates greater understanding and can add important knowledge, but cannot provide the actual guidance a policymaker needs or the answer to a policy question. Models are also limited by available data, time constraints, and number of factors the model can handle. Many times decision makers are not trained to understand analysis and do not find the results applicable to their decision processes. There are also a number of social, political, and ethical issues that are difficult to encompass in a model or analysis tool. The complexities of FAD policy complicate analysis efforts, which are further complicated because animal disease outbreaks are low-probability, high-consequence events. Further tools and policy frameworks are needed to provide an interface between existing policy analysis and decision makers.

Chapter 6 - Policy Considerations and Implications

Policies and programs dealing with food and agricultural security need to be given our utmost consideration. Effective policy must balance economic, political, social, and scientific criteria. Policymakers need better information with which to make decisions, and the agricultural industry needs to be more effective at providing that information. A multidisciplinary policy approach to food and agricultural security should consider all critical factors, including animal health, disease control, animal welfare, public health, environmental impact, regulatory issues, logistical issues, geography, physical security, economics, trade, public perception, risk communication, social and psychological impacts, emergency management, history, and political realities. The challenge comes in attempting to analyze policy and provide policy recommendations that treat these issues interdependently, rather than independently.

Structure of Policy Analysis and Problem Identification

A number of policy analysis tools have been defined in Chapter 5 in order to provide insight into the field of policy analysis and the number and types of disciplines engaged in policy evaluation and providing advice to decision makers. However, few of these tools actually provide information in a format that meets the needs of decision makers and helps them make better policy decisions. The policy analyst should not be identifying the pros and cons or offering a policy recommendation. The role of policy analysis should be to improve policy making by providing decision makers with a framework that defines the problem, identifies alternatives, acknowledges issues to be considered, analyzes tradeoffs, and compares potential consequences. This is similar to identification of ends, ways, and means as defined in strategic mission analysis. Policy analysis should not be focused on determination of the best policy, but instead should provide the policymaker the information needed for them to make the decision. Policymaking is always about tradeoffs and the policy analysis needs to provide an objective review of facts and myths and allow the decision maker to apply values to make the final decision. And, as noted by agricultural policy economist Dr. Barry Flinchbaugh, “politics will always trump science” (personal communication).

It is also important to note that term combinations such as pros and cons, costs and benefits, and advantages and disadvantages are used constantly in policy analysis, but can be misleading because a cost to one might be a benefit to another, a pro to one is a con to another, and an advantage to one is a disadvantage to another.

For each of the three foreign animal disease (FAD) policy issues discussed in this dissertation, the analysis will identify the problem, summarize related issues and symptoms, identify alternatives, compare consequences in different formats, and provide a tool that can be used by policymakers to guide their decision process. For the purposes of this dissertation, policy analysis will be applied to FAD response in Kansas with a specific focus on foot and mouth disease (FMD).

Agriculture in Kansas

Agriculture is the largest economic driver in Kansas, valued at more than \$33 billion. In 2012, agriculture accounted for approximately 19% of the state's GDP and directly employed 427,000 people, approximately 17% of the Kansas labor force and representing nearly one in five jobs in Kansas. The state utilizes more than 90% of its land for agricultural purposes. There are 65,500 farms in Kansas, which generate more than \$17 billion in agricultural output annually. Livestock receipts increased 18% in 2012 and accounted for 56% of all agriculture receipts. In 2011, Kansas ranked 7th in agricultural exports and exported nearly \$5.3 billion in agricultural products. Kansas is ranked first in wheat milling and wheat production, second in sorghum production, third in cattle production and beef processing, 10th in hog production, 16th in milk production (and currently first in milk production percentage increase), and 23rd in sheep production. Nearly 19% of cattle slaughtered in the US, 17% of cattle and calves on feed, and 11% of red meat production in commercial slaughter plants occur in Kansas (Kansas Department of Agriculture [KDA], 2013). Lee et al. (2011) estimated the economic impact of an FMD outbreak on individual states in a state-specific outbreak in other states. They found Kansas, along with Texas, Iowa, and Nebraska, to have the largest economic losses regardless of the location of the outbreak.

The size, scope, and scale of the state's agriculture industry make Kansas not only vulnerable to an accidental or intentional agricultural emergency, but also make the state's response critical to the state, national, and global economy.

Kansas Response Plan

The Kansas Response Plan (KRP) Food and Agriculture Incident Annex is the primary policy document that directs the actions of Kansas governmental agencies in the case of a food or agriculture incident, including an FAD. The KRP Food and Agriculture Incident Annex outlines the responsibilities related to incident identification; incident management; communication and coordination; assessment, control, and containment; and recovery related to an agriculture emergency. Three appendices accompany the annex; one each focused on food, plant health, and livestock emergencies. In addition, there is a specific response plan for highly pathogenic avian influenza (HPAI) and one is in development for FMD. The KRP includes parallel emergency support functions (ESF) parallel to the ESFs in the National Response Framework (NRF). ESF#11 supports Agriculture and Natural Resources (Kansas Response Plan [KRP], 2013).

The KRP Food and Agriculture Incident Annex addresses specific organizational structures, authorities, roles, and responsibilities related to the emergency response to a threat to the health of our livestock industry. The Livestock Emergency Appendix of the KRP Food and Agriculture Index identifies the Kansas Department of Agriculture (KDA), under the direction of the animal health commissioner, as the statutory authority with responsibility to direct all aspects of animal disease control, including investigation, surveillance, movement control, diagnostics, biosecurity, depopulation, vaccination, disposal, cleaning, disinfection, and recovery. The KRP notes the likelihood that "extraordinary response measures may be required to effectively control the expansion of highly infectious diseases, including quarantine, movement control, and animal disposal measures" (KRP, 2013, p. 379).

The KDA will use an incident command system to manage the response and recovery activities. The Kansas Animal Health Commissioner will serve as the incident commander under unified command and is responsible for the coordination of all state activities related to monitoring, permitting, quarantining, confiscation, disposal, and disinfections. The Commissioner will establish an incident command structure to work in conjunction with county ICS and USDA Animal and Plant Health Inspection Service (APHIS). USDA Veterinary Services (VS) will direct national response efforts and the assistant distant director (formerly referred to as the area veterinarian in charge) will serve as a joint incident commander with the animal health commissioner. Under new USDA VS organization, this position for Kansas is located in Nebraska. The concept of joint operational control under unified command between state and federal officials make animal disease emergency management protocols atypical to traditional disaster and emergency response. In addition, response direction will come from the state level down to the local which is opposite the typical authority hierarchy where emergency response decisions start at the local level (KRP, 2013).

To minimize the impact on the agriculture industry, the KRP recognizes the need for cooperation between all local, state, and federal agencies to control and eradicate FAD. The USDA is a key player because only they can declare the existence of an FAD. Regardless if an FAD begins in another state and threatens to spread to Kansas, if an FAD does spread to Kansas, or if Kansas is home to the index case (first confirmed case), the KRP will be activated. The U.S. Department of Homeland Security (DHS) will consider an FAD a terrorist event until or unless proven otherwise and the FBI will initiate an investigation in conjunction with disease response (KRP, 2013).

The emergency authorities of the KDA have far-reaching implications in disaster response and recovery operations. The authority to order the confiscation and disposal of any infected or exposed animals is given to the Animal Health Commissioner by Kansas' law. A Governor's Disaster Declaration is expected in the case of an FAD outbreak. Under such a declaration, the Adjutant General (TAG) can suspend any regulatory statute if adherence to the statute will prevent, hinder, or delay disaster response (KRP, 2007; KRP, 2013). If the USDA Secretary declares an extraordinary emergency, they may use Federal authorities to take over disease response within a state if the affected state is unable or selects not to take appropriate action to control and eradicate the disease (DHS, 2013b).

In addition to the KDA Division of Animal Health and USDA APHIS, several other state officials and agencies as well as volunteer organizations have responsibilities related to an animal disease emergency response. Those agencies and officials include the Governor, the Secretary of Agriculture, Kansas Department of Emergency Management (KDEM), the Adjutant General, other KDA programs and divisions (Dairy, Meat and Poultry, etc.), state laboratories, Kansas Highway Patrol, Kansas Department of Transportation, Kansas Department of Health and Environment (KDHE), Kansas State Fire Marshal Office, trade associations, private farmers, ranchers, agribusinesses, livestock markets, Kansas Veterinary Response Corps, Kansas State University College of Veterinary Medicine, K-State Research and Extension, and Kansas Department of Wildlife, Parks, and Tourism (KRP, 2013).

KDEM is directed by the TAG, who is also responsible for homeland security activities. KDEM and TAG will implement all decisions related to emergency management and homeland security. They will direct the cooperation and assistance of state and local agencies and designate agency support of each emergency support function. The Governor has the power to make, amend, and rescind orders and regulations, including those that can be directly related to mass depopulation and disposal efforts. The Secretary of Agriculture serves as the policy leader in the policy group based at area command (KRP, 2013).

Euthanasia and Depopulation

In any FMD outbreak, there will be a need for mass depopulation with the scale of the effort determined by the policy approach. At a minimum, diseased and exposed animals as well as susceptible animals within the infected zone of a minimum of a 3-km (approximately 1.86 mi) radius from the infected premises will be depopulated. Depending on the circumstances, all susceptible animals within the entire control area with a minimum radius of 10 km (approximately 6.2 mi) may need to be depopulated.

The actual size of the infected zone, buffer zone, and control area will be determined by factors such as patterns of livestock movements, livestock population and concentrations, weather and prevailing winds, geographic factors and terrain, distribution and movement of susceptible wildlife, and disease characteristics. Once zones are established, decisions will need to be made regarding the disease response.

Two primary policy questions will need to be addressed:

- What method(s) of mass depopulation will be utilized?
- In addition to the infected zone, where and when will mass depopulation be utilized as a method of disease control or for welfare purposes?

Policy decisions need to balance scientific, economic, political, and ethical issues with specific attention paid to the biological and geophysical factors leading to disease spread. In method selection, a number of consequences will be under consideration:

- Animal disease control. How does the need to stop and mitigate disease spread influence method selection? How is appropriate depopulation method impacted by disease virulence and risk of disease spread? Can appropriate biosecurity measures be followed? Can tissues be salvaged if necessary?

- Animal welfare. How does the euthanasia method impact animal welfare? Can animals be appropriately restrained? Will loss of consciousness and death be induced with minimal pain and distress? Can animal stress and excitement be reduced with proper handling? Can animal handling be minimized? Is the method reliable and irreversible? Is unconsciousness induced in a timely fashion?
- Species. How do the species, number, age, and health status of animals to be depopulated influence method selection and order of depopulation?
- Transportation. Can animals be euthanized on site or is transportation of live animals to another location necessary? Once animals are depopulated, where do they need to be transported for disposal? Can depopulation and disposal occur at the same location?
- Housing and location. How do the housing and husbandry practices influence appropriate methods? Is the farm or ranch easily accessible? Where are the animals located and how does their location influence method selection?
- Disposal. How will the depopulated animals be disposed? Can carcasses be easily and safely moved for disposal? Does the disposal method influence the choice of depopulation method or vice versa?
- Economic and cost considerations. Are there economic considerations to be considered when selecting the method of depopulation? How many steps are required (economy of manipulation)?
- Environmental. Are there environmental factors that influence the method selection?
- Weather. How do weather conditions influence the decision?
- Public relations. How will the public react to the decision to depopulate, the number of animals depopulated, and the method? How will the decision be communicated to the public?
- Public health. Does the method of depopulation impact public health? Is the public health impact influenced by the depopulation and disposal method combination?
- Aesthetic acceptability. Is the method aesthetically acceptable?

- Availability of technology. Are the tools and technology accessible and available? Can equipment be properly maintained in good working order?
- Resources and personnel. Are the necessary resources available in sufficient quantities? Are personnel adequately trained and are there sufficient numbers of adequately trained personnel to implement depopulation?
- Worker safety. Is the method selected safe for depopulation personnel to implement? Are established protocols safe for workers?
- Emotional and psychological toll. How does the method impact producers, personnel, and observers? Can the emotional and psychological toll be minimized?
- Safety of other animals. How closely located are other domestic or wild animals? How does predator and scavenger safety influence method selection? Can birds or other animals access the carcasses and carry the disease to other locations?
- Compatibility and consumer safety. Is the method selected compatible with animal use and purpose? If food products are going to enter food chain, how is the method selected influenced?
- Legal and regulatory requirements. What are the legal and regulatory requirements in the jurisdiction?

Kansas Response Plan – euthanasia

In the KRP Food and Agriculture Annex Livestock Emergency Appendix, euthanasia is covered by 56 words in three sentences. "Animals will be treated humanely from the time they are identified as presumptive or confirmed positive until they are euthanized. Euthanasia must be performed as rapidly and humanely as possible by chemical or mechanical means. Response efforts will encompass depopulation of non-domesticated animals that are susceptible or possible carriers of the FAD (e.g. deer, elk, etc.)" (KRP, 2013, p. 389).

Animal health officials have indicated the only alternatives to be considered are those methods considered as acceptable or acceptable with conditions as noted in the AVMA and NAHEMS guidelines and discussed in Chapter 2. The acceptable methods are listed in Table 6-1 for those species susceptible to FMD.

Table 6-1 *Acceptable Alternative Methods of Euthanasia*

Animal	Acceptable	Acceptable with Conditions
Cattle	Intravenous barbiturates	Penetrating captive bolt, gunshot
Hogs	Injected barbiturates	CO2, CO, N2, Ar, gunshot, electrocution, nonpenetrating captive bolt, manually applied blunt force trauma
Sheep	Injected barbiturates	Gunshot, penetrating captive bolt

Note: AVMA (2013a).

In making a policy decision about the appropriate euthanasia method to be used, the list of factors will first be prioritized and balanced with each other. If animal welfare is a top or high priority, then the methods listed as acceptable or acceptable with conditions are the only methods that may be considered. Then, according to Kansas animal health officials, the next factor to be considered will be the availability and accessibility of resources. They do not believe state officials would be able to access enough barbiturates to use a chemical method of euthanasia, leaving, in the case of cattle, penetrating captive bolt and gunshot. Again, access to technology may limit use of captive bolt, resulting in the use of gunshot. This falls in line with the long believed approach that any answer to FMD will result in a “shoot ‘em and bury ‘em” response. However, such an approach fails to acknowledge many of the other factors previously listed. The resulting policy decision may then be as much about how to implement the policy decision as actually making the decision. A decision tree in Figure 6-1 illustrates these policy considerations.

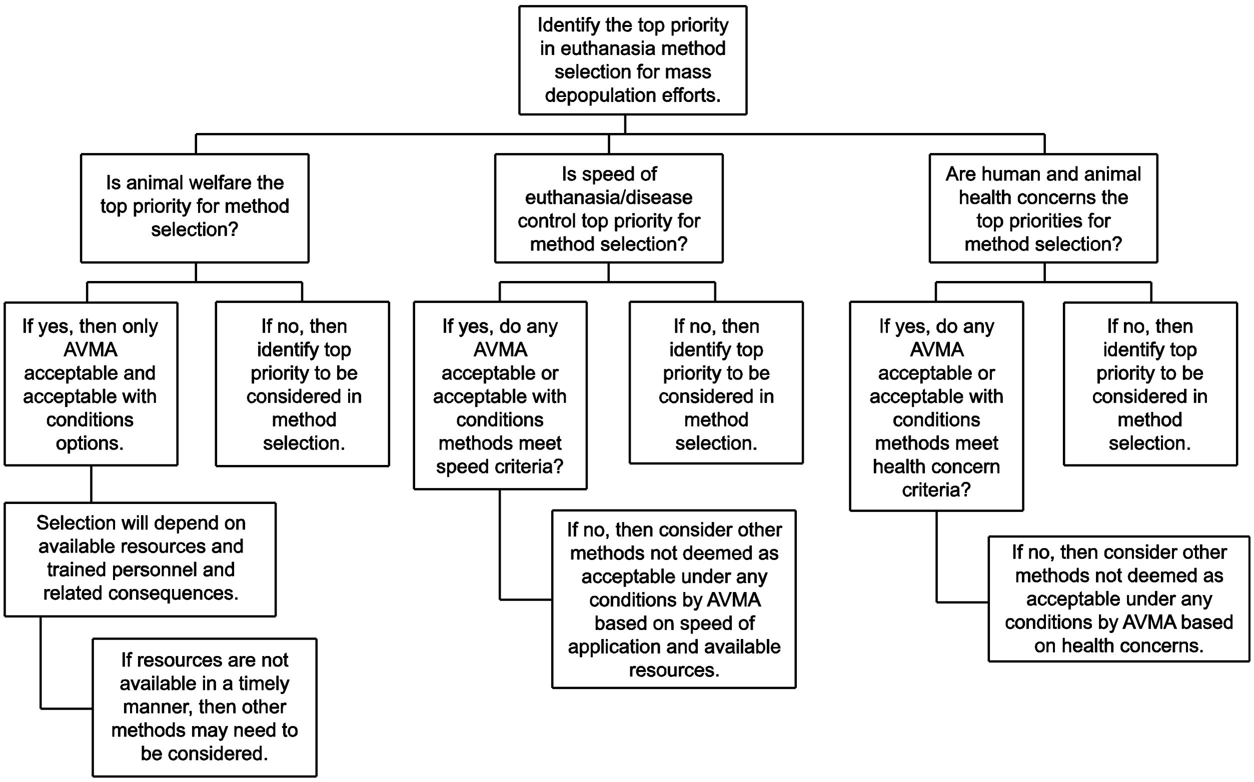

Figure 6-1 Euthanasia decision tree

The decision tree begins by asking the question "Is animal welfare the priority?" If the answer is yes, the decision tree limits the choices to AVMA acceptable and acceptable with conditions methods with dependence on species involved. While other methods such as toxins supplied in the feed supply may be feasible, they are not considered acceptable. Decisions are then based on availability of resources beginning with chemical methods for all species, followed by penetrating captive bolt and gunshot for cattle and gas, non-penetrating captive bolt, and gunshot for swine.

Summary

The selection of a euthanasia method will be limited to just a few choices as long as animal welfare is considered a priority. If at any time animal welfare is no longer considered a priority, the selection of euthanasia methods will be more complex. The larger, more overarching policy question relates to the decision of vaccination versus euthanasia and depopulation, or even more simply to moving as many animals as possible into the traditional slaughter process rather than destroying them. Kansas animal health officials have indicated the first response is likely to be to move as many animals as possible into the slaughter and processing system, with or without vaccination and regardless of harvest readiness. Discussions with packers and processers are paramount to pre-establishing contracts and cooperative plans. Further discussion over vaccination versus a depopulation and disposal approach will be covered in the vaccination section.

Carcass Disposal

There are numerous factors that will impact large-scale carcass disposal policy decisions. It is necessary to identify the factors to be considered. The goal of any carcass disposal policy is to effectively and efficiently dispose of all infected and exposed carcasses in a timely manner. As noted by the Center for Food Security and Public Health (2012), the method of carcass disposal utilized needs to take into account a number of factors, including animal species, number of animals to be disposed, pathogen and its ability to spread, environmental issues, public health issues, and existing regulations. Numerous additional objectives will also be considered.

One of the first factors to be highlighted is the cause of death. If death is due to a contagious disease, then finding a biosecure solution is critical. For many stakeholders, biosecurity concerns often outweigh nearly all other concerns when a highly contagious disease is involved. In those cases, public exposure needs to be limited, transportation needs to be minimized and performed in a manner that will ensure containment of the infectious agent, and biosecurity measures are a priority. If deaths are due to a natural disaster, then emphasis could be placed on an environmentally friendly solution. Each method has a different impact on the environment and creates different lasting impacts. The USDA VS provides a list of environmental decisions to be made, and encourages decision makers to consider impacts on groundwater, wildlife, air quality, surface water, climate, public health, solid waste, cultural resources, utilities and vegetation. It is critical that greater consistencies exist in state regulations such as approved disposal methods and the mechanisms to waive those regulations.

The scale (numbers of carcasses) and scope (species) of the death loss are also important factors. Certain technologies can handle only limited numbers and may not be efficient enough in the case of a major emergency. Some disposal methods are more acceptable with cattle than poultry and vice versa. Logistical issues regarding location of the carcasses, spread of the animal deaths, and proximity to facilities and resources (e.g., fuel) becomes of critical consideration as well. The solution for one state may differ from another because of the location of large animal numbers and the distance to major population centers. This may also be true within state borders due to regional and geographic differences. Public health may likely be considered as the overriding factor in determining the most appropriate method of disposal by some policymakers. One factor often discussed in the decision process is the economic impact of the disposal method and the direct and indirect costs, including those related to direct disposal, transportation, facilities and equipment, energy requirements, environmental impact, and social costs.

Any final regulatory policy that provides emergency response personnel and animal health officials with decision-making guidelines will include consideration of the following criteria:

- Disease/biosecurity risk – Cause of death loss and diseases involved. Is the disposal method used in the policy considered biosecure? Depending on the disease agent, biosecurity concerns are paramount. Disposal policy will account for different disease agents and the limitation those diseases place on disposal method alternatives (Technical Feasibility).
- Scale of death loss. Is the disposal method used in the policy acceptable for different size disposal efforts? Is it timely? The number of animals to be disposed will greatly impact the direct and indirect costs of all disposal methods. The scale of the loss will also impact the expediency of the disposal process (Technical and Administrative Feasibility).
- Site and facility availability. Are sites and facilities required for the disposal method easily accessible? Access to disposal sites and equipment in different areas of the state will be a part of disposal policy. This is especially important when considering methods that require a fixed facility technology, such as rendering (Technical and Administrative Feasibility).
- Fuel and resources. Are the fuel and resources required for the disposal method easily accessible? The accessibility to the fuel and resources needed for disposal will be considered. For example, the amount of fuel necessary for incineration may eliminate burning as a viable option (Technical Feasibility).
- Environment – Water table, soil types and environmental life cycles. Is the approved disposal method environmentally friendly? The level of the water table, type of soil, and

other environmental factors will be a part of the policy consideration process. If the water table is high, a method, such as burial, may not be environmentally sound (Technical and Political Feasibility).

- Transportation options and distance to disposal sites. Does the disposal method require transportation? If so, is it limited or extensive travel? Policy will consider on-site versus off-site disposal options and consider the accessibility and viability of transportation to the disposal locations if done off-site (Technical and Administrative Feasibility).
- Costs and economic impacts. Is the disposal method approved in the policy economically efficient? The short-term and long term costs and economic impacts will play a role in analyzing the effectiveness of alternative policies (Economic Feasibility).
- Proximity to population centers and public health. Is the disposal method approved in the policy safe for the public? Public health will be of serious concern. If the disease agent is zoonotic, then public health is especially critical. However, any large-scale disposal effort may impact public health and create negative externalities especially problematic near population centers (Technical and Political Feasibility).
- Species involved. Can the approved disposal method be used for multiple species? Simply put, any policy will consider species. It clearly takes a different approach to dispose of chickens than it does cattle (Technical Feasibility).
- Public perception. Will the public find the approved disposal method acceptable? The perception of the general public plays a key role. Public opinion and support for the policy (or lack of support) greatly influences political feasibility. It also may determine the level of general economic impact (Political and Economic Feasibility).
- Interagency cooperation. Do current agency structures and regulations make this disposal policy feasible? Any policy will carefully identify the roles of different agencies and the process by which decisions will be made (Administrative and Political Feasibility).

Kansas Response Plan – carcass disposal

Eradication of any FAD will require rapid and effective carcass disposal. K.S.A. 47-1219 outlines the responsibilities of the KDA Division of Animal Health regarding carcass disposal. It specifically indicates burial; incineration; disposal plant, substation, rendering plant, or place of transfer licensed by the commissioner; or options adopted in rules and regulations adopted by KDHE (K.S.A., 2013a). While there are no Kansas Administrative Regulations related to livestock carcass disposal, the KDHE Bureau of Waste Management (BWM) has published technical guidance document SW-2001-G1 Disposal Options for Large Quantities of Dead Animals which details specific guidance for the disposal of large quantities of dead animals (defined as six or more animal units) (Kansas Department of Health and Environment Bureau of Waste Management [KDHE BWM], 2011).

Animal units are defined in Kansas Statutes in the confined animal feeding operations section. Six animal units is equivalent to six head of beef cattle weighing more than 700 lbs, 12 head of beef cattle weighing 700 lbs or less, 5 head of mature dairy cattle, 3 horses, 60 sheep or lambs, 15 pigs weighing more than 55 lbs, 60 pigs weighing 55 lbs or less, 334 turkeys, 600 laying hens or broilers, or 30 ducks (K.S.A., 2013b).

K.S.A. 65-3407c allows for permit exemptions to dispose of whole unprocessed livestock carcasses on property at, adjacent, or near the location of the animals' deaths assuming death was due to a natural disaster or has created an emergency situation. Such disposal efforts still require minimizing the threat to human health and the environment, written permission from the landowner and appropriate local government authorities, and KDHE authorization (K.S.A., 2013b).

The statutory options for disposal as listed in order of preference in the KDHE BWM technical guidance are rendering, composting, municipal solid waste landfill, burial on site, and incineration or open burning. Composting moved to second most preferred option from fourth on the preference list when the technical guidance was published in 2011; composting was previously considered as an option for only small animals but is listed currently as an option for large animals as well. The KDHE BWM technical guidance document on carcass disposal acknowledges rendering and landfill use will be challenging when very large quantities of dead animals as a result of infectious disease require disposal because of the need for transportation and large capacities (KDHE BWM, 2011).

While these disposal methods differ from those listed in Kansas statute, they are the same, but listed in a different order, as the appropriate disposal methods listed in the KRP Food and Agricultural Incident Annex. The KRP states that the preferred method of disposal of carcasses, milk, and feedstuff is on-site burial or composting. Composting was added in the 2012 revision of the KRP as only burial was listed as a preferred option in the 2007 Kansas

Response Plan and the 2003 Kansas Emergency Plan. Preselection of sites is encouraged when feasible (Kansas Emergency Plan [KEP], 2003; KRP, 2007; KRP, 2013). In 2007, the FMD operational guidelines contained in appendix 5 of the KRP described burial as "generally easier, quicker, using fewer resources, and less polluting than other methods" (KRP, 2007, p. 36). The only other method considered acceptable was burning. The plan did note the commissioner could approve rendering, composting, and alkaline hydrolysis if burning and burial did not meet the disposal needs (KRP, 2007).

In a personal interview with KDHE BWM officials, it was noted the decision to move composting up on the priority list was a made at the Bureau level and was based on the desire to put fewer carcasses in the ground, reduce the potential risk of nitrate contamination, and to minimize waste. Because composting has been shown to be effective at killing FMD and would reduce protein waste, it was made a higher priority option. The decision did not follow any prescribed framework, was not written down, and was not considered at any levels above the Bureau. However, it was also acknowledged that due to the speed with which animal health officials may respond to a disease outbreak that burial will likely be the first method used to dispose of everything although that is not the preference of KDHE personnel. Composting will be done only after disease response has calmed down. KDHE BWM officials believe the only realistic options for significant carcass disposal operations are burial and composting. It is unlikely that any other method will actually be used as the capacity does not exist for incineration, renderers do not want to take potentially diseased carcasses, and landfills do not have necessary interest or capacity (personal communication).

Numerous factors will influence the feasibility of using a disposal site. Sites will be chosen (preferably prior to an outbreak) by a joint effort between KDHE BWM and KDA using the best available information. KDHE Bureau of Air (BOA) will provide guidance if burning is used. Geographic Information Systems (GIS) will be used to map and track quarantine areas as well as decontamination and disposal zones. GIS has been used to pre-identify burial sites in some locations. The KRP states that consideration will be given to human and animal health hazards as well as environmental impacts. Long-term monitoring of the disposal area will also be considered (KRP, 2013).

KDHE will provide technical advice and has final approval authority on carcass disposal locations. They are responsible for analyzing the sites' impact on ground water and air pollution and providing technical advice to disposal teams regarding environmental regulations. KDHE will identify and approve all regulated disposal and treatment activities (KRP, 2013).

The only method selection tool included in the technical guidance is a table indicating the concerns to be considered when choosing a disposal method.

Table 6-2 *KDHE BWM TGD SW-2001-G1: Disposal Options for Large Quantities of Dead Animals*

	Method			
Area of concern	Burial	Incineration or open burning	Rendering	Composting
Surface water	X,K		X,R	X,K
Groundwater	X,K			X,K
Air	X	X,R,K	X,R	X
Wildlife	X			
Public safety and worker health	X	X	X	
Solid waste	X,K	X		X,K
Vegetation	X	X		
Cultural and historical	X	X		
Utilities	X	X		
Climate	X	X		X

X- denotes applicability
R- denotes all Federal, State, and local discharge permit requirements to be satisfied in order to mitigate or eliminate any impacts
K- denotes KDHE has specific regulations to be met
Note. Adapted from KDHE BWM (2011, p. 2).

The cost of all animal euthanasia and disposal of animal carcasses will be paid for by the State of Kansas (K.S.A. 47-626). Euthanasia and disposal operations are linked. If euthanasia gets ahead of the ability to dispose of the carcasses, there will be biosecurity, animal welfare, and pest management issues (KRP, 2013).

As discussed, the KRP policy sets burial as the disposal method of choice. The goal of this section is to compare that policy to other disposal alternatives. First, the method of disposal is compared to other technologies in the areas of cost effectiveness. Secondly, a matrix evaluation system is used to analyze the disposal policy included in the KRP. Third, a weighting strategy is applied to the matrix analysis to compare the impact of differing priorities on the end result.

Cost effectiveness

The first method of analysis is a consideration of cost effectiveness. Cost-effectiveness analysis finds the policy that meets the goals and objectives at the least cost. Because public funds are limited, this method appears to be the most logical and potentially the most useful to the KDA Division of Animal Health. To compare costs, the costs described earlier are summarized in the following subsection. While this approach is not as comprehensive as cost-benefit analysis, not all associated costs can be monetized in a consistent manner and it is difficult to define benefits related to any aspect of emergency carcass disposal.

While numerous cost examples are available in the literature and have been highlighted in Chapter 3, few reliable cost estimates exist for large-scale, emergency disposal. In the case of an FAD outbreak or natural disaster, total actual costs are unknown. Both fixed and variable costs are simply approximations developed from a small number of experiences and routine disposal estimates. In addition, little to no attention has been paid to indirect costs of these technologies. The impact on the environment, land values, public opinion, and general economic factors will be evaluated as well. This type of economic analysis is critical to any decision making process.

The available numbers do provide the opportunity to compare expected fixed and variable costs per ton of carcasses; however, these comparisons should be considered with caution because these estimates are the result of an extensive literature review which utilized numerous different sources; the data available from these various sources are based on a variety of assumptions, including differing circumstances, cause of death, scale of disposal efforts, species, dates, and geographical locations; and these various sources do not consistently incorporate capital, transportation, labor, or input costs into the estimates. Despite these limitations, Table 6-3 summarizes the cost information identified in the literature. Because of the minimal cost data available on novel technologies, these innovations are not included in the table.

The table highlights the following information: the range of cost estimates cited in previous studies and experiences; comparative representation of cost indicators for capital, transport, labor and input costs ($ - low, $$ - intermediate, $$$ - high, $$$$ - very high); comparative representation of indirect cost indicators, including environment/public health and public perception; an example of other indirect cost considerations; and an indication of the existence of valuable or beneficial byproducts. Figure 6-2 reflects the high and low cost estimates as well as the most likely representative estimate. The representative estimate was derived by analyzing the data and weighting the average costs found in the literature.

The only portions of the costs that can be considered in a cost-effectiveness comparison are the direct costs. To compare cost effectiveness for the State of Kansas, these numbers are to be converted into potential disposal costs in the case of an FMD outbreak. The values have been extrapolated by using the Kansas inventory of livestock and the percentage loss of the U.K. livestock inventory in their FMD outbreak. These figures were used to calculate the proportional Kansas livestock inventory loss which was then multiplied by the average market weight of each species, resulting in a total tonnage of carcasses for disposal (Table 6-4). This figure – 295, 218.5 tons of carcasses – was then multiplied by the representative costs figures per method as indicated in Table 6-3. These costs are shared in Table 6-4. These figures are conservative, because the highly concentrated structure of the Kansas cattle industry would likely result in a higher percentage loss than occurred in the U.K.

Table 6-3 *Summary of Technology Costs*

Technology	Cost Ranges: Range of cost estimates per ton of carcass material disposed[a]	Direct Cost Indicators: Initial Capital[b]	Transportation[c]	Labor	Inputs	Indirect Cost Indicators: Environment /Public Health	Public Perception	Other cost considerations	Creates valuable or beneficial byproducts
Burial (on- and off-site)	$15-200	$	$	$$$	$	$$$	$$$$	Land use and values, predator activity	
Landfill usage	$10-500	$$	$$$	$	$	$$	$$$	Municipal costs, management costs	
Open burning	$200-725	$	$	$$$	$$$	$$$	$$$$	Disposal of ash, permit fees	
Fixed-facility incineration	$35-2000	$$	$$$	$$	$	$$	$$$	Disposal of ash, permit fees	
Air-curtain incineration	$140-510	$$	$$	$$	$$	$$	$$$	Disposal of ash, permit fees	
Bin- and in-vessel composting	$6-230	$$	$	$$$	$$	$	$$	Land use, time efficiency	√
Windrow composting	$10-105	$	$	$$$	$$	$	$$	Land use, time efficiency, predator activity	√
Rendering	$40-460	$$	$$$	$	$	$	$$	Biosecurity risk	√
Fermentation	$65-650	$$ $$	$	$$	$	$	$	Time efficiency	√
Anaerobic digestion	$25-125	$$ $$	$	$$	$	$	$	Time efficiency	√
Alkaline hydrolysis	$40-320	$$ $	$	$	$	$	$	Disposal of effluent	

a. These estimates are the result of an extensive literature review summarized in Chapter 3 which utilized numerous sources. The data available is based on a variety of assumptions, including differing circumstances, cause of death, scale of disposal efforts, species, dates, and geographical locations. In addition, different cost estimates do not consistently incorporate capital, transportation, labor or input costs.
b. Includes capital costs directly associated with carcass disposal only.
c. Transportation costs depend on the location of the technology. These indicators assume minimal transportation for more likely available technologies.
d. The cost factors are indicated by $- low, $$ - intermediate, $$$ - high, $$$$ - very high).

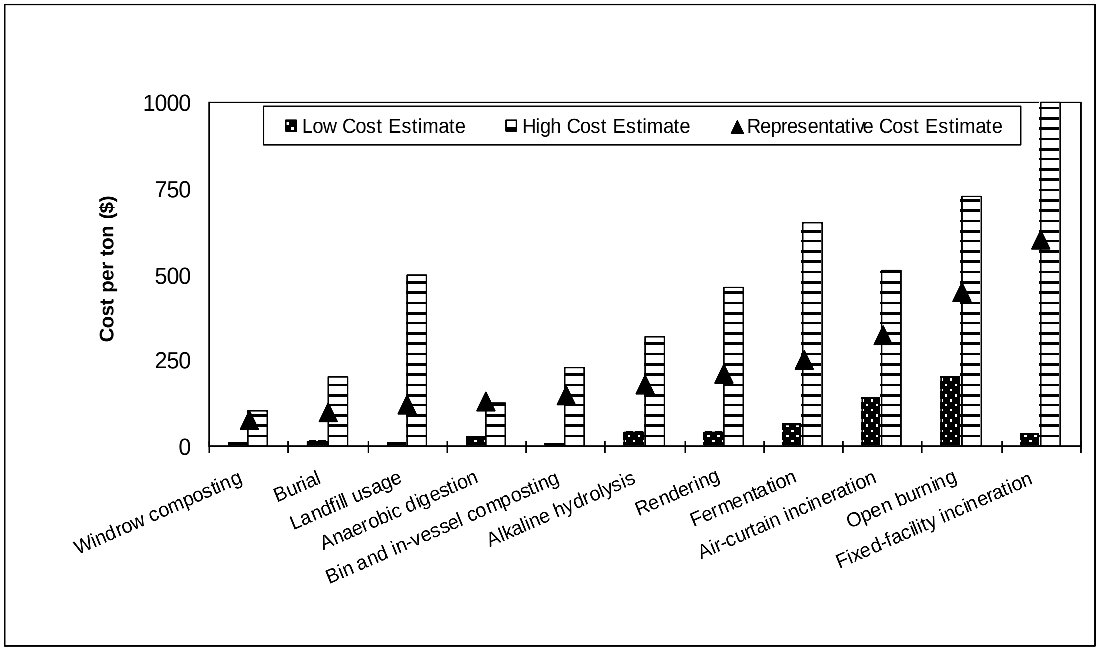

Figure 6-2 Summary of Technology Costs.

Table 6-4 *Estimate of Kansas Inventory Loss and Carcass Tons to be Disposed in an FMD Outbreak*

Species	% of U.K. inventory killed	2013 Kansas inventory[a]	Estimated Kansas inventory loss	Avg. market weight	Pounds to be disposed
Cattle	7.2	5,850,000	421,200	1,250	526,500,000
Sheep	6.5	65,000	4,225	125	528,125
Hogs	13.4	1,820,000	243,880	260	63,408,800
Total Tons of Carcasses to be Disposed				295,218.5	

Note. [a]Kansas Farm Facts, Kansas Department of Agriculture (2013).

Table 6-5 *Cost of Disposal by Method for a Kansas FMD outbreak.*

Disposal Methods	Representative Cost per Ton	Cost for Disposal (in millions of dollars)
Windrow composting	75	22.14
Burial	100	29.52
Landfill usage	120	35.43
Anaerobic digestion	130	38.38
Bin and in-vessel composting	150	44.28
Alkaline hydrolysis	180	53.14
Rendering	210	62.00
Fermentation	250	73.80
Air-curtain incineration	325	95.95
Open burning	450	132.85
Fixed-facility incineration	600	177.13

Note: Carcass disposal cost is based on the tons calculate din Table 6-4 based on inventory percentage lost in 2001 U.K. FMD outbreak.

When analyzing each alternative method compared to burial with a cost-effectiveness approach, burial is the second most cost-effective method. Windrow composting proves to be the most cost-effective method. Landfill usage is the third most cost-effective method. Another important aspect to note is that burning was considered the next most preferred method of disposal in the previous KRP. The cost-effectiveness comparison indicates all forms of burning and incineration are the least cost effective.

County scenario

In order to get a more realistic assessment of the number of animals that would need destroyed if FMD was present in southwest Kansas where cattle operations are more highly concentrated, an eight-county region is used to determine potential costs of carcass disposal. Haskell County has the largest cattle inventory with 395,000 head in 2012. Haskell County and the seven adjacent counties were used to create an eight-county region with 1.366 million cattle as of January 1, 2013 (KDA, 2013).

In the Pendell et al. (2007) study of an FMD outbreak in southwest Kansas, it was estimated 6.3% of cattle would need to be destroyed in the case of an index case at a cow-calf operation, 20.35% would be depopulated if the outbreak started at one medium-sized feedlot, and 84% of animals would be destroyed if FMD was introduced simultaneously at five feedlots. These numbers are still relatively conservative because they are based on a 1.5-mi infected zone rather than the 3-km zone (1.86 mi) called for in the KRP and the assumption that no animals are destroyed outside the infected zones. These percentages were applied to the eight-county region to estimate the minimum number of cattle to be destroyed in Table 6-6.

Table 6-6 *Cost-effectiveness of Disposal in Eight County Region in Southwest Kansas*

		Minimum number of cattle destroyed by scenario		
County	Cattle inventory	Cow-calf scenario (6.3%)	Single feedlot scenario (20.35%)	Five feedlot scenario (84%)
Haskell	395,000	24,885	80,383	331,800
Finney	240,000	15,120	48,840	201,600
Gray	230,000	14,490	46,805	193,200
Meade	59,000	3,717	12,007	49,560
Seward	120,000	7,560	24,420	100,800
Stevens	41,000	2,583	8,344	34,440
Grant	210,000	13,230	42,735	176,400
Kearny	71,000	4,473	14,449	59,640
Total Head	1,366,000	86,058	277,983	1,147,440
Converted to Tons		53,786	173,739	717,150
Burial Cost		$5,378,600	$17,373,900	$71,715,000
Landfill Cost		$6,454,320	$20,848,680	$86,058,000
Composting Cost		$4,033,950	$13,030,425	$53,786,250
Burning Cost		$24,203,700	$78,182,550	$322,717,500

Note: Percentage of cattle destroyed based on estimates from Pendell et al., 2007 and costs based on representative costs identified in Table 6-3.

The representative costs developed from the literature review were applied, thus indicating composting as the most cost-effective alternative with burial and landfill the next two cost-effective methods. Burning remains a high cost alternative and does not take into account the limited fuel resources in the region. Composting with these numbers of animals would be challenging due to the amount of composting materials required and the fact that on-site composting at feedlot locations would significantly limit their ability to continue or commence business activity. There are limited landfills in the regions averaging less than one small landfill per county, each being able to take no more than 1-5 carcasses per day. There are three larger landfills in southwest Kansas located in Finney, Ford, and Seward counties, but no single landfill could handle any more than 50-100 carcasses per day. On a side note, while landfills in eastern Kansas are larger, it is unlikely they would accept carcasses according to KDHE BWM officials. If burial were the carcass disposal method used and burial pits were 6 ft deep, 3073.5 sq ft (18,441 cu ft), 1,945,881 sq ft (11,675,286 cu ft), and 8,032,080 sq ft (48,192,480 cu ft) would be required for each scenario in Table 6-6, respectively. In the last scenario, this is equivalent to a hole the size of 1338 football fields dug 6 ft deep or a trench that is 25 ft wide, 6 feet deep, and 321,283.2 ft or 60.85 mi long.

The cost-effectiveness comparison does provide the type of cost data most decision makers are interested in considering. However, this method clearly has limitations. These results, combined with information in Table 6-3, do provide additional insight. For example, when comparing burial to windrow composting, Table 6-3 indicates composting requires more inputs but results in fewer negative externalities related to the environment and public perception. Other policy evaluation methods may also be utilized that incorporate more than economic feasibility.

Matrix scorecard analysis

Economic efficiency should not serve alone in selecting the best carcass disposal policy. Decision makers need additional information about each disposal technology to select the best policy. Conflicting objectives and differing priorities on each of the policy criteria and considerations make the evaluation process even more difficult. To one individual, environmental impact is the highest priority; to another, it may be cost; and, to a third person, it may be disease control. Multicriteria decision making analysis allows for this type of comparison.

In this case, a matrix scorecard system is used to allow all criteria to be considered for each policy alternative. The carcass disposal criteria identified earlier in this chapter are listed in Table 6-7 along with each disposal technology. A scale of 1 – 4 is used to indicate the ability of each specific technology to meet the policy criteria. The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria. The far right column indicates the total score, with a high number indicating the best policy. These scores are based on the information collected for this dissertation. To develop this scorecard into a final policy tool, specialists could be used to assign these scores based on the specific situation before the policy maker applies the weightings developed in Table 6-8.

Table 6-7 *Disposal Technology Matrix Scorecard.*

	Disposal Technology Policy Criteria											
Disposal Technologies	Disease & Biosecurity Risk	Scale and Expediency	Site and Facility Accessibility	Fuel & Resources	Environment	Transportation	Cost & Economics	Public Health	Species Applicability	Public Perception	Regulatory Compliance and Interagency Cooperation	Overall Score
Burial (on- and off-site)	3	3	3	4	2	4	4	2	4	1	3	33
Landfill usage	3	4	3	4	3	3	4	4	4	2	3	37
Open burning	3	3	2	1	2	4	1	2	3	1	3	25
Fixed-facility incineration	4	2	1	3	3	1	1	3	3	2	3	26
Air-curtain incineration	3	2	2	2	2	2	2	2	3	2	3	25
Bin- and in-vessel composting	3	2	2	2	4	3	3	3	2	3	3	30
Windrow composting	3	3	3	3	4	4	4	3	2	3	3	35
Rendering	1	3	2	3	4	2	2	2	2	3	2	26
Fermentation	4	1	2	3	4	1	2	4	3	4	2	30
Anaerobic digestion	4	1	1	3	4	1	3	4	3	4	2	30
Alkaline hydrolysis	4	1	1	3	4	1	2	4	3	4	2	29

The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria.

Based on this comparison, landfill usage is the top policy choice followed by windrow composting and burial. This analysis allows decision makers to look at multiple policy alternatives and compare them to their selected criteria. Again, burning was last on the list of technologies. Local factors will have an influence in scoring criteria. For example, in southwest Kansas, landfill space is not available to meet potential disposal needs regardless of its ability to successfully meet other criteria.

The two biggest problems with this method of analysis are that it is dependent on the subjectivity of the analyst and implies that each criterion is equally important. A criteria weighting system would make this analysis even more useful, but would require agreement on the weightings of the criteria by decision makers.

In order to make the analysis a better tool for policymakers allowing them to use available information but leaving the decision in their hands, the first step would be to ask the decision makers to apply a weight to each criteria. A weighing or priority system that allowed the most flexibility to the decision maker is likely to be more useful.

For example, instead of simply ranking the criteria from most to least important, decision makers could be asked to take 100 points and distribute them according to their priorities for each criteria. If there is one decision maker, then his/her priorities would direct policy. If there are multiple leaders involved in the policy decision, the weighting could be done as a group or individually and then aggregated.

Table 6-8 *Weighting of Disposal Method*

Disposal Method Criteria	Weight and priority of each criterion Instructions: You have 100 points to distribute amongst the criteria. Please assign points based on the priority you place on each criterion in selecting a disposal method. The total points allocated must equal 100 points.
Disease and biosecurity risk	
Scale and expediency	
Site and facility accessibility	
Fuel and resources	
Environment	
Transportation	
Cost and economics	
Public health	
Species applicability	
Public perception	
Regulatory compliance and interagency cooperation	
Total points assigned	Must sum to 100

A completed example weighing each disposal method is seen below. This example included four decision makers involved in the policy decision: one animal health official, one health and environment official, one budget official, and one elected official. The intent is simply to illustrate how different officials may have different priorities but assumes each has an understanding of the critical nature of carcass disposal policy decisions in the face of an animal disease outbreak. The priorities exhibited in Table 6-9 are based solely on personal impressions of what issues are of the greatest concern to each type of decision maker developed through the literature review, research, exercise activities, and personal conversations.

Table 6-9 *An Example Weighting of Disposal Method*

Disposal Method Criteria	Weight and priority of each criterion Instructions: You have 100 points to distribute amongst the criteria. Please assign points based on the priority you place on each criterion in selecting a disposal method. The total points allocated must equal 100 points.				
Decision Maker	Animal Health	Health and Environment	Budget	Elected	Average
Disease and biosecurity risk	15	10	10	15	12.5
Scale and expediency	10	5	10	10	8.75
Site and facility accessibility	10	10	10	5	8.75
Fuel and resources	7	10	10	5	8
Environment	5	15	5	5	7.5
Transportation	10	5	5	5	6.25
Cost and economics	5	5	20	15	11.25
Public health	15	15	10	15	13.75
Species applicability	10	5	5	5	6.25
Public perception	3	5	5	15	7
Regulatory compliance and interagency cooperation	10	15	10	5	10
Total points assigned (Must sum to 100)	100	100	100	100	100

Table 6-10 *Disposal Technology Matrix Scorecard with Weighting Applied*

Disposal Technologies	Disease and Biosecurity Risk	Scale and Expediency	Site and Facility Accessibility	Fuel and Resources	Environment	Transportation	Cost and Economics	Public Health	Species Applicability	Public Perception	Regulatory Compliance and Interagency Cooperation	Overall Score
	Disposal Technology Policy Criteria											
Weight %	12.5	8.75	8.75	8	7.5	6.25	11.25	13.75	6.25	7	10	
Burial (on- and off-site)	3	3	3	4	2	4	4	2	4	1	3	2.97
Landfill usage	3	4	3	4	3	3	4	4	4	2	3	3.41
Open burning	3	3	2	1	2	4	1	2	3	1	3	2.24
Fixed-facility incineration	4	2	1	3	3	1	1	3	3	2	3	2.44
Air-curtain incineration	3	2	2	2	2	2	2	2	3	2	3	2.29
Bin- and in-vessel composting	3	2	2	2	4	3	3	3	2	3	3	2.76
Windrow composting	3	3	3	3	4	4	4	3	2	3	3	3.19
Rendering	1	3	2	3	4	2	2	2	2	3	2	2.26
Fermentation	4	1	2	3	4	1	2	4	3	4	2	2.81
Anaerobic digestion	4	1	1	3	4	1	3	4	3	4	2	2.83
Alkaline hydrolysis	4	1	1	3	4	1	2	4	3	4	2	2.72

The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria.

In Table 6-10, weightings were applied based on Table 6-9 and different criteria were compared for each disposal technology. Landfill usage followed by windrow composting and then burial were the top three methods based on the hypothesized weights and scores.

Summary

The KRP addresses carcass disposal and indicates KDA, KDHE, and USDA APHIS have worked well together in establishing a process and procedures. Effective means of carcass disposal are essential in the case of an animal disease emergency, and a state policy that provides guidance in that area is recommended.

Strategies for timely, efficient, and effective disposal require significant planning and preparation. While significant work has gone into developing the state emergency disposal policy, further evaluation of disposal technologies may need to occur. The KRP identifies burial and composting as preferred disposal methods. Burial, composting, and landfill usage appear to be the most effective tools in the analysis provided but may not be logistically feasible.

The KRP may be more effective if it detailed different policies for different situations. The "one size fits all approach" may be a problem if burial is not a feasible option. This could be the case if a large-scale death loss occurred in a geographic location with high water tables or if the disease in question eliminates burial as an option. Any disposal policy should utilize multiple disposal methods, allowing for each region of the state to adapt to the methods that best meet their needs and to respond to the specific disease agents and species involved.

Decision makers need to understand all disposal alternatives and be prepared to utilize them when necessary. Development of new or more efficient technologies, changes in laws or regulations, or shifts in market conditions may influence the decision as well. Further consideration should be given to expanding the list of preferred disposal methods, and decision makers may need to reconsider their preferred method policy.

Vaccination

Stamping out has been considered the primary U.S. policy approach to FMD for decades. Lessons learned from FMD outbreaks in other countries and emergency exercises completed in the US have led to a revolutionary change in thinking about FMD vaccination. Animal health officials have concluded stamping out may simply not be a feasible option, but also acknowledge that vaccination is not an "easy button" or "silver bullet". At a December 2013 FMD emergency exercise with representatives from multiple federal agencies and state officials from Kansas, Missouri, Iowa, and Nebraska, it was markedly apparent that the vaccination infrastructure and decision process is not in place to meet the needs anticipated in a major FMD outbreak. Kansas animal health officials concluded states will find themselves fighting each other for vaccine and it is unlikely to be provided in a sufficient, timely manner. However, vaccination-to-slaughter remains the goal of Kansas animal health officials and eradicating the disease is considered paramount to economic and trade impacts. These policy considerations need further consideration and a framework has been created to provide decision makers with insight into this challenging policy dilemma.

Kansas Response Plan – vaccination

The Kansas Response Plan Food and Agriculture Incident Annex notes vaccination can be used in a number of different situations in the case of FAD. USDA APHIS will control access and permission to use vaccines, because of their implications in international trade. The Kansas Department of Agriculture Division of Animal Health could seek the approval to use vaccines if a highly infectious disease cannot be contained by euthanasia of exposed and infected animals. Then, ring vaccination could be used to vaccinate susceptible, non-exposed animals that would form a barrier to slow the progression of the disease spread. Vaccines may also be used to protect large numbers of susceptible animals in a feedlot, dry lot dairy, or swine confinement facility. These vaccinated animals would be slaughtered after the disease is contained and enter the food chain. Vaccination in these cases would avoid mass euthanasia and preserve meat for human consumption (KRP, 2013).

Framework analysis

The Alternatives-Consequences approach is applied to vaccination versus depopulation policy decision in the following framework analysis. A number of factors related to the specific outbreak will influence the specific consequences of each alternative, such as speed of disease spread, size of outbreak, species involved, and number of jurisdictions involved. The framework in Table 6-11 is designed to provide a conceptual framework comparing alternatives and consequences. This conceptual framework can provide a basis for policy decisions, but to be more useful and effective, details related to the specific outbreak would need to be completed and provided to decision makers within hours of disease notification. To provide additional resources to decision makers, results from previous economic and epidemiological models as shared in Chapter 4 can also be provided.

To add to the usefulness of the framework, a weighting mechanism can be added to allow decision makers to more clearly prioritize the consequences of each policy alternative. Two components can be added, one to quantify the ability of each alternative to meet the goals of each consequence area and the second to value the importance of that area of consideration. The first method of quantification would be dependent on expert input to the policymakers on the consequences of each policy alternative. For example, an epidemiologist can provide information on the ability of each policy alternative to stop disease spread given the disease outbreak scenario and an economist can provide details on the economic and trade impact for the given region based on the disease outbreak. Then, the policymakers need to decide which factors they value the most and provide an appropriate weight reflecting their policy priorities. Feasibility may be considered initially, because there is no point becoming dependent on a policy solution that is simply not feasible to implement. In Table 6-12, “expert” scoring is hypothesized for a large scale, rapidly spreading FMD outbreak based on general interpretation of previous economic and epidemiological work and a scale of 1 – 4 is used to indicate the ability for each policy alternative to meet the criteria. The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria. While specialists can be used to finalize criteria scoring before the tools is provided to the generalist or policy maker to apply weighting, the examples provided were based on the general factors described in Table 6-11. In addition, value weighting is applied based on a total scoring system of 100 points. The example values are estimated to be those of an animal health official.

Table 6-11 *Consequences of Vaccination Alternatives*

Policy Alternatives	Consequences to be considered					
	Animal Health	Economic	Political	Consumer Reaction	Industry Reaction	Feasibility
Top priority within each area of consideration	Eliminate disease, reduce number of infected and susceptible animals	Minimize economic impact and time to economic recovery	Minimize social and political disruption	Maintain consumer support for industry	Gain and maintain industry support for response and business continuity	Viable implementation
Stamping out, no vaccination	Low speed of disease spread Low animal population density Limited animal movement Animal welfare concerns	Trade is reinstated no less than 3 months after last diseased animal is depopulated Cost of control strategy Impact on domestic demand Impact on related sectors	Influence of stakeholders Influence of activist groups International reaction Media coverage	Public reaction to animal depopulation, especially of apparently healthy animals General response to disease outbreak	Reaction to depopulation of apparently healthy animals Consideration of genetic preservation Compensation factors	Feasibility of stamping out
Stamping out modified with vaccination-to-kill/cull	High speed of disease spread High animal population density Extensive animal movement Animal welfare concerns	Trade is reinstated no less than 3 months after last vaccinated animal is depopulated Cost of control strategy Impact on domestic demand Impact on related sectors	Influence of stakeholders Influence of activist groups International reaction Media coverage	Public reaction to animal depopulation, especially of apparently healthy animals General response to disease outbreak	Reaction to depopulation of apparently healthy animals Consideration of genetic preservation Compensation factors	Availability and accessibility of vaccines Feasibility of stamping out
Stamping out modified with vaccination-to-slaughter	High speed of disease spread High animal population density	Trade is reinstated no less than 3 months after last vaccinated animal is slaughtered	Influence of stakeholders Influence of activist groups International	Consumer acceptance of vaccinated product Consumer demand for labeled products Consumer confidence	Meat industry reaction to potential consumer desire for labeled product Meat industry concerns	Availability and accessibility of vaccines Feasibility of stamping out Processing plant

Policy Alternatives	Consequences to be considered					
	Animal Health	Economic	Political	Consumer Reaction	Industry Reaction	Feasibility
	Extensive animal movement Animal welfare concerns	Cost of control strategy Impact on domestic demand Impact on related sectors	reaction Media coverage	in entire meat supply	about overall impact on demand	willingness to accept vaccinated animals
Stamping out modified with vaccination-to-live	High speed of disease spread High animal population density Extensive animal movement Animal welfare concerns	Trade is reinstated no less than 6 months after last diseased animal is depopulated or last animal was vaccinated Cost of control strategy Impact on domestic demand Impact on related sectors	Influence of stakeholders Influence of activist groups International reaction Media coverage	Consumer acceptance of vaccinated product Consumer demand for labeled products Consumer confidence in entire meat supply	Meat industry reaction to potential consumer desire for labeled product Meat industry concerns about overall impact on demand	Availability and accessibility of vaccines Feasibility of stamping out
Vaccination-to-live, no stamping out	Extremely high speed of disease spread Extremely high animal population density Extensive and unknown animal movement	Trade is reinstated no less than 12 months after last diseased animal was identified or last animal was vaccinated Cost of control strategy Impact on domestic demand Impact on related sectors	Influence of stakeholders Influence of activist groups International reaction Media coverage	Consumer acceptance of vaccinated product Consumer demand for labeled products Consumer confidence in entire meat supply	Meat industry reaction to potential consumer desire for labeled product Meat industry concerns about overall impact on demand	Availability and accessibility of vaccines

Table 6-12 *Vaccination Versus Stamping Out Weighted by Animal Health Official*

Consequences to be considered	Top Priority of each consequence area	Weighting Value (must add up to 100)	Policy Alternatives: Stamping out	Stamping out with vaccination-to-kill/cull	Stamping out with vaccination-to-slaughter	Stamping out with vaccination-to-live	Vaccination with no stamping out
Feasibility	Viable implementation	If Yes – proceed	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?
Animal health	Eliminate disease, reduce number of infected and susceptible animals	50%	2	3	3	2	2
Economic	Minimize economic impact and time to economic recovery	10%	3	2	3	2	1
Political	Minimize social and political disruption	5%	2	1	2	1	2
Consumer reaction	Maintain consumer support for industry	10%	2	1	1	1	2
Industry reaction	Gain and maintain industry support for response and business continuity	25%	2	1	2	2	1
TOTAL SCORE		100%	2.10	2.35	2.5	1.85	1.65

A scale of 1 – 4 is used to indicate the ability for each policy alternative to meet the criteria. The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria.

According to the factors and weighted values in Table 6-12, if animal health and disease control is the priority and assuming all policy alternatives are feasible, vaccination-to-slaughter scores the highest with vaccination-to-kill/cull second and stamping out ranking third. However, if weights were shifted to reflect priorities placing a higher value on economic and political impact, results will differ as seen in Table 6-13 where stamping out is the preferred policy alternative.

Qualitative cost-benefit assessment

Another method of comparing policy alternatives and consequences can be provided to policymakers in a qualitative cost-benefit analysis. The goal is to provide policy makers a tool that explains the cost and benefit impact of the consequences faced by different stakeholders. A cost to one stakeholder may be a benefit to another, so tradeoffs can be compared. A qualitative assessment allows for alternatives that cannot be sufficiently quantified in a traditional cost-benefit analysis to be compared. When quantitative information is available from economic or epidemiological models, it can be used to help complete the assessment. The policymakers can then assess the impact of each consequence and make a policy decision. A sample qualitative cost-benefit assessment is provided in Table 6-13 that highlights a few of the potential consequences of FMD control strategies on different groups of stakeholders with different interests that would allow decision makers to compare the consequences of each alternative.

Table 6-13 *Vaccination Versus Stamping Out Weighted by Official Focused on Economic and Political Impact*

Consequences to be considered	Top Priority of each consequence area	Weighting Value (must add up to 100)	Policy Alternatives: Stamping out	Stamping out with vaccination-to-kill/cull	Stamping out with vaccination-to-slaughter	Stamping out with vaccination-to-live	Vaccination with no stamping out
Feasibility	Viable implementation	If Yes – proceed	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?	Is this approach feasible?
Animal health	Eliminate disease, reduce number of infected and susceptible animals	15%	2	3	3	2	2
Economic	Minimize economic impact and time to economic recovery	30%	3	2	3	2	1
Political	Minimize social and political disruption	20%	2	1	2	1	2
Consumer reaction	Maintain consumer support for industry	20%	2	1	1	1	2
Industry reaction	Gain and maintain industry support for response and business continuity	15%	2	1	2	2	1
TOTAL SCORE		100%	2.30	1.60	2.25	1.60	1.55

A scale of 1 - 4 is used to indicate the ability for each policy alternative to meet the criteria. The scale is as follows: 4 – meets the criteria well, 3 – somewhat meets the criteria, 2 – fairly meets the criteria, and 1 – poorly meets the criteria.

Table 6-14 *Qualitative Cost-Benefit Assessment of FMD Control Strategies*

	Agriculture Industry		Consumers and General Public		Government and Public Sector	
Policy Alternatives	Livestock producers who own infected and susceptible animals	Livestock producers and processers impacted by trade	Public concerned about animal welfare and food safety	Consumers who purchase meat products	Direct and indirect costs	Ability to address animal disease control
Stamping out, no vaccination	More animals depopulated Compensation will be provided for depopulated animals	Fastest return to normal trade	See large number of animals killed and disposed including those that are not diseased	Initial reduction in meat supply may increase prices if excessive numbers of animals are depopulated Trade restrictions will eventually lead to price declines and increases in domestic consumer welfare	Large number of animals depopulated and disposed will lead to high government costs, including producer compensation	May lead to fastest disease eradication depending on circumstances
Stamping out modified with vaccination-to-kill/cull	Likely the most number of animals depopulated Compensation will be provided for depopulated animals	Next to the fastest return to normal trade	See large number of animals killed and disposed including those that are have been vaccinated	Trade restrictions will lead to price declines and increases in domestic consumer welfare	Likely the high cost alternative when considering vaccination, depopulation, disposal, and compensation	Will likely result in a median duration of disease outbreak
Stamping out modified with vaccination-to-slaughter	Fewer animals depopulated and most still move into food chain Compensation will be provided for only depopulated animals	Median time to return to trade	See fewer animals killed and disposed Vaccinated products enter the food chain	Trade restrictions will lead to price declines and increases in domestic consumer welfare	Lower cost alternative as fewer animals culled and disposed and less need for compensation	Will likely result in a median duration of disease outbreak
Stamping out	Next to least number	Next to slowest	Fewer animals	Trade restrictions	Lower cost	May extend duration

Policy Alternatives	Agriculture Industry: Livestock producers who own infected and susceptible animals	Agriculture Industry: Livestock producers and processers impacted by trade	Consumers and General Public: Public concerned about animal welfare and food safety	Consumers and General Public: Consumers who purchase meat products	Government and Public Sector: Direct and indirect costs	Government and Public Sector: Ability to address animal disease control
modified with vaccination-to-live	of animals depopulated Normal slaughter channels Compensation will be provided for depopulated animals	return to trade	killed and disposed Vaccination saves animals lives Vaccinated animals enter the food chain	will lead to price declines and increases in domestic consumer welfare	alternative as fewer animals culled and disposed and less need for compensation	of disease outbreak
Vaccination-to-live, no stamping out	Least number of animals depopulated Normal slaughter channels	Slowest return to normal trade	No animals killed and disposed Vaccinated and previous disease animals enter the food chain	Trade restrictions will lead to price declines and increases in domestic consumer welfare	No costs for disposal, depopulation, and compensation but high costs for vaccination	May lead to longest outbreak duration

Each cell is shaded to represent the qualitative cost/ benefit, advantage/disadvantage impact of each listed consequence for each policy alternative. The key is shown below.

Key				
Key	Increased benefits/ reduced costs	Changes in costs and benefits counter each other	Decreased benefits/increased costs	Unable to determine impact

Summary

The decision to vaccinate in the case of an FMD outbreak is complex and multifaceted. Policymakers will need to be well-informed on the disease outbreak scenario and have a clear understanding of the potential consequences of their decisions. However, the most telling factor will be the value the policymakers place on the various consequences of each policy alternative. Also of concern is the feasibility of all policy alternatives. While stamping out has been identified by some animal health officials as infeasible, questions over the how and when vaccination will be available also makes all vaccination protocols potentially unreliable as well. In a 2013 FMD emergency exercise when vaccination was being discussed, it became clear that there would not be enough vaccine to serve the four states participating in the exercise and that no vaccine would be available for 14-21 days. In addition, a comment was made by a veterinarian in response to a comment made by an economist that “this is why we do not want economists making decisions” and another comment followed later in the discussion that “doctors of veterinary medicine will be making the important decisions” (personal communication). In general, across state and federal levels, there appears to be a lack of understanding of how policy decisions are made or that all decision makers in an animal health emergency answer to elected officials who may value or prioritize policy consequences differently. Better policy analysis tools and a significantly better understanding of the impact of vaccination policy alternatives are needed. Basic frameworks as presented here can begin to open the door to more effective policy making in an emergency disease situation.

Chapter 7 - Summary, Conclusions, and Future Considerations

The U.S. agriculture industry is diverse and dynamic, plays a vital role in the Nation's economy, and serves as a critical component in providing the global food supply. Agriculture has and always will be susceptible to threats such as pests, disease, and weather, but it is also threatened by intentional acts of agroterrorism. The crop and livestock industry are both vulnerable to deliberate attacks in addition to the natural risks they face every day. History indicates that threats against the food system have always existed, and while attacks have not been frequent, they continue to be a feasible alternative for those wanting to inflict damage with limited risk to the perpetrator and high consequence for the target. These low-probability but high-consequence risks need to be taken seriously by industry and policymakers in order to ensure appropriate preventive and response policies are in place.

One specific area of concern is foreign animal diseases (FAD) and the danger these diseases create for the U.S. livestock industry. Regardless of whether a disease outbreak is intentional or accidental, it could devastate animal agriculture and the food infrastructure and have a long-lasting impact on state, national, and global economies. The highly concentrated nature of the livestock industry, open access production in sparsely populated areas, and the simplicity of some forms of attack make agriculture vulnerable to disease outbreaks. A number of diseases can be considered of greater concern including classical swine fever, bovine spongiform encephalopathy, avian influenza, chronic wasting disease, exotic Newcastle disease, and swine influenza. One of the most economically devastating diseases that raise fear and anxiety in the livestock industry is foot and mouth disease (FMD).

A number of administrative, regulatory, and legislative actions have been implemented at state and federal levels designed to protect the agriculture industry and to prevent, prepare for, and respond to an accidental or intentional introduction of an FAD. However, the consistency, clarity, and long-term commitment of these policy approaches remains in question. Controversy exists in some cases over roles, responsibilities, and statutory authorities between agencies and between state and federal governments and the practicality of some policy decisions.

Effective policy decisions require a multidisciplinary approach that consider and balance science, economics, social factors, and political realities. Relative to an FAD these considerations need to include animal health, disease control, animal welfare, environmental impact, consumer reaction, ethical concerns, regulatory impact, logistics, social and psychological impacts, physical security, geography, public health, economics, trade impacts, industry response, and political realities. A significant number of policy analysis tools exist and have been applied to animal emergency scenarios but few actually address the complexity of these policy dilemmas and provide information to policymakers in a format designed to help them make better policy decisions. Policy analysis should not be focused on the identification of the best solution, but should instead provide decision makers with a clear understanding of the policy problem, issues of concern, policy alternatives to consider, consequences to compare, and a framework with which to make a strategic decision.

Three FAD policy dilemmas that deserve further discussion, consideration, and a multidisciplinary approach are mass euthanasia and depopulation, carcass disposal, and vaccination. While these policies are important in dealing with numerous FADs, significant concerns exist in FMD policy decisions on these issues.

Mass euthanasia and depopulation are necessary to stop disease spread and may be necessary to deal with animal welfare issues. Decision makers will need to determine when and where mass euthanasia and depopulation approaches will be implemented and what methods of euthanasia will be used. Economic, animal health, social and other factors will play a role in the decision process. In selecting appropriate methods, policymakers need to first select the highest valued priority. If it is animal welfare, the methods to be considered are limited. If another priority is valued higher such as speed of disease control, other methods may prove more successful. A decision tree can serve as a guidance tool for the policy decision.

Carcass disposal during an FMD outbreak is a complex and challenging policy dilemma influenced by a number of factors including biosecurity risk, scale of death loss, site and facility availability, fuel and resources, environmental impact, transportation requirements, costs, economic impacts, public health, species, public perception, and interagency and intergovernmental cooperation. Cost-effectiveness analysis and a multicriteria decision matrix are developed for policy analysis. The decision matrix requires policymakers to rank their policy outcome priorities to help determine the best policy solution.

Vaccination has become the most significant policy dilemma facing decision makers in an FMD outbreak. While vaccination was not considered a realistic alternative just a few years ago, opinions have shifted and it is now seen as the preferred policy response by many government officials. However, policymakers need to be provided information on the full impacts of the vaccination policy alternatives before a decision is made. A framework is provided based on the alternatives-consequences approach that requires policymakers to consider all facts and multidisciplinary impacts before making a decision. A weighted version of the framework is provided to reflect policymakers' values and priorities. One of the remaining questions regarding the vaccination versus mass depopulation decision is the feasibility of all of the policy alternatives.

Recently, at an FMD emergency exercise with participants from multiple federal agencies and four Midwestern states, it was apparent vaccination protocols for distribution are not in place and it is unlikely vaccination would be provided to states quickly enough to serve as a disease control tool. Yet, vaccination was still deemed to be preferred over mass depopulation. It was also apparent in this discussion that decisions were solely focused on animal health, and other factors such as economics, were considered inferior. This way of thinking seems to lack an understanding of the political reality that elected and appointed officials will expect policy decisions to be made that weigh all concerns and balance all potential impacts. If those delegated the decision making responsibility do not meet these expectations, it is likely the decisions will be made by those without the necessary expertise. Thus, policy development needs to take a more multidisciplinary approach and better policy tools are needed to help decision makers determine the best policy choices. The approaches in this dissertation are designed to serve as a next step in the policy development process.

As policymakers look to the future, a number of additional questions need to be considered. Animal disease response tools such as stop- and permitted-movement controls, surveillance, disease diagnostics, vaccination priorities, new vaccine technology, and especially animal identification and traceability need further review in addition to euthanasia, disposal, and vaccination protocols. Communication and cooperation need to be improved between state and federal authorities, executive and legislative branches, and government, private industry, and the public. Ex ante investment, indemnity insurance for livestock emergencies, producer compensation policies, business continuity plans, and herd rebuilding options need to be evaluated. Plans should be developed for addressing the existing shortage of large animal veterinarians trained in FAD diagnostics and response.

The impact of an FAD outbreak and various policy responses on domestic consumer demand and confidence in the food supply along with long-term impact on trade reputation and ability to regain lost market share deserve further analysis. Regionalization for trade purposes and acceptability of zoning in other countries should be explored, and the U.S. reactions to international disease outbreaks need to be strategically assessed. Consideration may also need to be given to broader more overarching global FMD policy questions, such as global eradication or international acceptance of vaccination as a normal, non-emergency protocol. While initially concepts like these seem too controversial for realistic consideration, they deserve to be discussed in light of the complexity, potential, and high consequences of FMD outbreaks in currently FMD-free exporting countries.

Agricultural biosecurity and defense policy is challenging, complex, and shrouded in uncertainty. Decision making will be dynamic in nature and must adjust for limited information and timing. A holistic approach is needed that addresses science, economics, political realities, and social factors. Priorities need to be identified and policy tools developed that accurately reflect those priorities. Multidisciplinary factors may be considered in the decision making process, and policymakers need to be provided the appropriate facts and framework with which to make policy decisions. The policy issues, consideration, and tools described in this dissertation can provide a start to improving the policy-making process in dealing with a threat to the agriculture industry.

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Appendix A - OIE Listed Diseases

Multiple species diseases

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever

Cattle diseases

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovagi nitis
- Lumpy skin disease
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted)

Sheep and goat diseases

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Maedi-visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Peste des petits ruminants

Equine diseases

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders

- Salmonellosis (*S. abortusovis*)
- Scrapie
- Sheep pox and goat pox
- Venezuelan equine encephalomyelitis

Swine diseases

- African swine fever
- Classical swine fever
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- Transmissible gastroenteritis

Avian diseases

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*M. gallisepticum*)
- Avian mycoplasmosis (*M. synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Highly pathogenic avian influenza and low pathogenic avian influenza in poultry as per Chapter 10.4. of the *Terrestrial Animal Health Code*
- Infectious bursal disease (Gumboro disease)
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis

Lagomorph diseases

- Myxomatosis
- Rabbit haemorrhagic disease

Bee diseases

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*)
- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees

Fish diseases

- Epizootic haematopoietic necrosis
- Epizootic ulcerative syndrome
- Infection with *Gyrodactylus salaris*
- Infectious haematopoietic necrosis
- Infectious salmon anaemia
- Koi herpesvirus disease
- Red sea bream iridoviral disease
- Spring viraemia of carp
- Viral haemorrhagic septicaemia

Mollusc diseases

- Infection with abalone herpes-like virus
- Infection with *Bonamia exitiosa*
- Infection with *Bonamia ostreae*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*

Crustacean diseases

- Crayfish plague (*Aphanomyces astaci*)
- Infectious hypodermal and haematopoietic necrosis
- Infectious myonecrosis
- Necrotising hepatopancreatitis
- Taura syndrome
- White spot disease
- White tail disease
- Yellowhead disease

Amphibians

- Infection with *Batrachochytrium dendrobatidis*
- Infection with ranavirus

Other diseases

- Camelpox
- Leishmaniosis

Appendix B - List of Acronyms

AABP	American Association of Bovine Practitioners
AASP	American Association of Swine Practitioners
AAZV	American Association of Zoo Veterinarians
AERO	Animal Emergency Response Organization
AI	avian influenza
ALF	Animal Liberation Front
APHIS	Animal and Plant Health Inspection Service
ARS	Agriculture Research Service
ASF	African Swine fever
AUSVET	Australian Veterinary Plan
AVMA	American Veterinary Medicine Association
BOA	Bureau of Air
BRAC	breakeven risk aversion
BSE	bovine spongiform encephalopathy
BSL	biosafety level
BST	bovine somatotropin
BWM	Bureau of Waste Management
CAFO	confined animal feeding operation
CARA	constant absolute risk aversion
CAST	Council for Agriculture Science and Technology
CATRC	Counter Agro Terrorism Research Center
CBA	cost-benefit analysis
CBO	Congressional Budget Office
CBPP	contagious bovine pleuropneumonia
CDC	Center for Disease Control
CDFA	California Department of Food and Agriculture
CDP	Center for Domestic Preparedness
CEEZAD	Center of Excellence for Emerging and Zoonotic Animal Diseases
CFR	Code of Federal Regulations
CFSPH	Center for Food Safety and Public Health
CGE	computable general equilibrium
CIA	Central Intelligence Agency
CIDRAP	Center for Infectious Disease Research and Policy
CIKR	critical infrastructure and key resources
COBRA	Cabinet Office Briefing Room
CRS	Congressional Research Service
CSF	classical swine fever
CVB	Center for Veterinary Biologics
CVO	chief veterinary officer
CWD	chronic wasting disease
DAW	Department of Animal Welfare (UK)
DEA	Drug Enforcement Agency

DEFRA	Department for Environment, Food and Rural Affairs (UK)
DHS	Department of Homeland Security
DIVA	differentiated from infected animals
DOD	Department of Defense
DOI	Department of the Interior
EADW	Emergency Animal Disposal Workgroup
EC	European Commission
EHD	epizootic hemorrhagic disease
ELF	Earth Liberation Front
END	exotic Newcastle disease
EPA	Environmental Protection Agency
ERS	Economic Research Service
ESF	Emergency Support Function
EU	European Union
FA	food and agricultural
FAD	foreign animal disease
FADD	Foreign Animal Disease diagnostician
FADPReP	Foreign Animal Disease Preparedness and Response Plan
FADT	Foreign Animal Disease Threats
FAO	Food and Agriculture Organization of the UN
FASCC	Food and Agriculture Sector Coordinating Council
FAWC	Farm Animal Welfare Council
FAZD	Foreign Animal and Zoonotic Disease Defense
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FDI	first day incidence
FEMA	Federal Emergency Management Agency
FFADDR	Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities
FFI	first fortnight incidence
FMD	foot and mouth disease
FR	Federal Register
FSIS	Food Safety and Inspection Service
FSMA	Food Safety and Modernization Act
GAO	Government Accountability Office
GDP	Gross Domestic Product
GIS	geographic information system
GMO	genetically modified organisms
HHS	Department of Health and Human Services
HPAI	highly pathogenic avian influenza
HSPD	Homeland Security Presidential Directive
ICS	Incident Command System
IICAB	Institute for International Cooperation in Animal Biologics
I-O	input-output
ISP	InterSpread Plus

ITC	International Trade Commission
KDA	Kansas Department of Agriculture
KDEM	Kansas Department of Emergency Management
KDHE	Kansas Department of Health and Environment
KRP	Kansas Response Plan
KSA	Kansas Statutes Annotated
LFD	lateral flow devices
LPAI	low pathogenic avian influenza
LWDS	livestock welfare disposal scheme
MAFF	Ministry of Agriculture, Fisheries and Foods
MAF	Ministry of Agriculture and Forestry (NZ)
MAK	modified atmosphere killing
MaTCh	matrix, tree, and checklist
MBM	meat and bone meal
MIIS	Monterey Institute of International Studies
MLC	Meat and Livestock Commission
MLHMP	multilevel hierarchic Markov decision process
NAADSM	North America Disease Spread Model
NAFMDVB	North American Foot and Mouth Disease Vaccine Bank
NAHEMS	National Animal Health Emergency Management System
NAO	National Audit Office (UK)
NASDA	National Association of State Departments of Agriculture
NASS	National Agricultural Statistics Service
NBAF	National Bio- and Agro-Defense Facility
NCAHEM	National Center for Animal Health Emergency Management
NCEDR	National Center for Environmental Decision Making Research
NCFPD	National Center for Food Protection and Defense
NFU	National Farmers Union
NIAA	National Institute on Animal Agriculture
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NRC	National Research Council
NRF	National Response Framework
NROS	Natural Resources Conservation Service
NRP	National Response Plan
NSC	National Security Council
NSTC	National Science and Technology Council
NVS	National Veterinary Stockpile
NZFMG	New Zealand Combined Government and Industries FMD Preparedness Working Group
OECD	Organization for Economic Cooperation and Development
OIE	Office International des Epizooties
OLPC	Ontario Livestock and Poultry Council
PAM	policy analysis matrix
PCR	polymerase chain reaction

PD	protective dose
PETA	People for the Ethical Treatment of Animals
PIADC	Plum Island Animal Disease Center
PPD	Presidential Policy Directive
PPR	peste des petits ruminant
PTSD	posttraumatic stress disorder
RDM	robust decision making
ROW	rest of world
RPA	Rural Payments Agency
RSPCA	Royal Society for the Prevention of Cruelty to Animals
RVF	Rift Valley fever
SAM	social accounting matrix
SAT	South African territories
SART	state animal response team
SI	swine influenza
SPPA	Strategic Partnership Program Agroterrorism
SPS	Sanitary and Phytosanitary Agreement
SVC	Scientific Veterinary Commission
SVS	State Veterinary Service
TAD	Targeted Advanced Development
TAG	Adjutant General
TSE	transmissible spongiform encephalopathy
TXAHC	Texas Animal Health Commission
UK	United Kingdom
UN	United Nations
UPC	United Poultry Concerns
US	United States
USACE	U.S. Army Corps of Engineers
USAHA	U.S. Animal Health Association
USDA	United States Department of Agriculture
USGS	U.S. Geological Survey
VC	values contribution
vCJD	variant Creutzfeld-Jakob disease
VS	Veterinary Service
WARRP	Wide Area Recovery and Resiliency Program
WASK	Welfare of Animals Regulations
WHO	World Health Organization
WMD	weapon of mass destruction
WR	Waste Reduction, Inc.
WTO	World Trade Organization