The Food Safety Modernization Act: A summary of the act, education, and implementation.

by

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Abstract

Since the Food Safety Modernization Act (FSMA) was signed into law in 2011, the government has taken huge strides toward making the food safety system preventive rather than reactive. Specifically, the Preventive Controls for Human Food (PCHF) final rule has required collaboration from government officials, educational institutions, industry professionals, and stakeholders to assist in the rulemaking, education, and implementation of the new rule. The rulemaking process for the PCHF final rule took 4 years to finalize. The Food and Drug Administration funded a grant to the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) to help create an educational program about food safety risk-based preventive controls. Since then, the Food Safety Preventive Controls Alliance (FSPCA) has been coordinating training programs to certify food professionals as Preventive Controls Qualified Individuals (PCQI). After gathering minor statistical evidence through course evaluations for 10 FSPCA facilitated education programs, extension personnel of the Food Science Institute at Kansas State University found that the educational materials are a big help to those in industry and in regulatory agencies.

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Chapter 1 - Scope of Food Safety and Foodborne Illness in the United States

Foodborne illness has plagued humans throughout history. One of the earliest recordings of foodborne illnesses dates to 323 B.C. Doctors at the University of Maryland, studied historical accounts of Alexander the Great's symptoms and death, they determined that he most likely died from a water or foodborne illness (Anderson 2011). Along with Alexander the Great, many other historical figures' deaths have now been recognized to be accompanied by symptoms of foodborne illness prior to their passing. The history of foodborne illness is expansive and foodborne illness is still prevalent today. According to 2011 estimates from researchers at the Centers for Disease Control and Prevention (CDC), roughly 48 million people get sick, 128,000 people are hospitalized, and 3,000 people die of foodborne diseases in the U. S. every year (Scallan et al.). There are 31 pathogens that are known to cause foodborne illness in the U. S. alone, with the most prominent and severe pathogens including *Salmonella* (non-typhoidal), *Clostridium perfrigens*, *Campylobacter spp*., *Staphylococcus aureus*, *Listeria monocytogenes*, Shiga-toxin producing *Escherichia coli*, and *Toxoplasma gondii*, requiring food safety controls during processing and in the home to prevent outbreaks (Scallan et al. 2011). The need for food safety laws was realized early in U.S. history (Merrill 2005).

In 1862, the Bureau of Chemistry was created when chemist, Charles M. Wetherill was appointed to serve in the newly established U. S. Department of Agriculture (USDA). This bureau would soon be the predecessor to what is now known as the Food and Drug Administration (FDA) which split from the USDA in 1940 (Merrill 2005). Since the creation of the Bureau of Chemistry, many attempts were made to pass a national food and drug law with little success and rejection from the USDA. This was the case until June 30, 1906 when the Pure

Food and Drugs Act (PFDA) and The Meat Inspection Act (MIA) were signed by President Theodore Roosevelt after muckrakers and, ultimately, Upton Sinclair's *The Jungle,* exposed the conditions of working in the meat packing industry (Merrill 2005). Then, the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 was passed by congress replacing the Pure Food and Drugs Act which was then deemed obsolete (FDA 2014). Since the FDCA, laws evolved based on the concerns of the times. In 1958, the Food Additives amendment was added to the FDCA and the Delaney Clause made any substance that was found to cause cancer in laboratory animals forbidden to be used in food. In 1960, the Color Additives Amendment was added to the FDCA. In 1973, after several botulism outbreaks from canned foods, the FDA created the Low-Acid Food Processing regulations. In 1982, Tamper-Resistant Packaging Regulations were issued by the FDA after deaths due to cyanide in Tylenol (Fortin 2009). In 1996, the USDA mandated a systematic preventative approach to food safety with the implementation of Hazard Analysis and Critical Control Points (HACCP) for meat and poultry products. To ensure the safe and sanitary production of fish and fishery products, the FDA also mandated HACCP for seafood processing facilities and importers in 1997 (60 FR 65096). Along with seafood, the FDA also mandated HACCP for juice products in 2002 (66 FR 6137). Since mandating HACCP, FDA's food safety laws saw no changes until the Food Safety Modernization Act (FSMA) was signed by President Barack Obama on January 4, 2011.

Chapter 2 - Overview of the Food Safety Modernization Act and the Preventive Controls for Human Food Rule

The Food Safety Modernization Act (FSMA) revolutionized FDA's food regulations and brought about changes by taking the food safety system from reactive to preventive. This was accomplished through almost 11 final rules (Shown in *Table 2-1*):

Table 2-1 – Rules finalized as a part of FSMA

Final Rule	Date Finalized
Administrative Detention of Food for Human and Animal Consumption	February 2013
Prior Notice of Imported Food	May 2013
Sanitary Transportation of Human and Animal Food	January 2014
Establishment, Maintenance, and Availability of Records	April 2014
Current Good Manufacturing Practice and Hazard Analysis Risk-Based Preventive Controls for Food for Animals	September 2015
Current Good Manufacturing Practice and Hazard Analysis Risk-Based Preventive Controls for Human Food	September 2015
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	November 2015
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	November 2015
Accredited Third-Party Certification	November 2015
Mitigation Strategies to Protect Food Against Intentional Adulteration	May 2016
Amendments to Registration of Food Facilities	July 2016

(FDA 2017i)

The Preventive Controls for Human Food (PCHF) final rule will be the focus of this report because it has had the biggest impact on food companies not only in the U.S. but around the world who export their products and ingredients to the U.S. The PCHF rule was finalized on September 30, 2015 and with this came new requirements. Under the new rule, all foreign or domestic facilities that are required to be registered with the FDA under section 415 of the FDCA and that hold, pack, manufacture, or process human food for sale in the United States must establish and implement a food safety system. Facilities must conduct a hazard analysis, risk-based preventive controls, monitoring procedures, corrective actions and corrections,

verification procedures, record-keeping procedures, and validation of the risk-based preventive controls. Facilities are also required to do a re-analysis of their food safety system at least every three years and/or when a change is made to the system. Another requirement for those covered by this rule is a written recall plan if a hazard requiring a preventive control is identified.

Some other key additions in the PCHF final rule include a change in the "farm" definition, the requirement of a supply chain program, and updates and clarifications to the Current Good Manufacturing Practices (cGMPs). The "farm" definition was revised to cover two types of farm operations: Primary Production Farms and Secondary Activities Farms. Primary Production Farms are defined as operations under one management in one contingent or non-contingent location that grow crops, harvest crops, raise animals, or any combination of these activities. A Secondary Activities Farm is an operation separate from a primary production farm that harvests, packs, and/or holds raw agricultural commodities. If either of these types of farms conduct activities on produce covered by the Produce Safety rule, they will be required to comply with that rule.

The requirement for a supply chain program was also a key addition in the PCHF final rule. This part of the rule mandates covered facilities to have a risk-based supply-chain program for the ingredients that have been identified to be associated with hazards in the hazard analysis. The facility is responsible to ensure these ingredients are coming from approved suppliers or unapproved suppliers with supplemental verification activities before use to ensure safety. A preventive control is only necessary if an identified hazard is not controlled by a subsequent entity such as a consumer or another processor. This is only accepted if the facility has written consent from the customer or other processor that the hazard will be controlled.

There have also been changes to the cGMPs. Once found in 21 CFR §110, cGMP's have been moved to 21 CFR §117 Subpart B. Along with a new location in the Code of Federal Regulations (CFR), the cGMPs have been revised to exclude nonbinding provisions, changing education and training to binding provisions, now requiring documentation of both. Management must make sure that all employees who manufacture, process, pack, or hold food are properly qualified to do so through documented education and training. This includes basic training on cGMPs, preventive controls training, and training specific to the applicable position. There are many ways to show that an employee has been trained but the most important information should always be present on training records; type of training, date of training, name and signature of trainer and trainee. Training should be done at least once a year and/or whenever a change in regulation or procedure occurs (FDA 2017a).

Chapter 3 - Timeline of the Food and Drug Administration's Actions for FSMA Rules

FSMA has been through many stages since President Obama first signed the law in January of 2011. There have been countless meetings between those writing the rules, meetings with the public, commenting periods on the proposed rules open to the public, revisions to proposed rules, reopening of commenting periods, more revisions, and finally the publication of the final rules. To understand the process of a creating a final rule fully and the process a final rule goes through, the PCHF's timeline will be examined more closely;

- January 4, 2011 – President Obama signs FSMA into law
- April 20, 2011 – Public Meeting: Discussion on Preventive Controls for Facilities
- May 23, 2011 to August 22, 2011 – Commenting Period on Preventive Controls for Registered Human Food and Animal Food/Feed Facilities
- November 1, 2011 to December 20, 2011 – Reopening of the Commenting Period on Preventive Controls for Registered Human Food and Animal Food/Feed Facilities
- January 4, 2013 – Published the Proposed Rule for PCHF: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- February 28, 2013 to March 1, 2013 – Public Meeting: Proposed Rules for Preventive Controls in Human Food and Produce Safety Standards; Washington DC
- March 11-12, 2013 - Proposed Rules for Preventive Controls in Human Food and Produce Safety Standards; Chicago, IL
- March 27-28, 2013 - Proposed Rules for Preventive Controls in Human Food and Produce Safety Standards; Portland, OR
- September 2014 – Proposed Supplemental Rule for PCHF
- September 2015 – Final Rule: PCHF (FDA 2017i)

As shown by the timeline above, it took about 4 years for the PCHF rule to become final. Shown below are the compliance date deadlines for each rule already final. *Table 3.1* shows general compliance for each rule; this compliance date is for businesses that do not fall under the category of a small business or very small business. *Table 3.2* shows the compliance dates for businesses that fall under the category of a small business. A small business is defined as a business with fewer than 500 full-time equivalent employees. Finally, *Table 3.3* shows the compliance dates for very small businesses which is defined as (in this rule) a business averaging less than $1 million per year in both annual sales of human food plus the market value of human

food manufactured, processed, packed, or help without sale. Businesses subject to the Pasteurized Milk Ordinance (PMO) will have 3 years to comply to allow time for changes to the PMO safety standards to incorporate requirements of the PCHF final rule. Also shown in all the tables are the compliance dates for the rest of the final rules of FSMA.

Table 3-1 **General business (> 500 employees, > $1M annual sales) compliance dates.**

Proposed Rule	Final Rule	Deadline
Preventive Controls for Human Food	8/30/2015	9/19/2016[a]
Preventive Controls for Animal Food	8/30/2015	9/19/2017[b]
Produce Safety	10/31/2015	12/31/2017[c]
Foreign Supplier Verification Program	10/31/2015	4/31/2017[d]
Sanitary Transportation	3/31/2014	3/31/2015[e]
Food Defense	5/31/2016	5/31/2019[f]

a (FDA 2017a) ; b (FDA 2017b) ; c (FDA 2017c) ; d (FDA 2017f) ; e (FDA 2017h) ; f (FDA 2017d)

Table 3-2 **Small business (fewer than 500 full-time equivalent employees) compliance dates.**

Proposed Rule	Final Rule	Deadline
Preventive Controls for Human Food	8/30/2015	9/18/2017[a]
Preventive Controls for Animal Food	8/30/2015	9/17/2018[b]
Produce Safety	10/31/2015	12/31/2018[c]
Foreign Supplier Verification Program	10/31/2015	4/31/2017[d]
Sanitary Transportation	3/31/2014	3/31/2016[e]
Food Defense	5/31/2016	5/31/2020[f]

a (FDA 2017a) ; b (FDA 2017b) ; c (FDA 2017c) ; d (FDA 2017f) ; e (FDA 2017h) ; f (FDA 2017d)

Table 3-3 **Very small business (business averaging less than limit specified below) compliance dates.**

Proposed Rule	Limit	Final Rule	Deadline
PC Human Food	< $1M	8/30/2015	9/17/2018[a]
PC Animal Food	< $2.5M	8/30/2015	9/17/2019[b]
Produce Safety	< $250K	10/31/2015	12/31/2019[c]
FSVP	< $500K	10/31/2015	4/31/2017[d]
Sanitary Transportation	Not required to comply[e]		
Food Defense	< $10M	5/31/2016	7/31/2021[f]

a (FDA 2017a) ; b (FDA 2017b) ; c (FDA 2017c) ; d (FDA 2017f) ; e (FDA 2017h) ; f (FDA 2017d)

Chapter 4 - Summary of Other Rules under FSMA

4.1 - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

The Preventive Controls for Food for Animals (PCFA) final rule located in 21 CFR §507 was finalized in September 2015 along with the PCHF final rule. Much like the PCHF final rule, facilities that produce food for animals must also comply with cGMPs. These are regulated at the same level as human food facilities and share the same rules as the PCHF's cGMPs. The similarities between the PCHF and the PCHA rule is most helpful to human food facilities also producing by-products for use in animal food. These facilities are required to ensure that the by-products are processed under cGMPs for the animal food's safety and to ensure the prevention of hazards being later introduced to the final product.

Another new requirement animal food facilities must establish, and implement is a food safety system. Again, this is identical to PCHF's required food safety system. Covered facilities must include an analysis of hazards and risk-based preventive controls, monitoring procedures, corrective actions and corrections, verification procedures, record-keeping procedures, and validation of the risk-based preventive controls. If preventive controls are needed, animal food facilities must also have a recall plan and reanalyze their food safety system every three years or if there is a change in the process flow or if new food safety concerns arise.

A supply-chain program is also required if an ingredient is identified to require a supply-chain-applied control due to a hazard. Facilities must ensure that all raw materials and ingredients needing a supply-chain control are from approved suppliers. Supply-chain controls typically include Certificate of Analyses (COAs) or Letters of Guarantee (LOGs) and suppliers are approved by the consideration of three factors; hazard analysis of the food, the entity that will

be controlling the hazard, and supplier performance. A preventive control will not be required to be implemented by a covered facility if the identified hazard will be controlled later in the distribution chain. This includes the customer or other processor being informed that the food is not processed to control the identified hazard and written assurance being sent regarding certain actions that the customer agrees to take to control of the identified hazard (FDA 2017b).

4.2 - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety)

The final rule regarding produce safety located in 21 CFR §112 was finalized on January 26, 2016. This produce safety rule enacted six key requirements regarding: 1) agricultural water: 2) biological soil; 3) sprouts; 4) domesticated and wild animals; 5) worker training, health and hygiene; and 6) equipment, tools, and buildings.

The requirements for agricultural water include regulations for water quality and water testing. First, the rule established criteria for microbial water quality based on the presence of generic *E. coli*. The presence of generic *E. coli* can indicate the presence of fecal material (CDC 2015). Therefore, generic *E. coli* are prohibited at detectible levels in certain agricultural water where pathogens could possibly contaminate the produce. Examples of this are hand washing water and water used on food contact surfaces. For agricultural water used for growing produce other than sprouts, criteria have been set based on numerical values; the geometric mean (GM) and the statistical threshold (STV). The GM represents the average amount of generic *E. coli* in a water source and the STV is the amount of variability in the water quality or the level at which 90 percent of samples taken are below the value. The criteria limits GM of samples to 126 colony forming units (CFU) or less of generic *E. coli* per 100mL of water and STV of samples to 410 CFU or less of generic *E. coli* per 100mL of water (Havelaar et al 2017). If these criteria are

not met, corrective actions must be initiated as soon as they are able to be practiced. Corrective actions can include treating the water or allowing potentially dangerous microbes like *E. coli* to die off over time, either in the field between last irrigation and harvest for no more than 4 days, between harvest and the end of storage, or leave them to be removed during commercial activities like washing. Second, a general approach to testing untreated water was created. The frequency of the tests are determined by the type of the water source. The rule explains testing for untreated surface water and untreated ground water (directly applied to growing produce and sources where no generic *E. coli* is allowed). Agricultural water that is received from public water systems is not required to be tested if the water systems meet requirements found in the rule or if they are treated according to the rules on treatment requirements (FDA 2017c).

Next, biological soil amendment requirements pertaining to raw manure and stabilized compost are included in the rule. A soil amendment is defined as any material added to soil to increase chemical or physical conditions for growing plants or to enhance its ability to hold water. Currently, the FDA is conducting risk assessments and research studies to determine the number of days that are optimal to minimize the risk of contamination between applications of raw manure as a soil amendment. In the meantime, farmers will not be disputed if the USDA's National Organic Program standards for raw manure used for crops are being implemented. The FDA recognizes that the standards in the organic program are a sensible step toward minimizing contamination while their research is ongoing. The standards in this program are a 120-day interval between the application of raw manure for crops in contact with the soil and a 90-day interval for crops not in contact with the soil. Microbial standards have also been set for *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *Escherichia coli* 0157:H7. These standards, found in 21 CFR §112.55(a), were set for the treatment of biological soil amendments.

Two composting methods that have been scientifically validated by the FDA are found in 21 CFR §112.56(a) and must be applied with little chance that the stabilized composted will encounter produce during and after application (FDA 2017c).

Requirements for sprouts have also been included in the produce safety rule. With 43 outbreaks between the years of 1996 and 2014, sprouts have been associated with 171 hospitalizations and 3 deaths (Gould et al 2017). Therefore, the new requirements include prevention of the contamination of seeds or beans with the introduction of pathogens. The rule also explains treatment methods to prevent the contamination of the seeds or beans used for sprouting. Testing of the irrigation water of each batch of sprouts is also required, along with environmental testing for the presence of *Listeria monocytogenes.* Corrective actions are expected to be taken if any sample tests positive (FDA 2017c).

The fourth key requirement addresses domesticated and wild animals. The standards for both wild and domesticated animals are the same, putting responsibility on the farmer to identify and not harvest produce that could be injurious to human health. Farms are required to visually inspect growing areas and covered produce to be harvested. The FDA encourages farm personnel to implement additional visual inspections during the growing season to ensure there have been no threats of contamination. If potential contamination is found, farm personnel are encouraged to mark the contaminated area in any way they see best. The FDA also encourages farms to establish waiting periods between grazing and harvest even though there are no requirements for it in the final rule (FDA 2017c).

Next the rule explains requirements for worker training, health, and hygiene. Like cGMPs in the requirements for human and animal food, preventing contamination of produce and food-contact surfaces are a main priority for these requirements. Hygienic practices and

worker training are the two solutions described in the rule. Finally, standards pertaining to equipment, tools, and buildings are also required to be maintained in a hygienic manner in order to prevent contamination of the produce (FDA 2017c).

4.3 - Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense)

Along with new food safety regulations, FSMA also enacted a law regarding food defense. Located in 21 CFR §121, Mitigation Strategies to Protect Food Against Intentional Adulteration requires covered registered facilities to create a food defense plan. The food defense plan required by this final rule follows similar steps as creating a food safety plan. A food defense plan requires facilities to conduct a vulnerability assessment, mitigation strategies, monitoring procedures, corrective actions, verification procedures, as well as, training and recordkeeping. The process of creating a food defense plan should be conducted in the same manner as a food safety plan.

Vulnerability assessments must include; 1) The severity and scale of the impact on public health, 2) The degree of physical access to the product, and 3) The ability to successfully contaminate the product. Things that should be considered when determining impact on public health are the volume of product, number of servings, number of exposures, time in distribution system, potential agents of concern and their infectious/lethal dose, and finally, the possible illnesses and deaths. Things to consider when determining the degree of physical access would include the barriers one would have to go through to contaminate the product; gates, doors, seals, lids, railings, and shields.

Mitigation strategies should minimize or eliminate vulnerabilities identified in the assessment by applying them in a direct and appropriate way to protect product from an insider

attack. Mitigation strategies must also have established monitoring procedures that implement frequent checks of the mitigation strategies. When mitigation strategies are found not to be properly implemented, corrective actions must be established to correct the mistake. Verification procedures should also be established to ensure monitoring procedures are being conducted appropriately. Recordkeeping and training of all food defense monitoring procedures must be maintained to ensure employees are aware of food defense protocol and to ensure consistency and concurrence with the facilities food defense plan (FDA 2017d).

Chapter 5 - Discussion of FSMA's Ancillary Rules

Of the rules finalized under FSMA, seven of these support the other four rules by covering general provisions. These are called ancillary rules. The ancillary rules amended by FSMA include;

5.1 - Registration of Food Facilities

Registration of food facilities was first introduced in 2002 when the Bioterrorism Act was signed into law. Recently, FSMA amended how facilities engaged in manufacturing, packing, processing, or holding food are to register their facilities. They must provide additional information including written assurance that the FDA will be permitted to inspect the facility as permitted by section 415 of the FDCA. Facilities are now also required to renew their registration every other year. More details about registration and what must be included is still located in 21 CFR §1 Subpart H (FDA 2017e)

5.2 - Prior Notice of Imported Food

To protect the public from a terrorist attack on the national food supply here in the United States, the Bioterrorism Act of 2002 also requires advance notice of shipments imported to the U.S. Amendments to this requirement have been enacted as a part of FSMA. Not only must importers give prior notice they must also provide addition information stating the name of any country in which the product (including foods for animal consumption) has been refused entry. This information gives the FDA an upper hand in decision making to manage risk. Prior notice of imported food and its amendments can be found in 21 CFR §1 Subpart I (FDA 2015).

5.3 - Establishment, Maintenance, and Availability of Records

First introduced in 2002 in the Bioterrorism Act, recordkeeping requirements have been amended to reflect the goals of FSMA. The amendments that are presented in 21 CFR §1

Subpart J expands the record-access authority of the FDA to improve the response to and containment of food safety problems that affect humans and animals including; the ability to access records of other food products that the agency believes could be affected in the same manner as a suspect food product and access to records of food that could cause serious adverse health effects (FDA 2016).

5.4 - Administrative Detention of Food for Human or Animal Consumption

Before FSMA, the FDA did not have the authority to issue a mandatory recall of potentially unsafe food from the market under the FDCA, having only the authority to detain potentially unsafe food. The finalization of FSMA amends the rule located in 21 CFR §1 Subpart K still giving the FDA the authority to detain but also giving the FDA the authority to issue a mandatory recall if a voluntary recall has not already begun (FDA 2013).

5.5 – Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

This new final rule found in 21 CFR §1 Subpart L requires importers to implement risk-based activities to ensure that food imported into the United States meet applicable food safety standards. Facilities that require an importer are subject to this rule and where their importers are responsible for the following; determining known or reasonable foreseeable hazards with each food, evaluating the risks based on the hazard analysis and the supplier's performance, using information collected to approve suppliers and determine proper verification procedures, conducting verification activities, and conducting corrective actions. All procedures must be written and should be followed to ensure only approved suppliers are able to import food (FDA 2017f).

5.6 - Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

This rule provides framework, procedures, and requirements for those who would like to be accreditation bodies recognized by the FDA along with requirements for third-party certification bodies seeking accreditation. These requirements can be found in 21 CFR §1 Subpart M. Uses for these certifications include; the establishment of eligibility for importers for participation in the Voluntary Qualified Importer Program (VQIP), and to prevent the entrance of potentially harmful food into the United States (FDA 2017g).

5.7 - Sanitary Transportation of Human and Animal Food

Found in 21 CFR §1 Subpart O, this final rule applies to shippers, receivers, loaders, and carriers who transport human and animal food for consumption in the United States. Requirements of this rule include: 1) vehicles and transportation equipment, 2) transportation operations, 3) training, and 4) records. Vehicles and transportation vehicles must be suitable enough to keep the food being transported safe and capable of maintaining temperatures to do so. Transportation operations include the measures to ensure the food remains safe. In order to perform these operations, the carrier personnel must be trained with documentation of the training on file. Records of all procedures and operations must be kept for validation activities (FDA 2017h).

Chapter 6 - Exemptions

The FDA realizes that some facilities under their jurisdiction may not have a need nor the resources to comply with new rules under FSMA. Exemptions have been determined for each rule to facilitate for those facilities who do not need to comply and sometimes facilities that are exempt have different requirements they must meet. Below are the exemptions for the 4 main final rules; PCHF, PCAF, Product Safety, and Food Defense.

6.1 - Preventive Controls for Human Food Exemptions

Exemptions for the PCHF final rule can be described best as “partial” exemptions because those who are exempt under this rule are only exempt from Subparts C and G, or hazard analysis risk-based preventive controls and supply chain program, respectively. Those who are exempt from these rules include activities that are subject to 21 CFR §123, also known as the regulations for fish and fishery products, activities subject to 21 CFR §120 or HACCP systems, 21 CFR §113 or regulations regarding thermally processed low-acid foods packaged in hermetically sealed containers, and activities subject to 21 CFR §111 or current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements and finally, activities subject to section 419 of the FDCA or the standards for produce safety (21 CFR §117.5).

6.2 - Preventive Controls for Animal Food Exemptions

The PCAF, final rule also has exemptions similar to those included in the PCHF final rule. Those that are exempt can either be exempt from subpart C and E, hazard analysis risk-based preventive controls and supply chain program, respectively, or subpart B which are the cGMPs for animal food.

Activities at an animal food facility that are subject to 21 CFR §500.23 and 21 CFR §113, thermally processed low-acid foods packaged in hermetically sealed containers, activities of a facility that are subject to section 419 of the FDCA standards for produce safety, a farm mixed-type facility that is a small or very small business that participates in on-farm packing or holding of processed animal food, and facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are all exempt from the hazard analysis risk-based preventive controls and supply chain program regulations.

Those exempt to cGMPs include the following: Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities; Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed) (21 CFR §507.5).

6.3 - Produce Safety Exemptions

For this rule, there are those the rule does not apply to and there are those who qualify for modified requirements or a qualified exemption. The produce safety rule does not apply to the following; produce that is not a raw agricultural commodity, commodities that FDA has identified as rarely consumed, food grains, and farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less (FDA 2017c).

A raw agricultural commodity is defined by the FDA as any food in its raw or natural state. Any foods that are processed would not be subject to this rule. Produce commodities that FDA has identified as rarely consumed include asparagus, most beans, sweet corn, and potatoes.

Food grains like rice, quinoa, and wheat are also exempt from this rule. See *Table 6-1* below for a complete list of all commodities exempt. The FDA also recognizes that produce that is used for personal or on-farm consumption as exempt. Produce that receives commercial processing that has been proved to significantly reduce the presence of microorganisms can be granted an exemption (FDA 2017c).

Table 6-1 Produce commodities and food grains exempt from the produce safety rule

Produce commodities	asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts
Food grains	barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)

(FDA 2017c)

Farms can also be eligible for a qualified exemption but must also meet modified requirements if a qualified exemption is granted. Qualified exemptions can be obtained by a farm if sales have averaged less than $500,000 per year during the last three years and sales to qualified end-users (e.g. the consumer of the food, a restaurant, or retail food establishment) are in the same state or not more than 275 miles away. Modified requirements for a farm with a qualified exemption includes; the name and complete business address of the farm on the label of the produce or at the point of purchase (FDA 2017c).

6.4 - Food Defense Exemptions

Those that are exempt from the food defense rule include businesses considered to be very small. A very small business, in this case, averages less than $10,000,000 per year, during

the past three-year period, in sales of human food plus the market value of human food held without sale. Another business that is exempt are those hold food (except the holding of food in liquid storage tanks). Food that has been packed, re-packed, labeled or re-labeled where the container that directly contacts the food remain intact is also exempt.

Some other exemptions include activities that fall within the FDA's definition of "farm", alcoholic beverages, any activities (Manufacturing, processing, packing, or holding) related to food for animals, and on-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices (FDA 2017d).

Chapter 7 - Review of Preventive Controls of Human Food Training Courses

After FSMA was signed in 2011, the FDA presented a grant to the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) to help support food safety in the U.S. by creating an educational program about food safety risk-based preventive controls. To do this, IIT IFSH joined up with industry, academia, and government stakeholders to create the Food Safety Preventive Controls Alliance (FSPCA) a broad-based public-private alliance (FSPCA 2015). The FSPCA's assignment was to develop a standardized curriculum, develop training materials, and provide input to the FDA regarding guidance for hazard analysis and preventive controls.

The FDA recognizes the FSPCA's curriculum to be the standard. The courses designed and facilitated by the FSPCA are taught by lead instructors. For those who are wanting to become lead instructors, they must get certified through a course also facilitated by the FSPCA. Once certified, lead instructors may start conducting their own courses with materials created by the FSPCA. These materials include PowerPoint presentations, participant manuals, participant workbooks/worksheets, and example food safety plans. Since the FDA recognizes this curriculum as the standard, no information is to be taken away from the materials and if changes are added, they must be reported and approved by the FSPCA. The PowerPoint slides include 16 chapters, each presenting the participants with lessons on each component of the PCHF final rule; 1) Welcome and Introduction to Preventive Controls, 2) Food Safety Plan Overview, 3) Good Manufacturing Practices & Other Prerequisite Programs,4) Biological Food Safety Hazards, 5) Chemical, Physical, & Economically Motivated Hazards, 6) Preliminary Steps in Developing a Food Safety Plan, 7) Resources for Preparing Food Safety Plans, 8) Hazard

Analysis & Preventive Controls Determination, 9) Process Preventive Controls, 10) Food Allergen Preventive Controls, 11) Sanitation Preventive Controls, 12) Supply Chain Preventive Controls, 13) Verification & Validation Procedures, 14) Record-keeping Procedures, 15) Recall Plan, 16) Regulation Overview. The duration of the courses are 2 and a half days and with the completion of the course, the participant will then become a certified "preventive controls qualified individual," also known as a PCQI. This certification is important and getting trained through the FSPCA's course is the recommended and standardized way to receive this certification.

7.1 – FSPCA Facilitated Courses Through Kansas State University

In 2016, the Kansas Department of Agriculture (KDA) presented a grant to extension specialists at Kansas State University (KSU) to help Kansas food companies comply with the PCHF final rule. Using the materials provided by the FSPCA, the extension specialists at KSU were able to train and certify 35 companies and 180 individuals during a 2-year period in 2016 and 2017 including 35 KDA and 20 FDA investigators. To measure the effectiveness of the training courses, evaluation summaries were distributed at the end of each course. Below in *Table 7-1, 7-2, 7-3,* and *7-4* are four evaluation summaries.

Table 7-1 - K-State's PCHF Workshop Evaluation Summary - May 17-19, 2016

Likert Scale Results			
Question	**Participant Category (n = 38)**	**Average of Answer (out of 5)**	**Total Average (out of 5)**
About the Course			
Course objectives were clearly presented.	Very Small Business (Sales < $1M)	4.73	4.74
	Small Business (less than 500 employees)	4.86	
	Student	4.55	
	Other	4.83	
Course expectations were clearly stated.	Very Small Business (Sales < $1M)	4.82	4.72
	Small Business (less than 500 employees)	4.86	
	Student	4.36	
	Other	4.83	
The course was well-organized.	Very Small Business (Sales < $1M)	4.73	4.58
	Small Business (less than 500 employees)	4.86	
	Student	4.56	
	Other	4.17	
The course was intellectually challenging.	Very Small Business (Sales < $1M)	4.18	4.25
	Small Business (less than 500 employees)	4.71	
	Student	4.09	
	Other	4.00	
The course increased my knowledge and understanding of the subject.	Very Small Business (Sales < $1M)	4.91	4.77
	Small Business (less than 500 employees)	4.86	
	Student	4.64	
	Other	4.67	
About the Workbook			
The workbook was a helpful tool for the development of my food safety plan.	Very Small Business (Sales < $1M)	4.91	4.81
	Small Business (less than 500 employees)	5.00	
	Student	4.82	
	Other	4.50	
I will use resources in this workbook after the course conclusion.	Very Small Business (Sales < $1M)	4.91	4.85
	Small Business (less than 500 employees)	5.00	
	Student	4.82	
	Other	4.67	
	Very Small Business (Sales < $1M)	4.82	4.68

I thought the workbook was well put together and organized.	Small Business (less than 500 employees)	5.00	
	Student	4.55	
	Other	4.33	

Short Answer Results

Question	Participant Category	Comments
About the Course		
Please describe the course activities that most enhanced your learning in this course.	Very Small Business (Sales < $1M)	• Recall Plan and how to write out/explain a food safety plan • Worksheets on flow charts and hazard analysis • Groups with students were very helpful • Working in small groups on notebook items and comments made by other groups • Relevant discussion, great participation and course activities • Discussion
	Small Business (<500 employees)	• Provision of templates so helpful • Working with groups and websites • Doing the examples • Learning the new laws of FSMA • Doing the provided worksheets • Understanding the required information • Developing hazard analysis in groups • Breaking into groups and actually working on the plans. • Supply-chain requirements • New structure of CFR regulations
	Student	• Group workshops • Group work • Changes from HACCP to FSMA • Writing a practice hazard analysis • Hands on helping companies • Group work • Groups sharing different issues • Group meetings to fill in sections of the small notebook • Hands on practice • Q&A about regulation requirements. • Working directly with the companies to create a physical food safety plan
	Other	• Examples and group work • Working/practice with small businesses was very helpful • Good connection between students and companies, discussing sections before working on them • All were helpful. Broad spectrum of participants good for learning • Group work

About the Course		
Please describe the course activities that were least helpful your learning in this course.	Very Small Business (Sales < $1M)	• Sanitation Practices • PowerPoint slides (although they are necessary) • Reading straight out of the book
	Small Business (<500 employees)	• When it pertained to wet processing. • Everything was helpful • Some of the slides seemed like they were glazed over and not fully explained • All good information but recent GFSI certification activities made most of this background info
	Student	• Basic HACCP principles • The lectures on day 1. However, already having been through HACCP made this repetitive
	Other	• All activities were good • Sanitation chapter
About the Workbook		
What are some things you would have liked to have seen in the workbook that wasn't included, if any?	Very Small Business (Sales < $1M)	• Include the FSMA checklist in the notebook. It's a helpful outline • It had everything • More samples of real life forms
	Small Business (<500 employees)	• Very good
	Student	• Mock HACCP plan • Schedule and checklist • Certain slides were left out, but you were good about making copies! • A clearer summary between HACCP and FSMA requirements • An example besides the book
	Other	• More about supplier chain, add some sanitation preventive control examples • Some forms had to be added in • Team building exercises
What are some things you liked to see, or thought was the most helpful part in the workbook?	Very Small Business (Sales < $1M)	• Conducting food safety plans • One on one with the students and Fadi • It was thorough • Organization, actual documentation needed, and appendix • All of it • Enjoyed getting both hard copies and files on the computer of all the examples • Forms filled out • Documents required for this certification
	Small Business (<500 employees)	• Checklist, cGMPs, and forms for food safety plan • Recall plan • Loved the worksheets • The worksheets and electronic forms • Sample forms

		• Examples of hazard analysis • Process and allergen controls • The actual forms in hard-copy are nice to have • Explanations of new regulations and expectations • The worksheets were fantastic
	Student	• Examples of many different plans/forms • Examples of forms • Any examples of how to fill in the charts/sheets! • The empty forms
	Other	• General templates were very helpful • Printed copies of hazard sheets • Recall procedures
General		
Please include any additional suggestions you have about the course structure. Constructive suggestions for improvement are welcome.	Very Small Business (Sales < $1M)	• Glad to see this course being offered to both FDA inspectors and food manufacturers • This was a great class! Thank you! • Only thing better would to have bought our lunch and dinner • Really good class • Samples from startup companies • Create a "bridge" document between FSMA and current GFSI plans so that FDA will be equipped to understand how BRC, SQF, or FSSC22000 relate. • This was a homerun! Exactly what I was hoping for and more.
	Small Business (<500 employees)	• Love it! More Fadi jokes, please! • I thought it was put together rather well. • More examples possibly
	Student	• More jokes! Awesome and funny! • More emphasis of the HACCP to FSMA differences at the start • Very well taught and organized • More examples
	Other	• Very well done – would recommend to others • Jokes. More jokes.

Table 7-2 – Chocolate Company: Location 1 Course Evaluation Summary - June 6–8, 2016

Personal Knowledge Ratings *(Before and After)* **(n = 22)**				
1 = I know nothing	2 = I know a little	3 = I know a fair amount	4 = I know a lot	5 = I am an expert

Topic	Before	After	Difference
Requirements of a food safety plan.	2.35	3.85	+1.50
Good Manufacturing Practices (GMPs) and Prerequisite Programs	3.25	3.90	+0.65
Food Safety Hazards	2.65	3.80	+1.15
Biological Hazards	2.60	3.65	+1.05
Physical Hazards	2.55	3.70	+1.15
Chemical Hazards (including Radiological Hazards)	2.45	3.65	+1.20
Preliminary steps to a food safety plan.	2.20	3.50	+1.30
How to conduct a hazard analysis.	1.75	3.35	+1.60
Preventive Controls	2.45	3.75	+1.30
Process Preventive Controls	2.15	3.70	+1.55
Allergen Preventive Controls	2.45	3.75	+1.30
Sanitation Preventive Controls	2.35	3.75	+1.40
Supplier Programs	1.65	3.45	+1.80
How to perform verification procedures.	2.00	3.45	+1.45
How to perform validation procedures.	1.75	3.35	+1.60
How to properly keep records of food safety activities.	2.05	3.45	+1.40
Recalls	1.70	3.10	+1.40
Standard Deviation	0.418	0.215	
Coefficient of Variance	0.1743	0.0461	

Likert Scale Results

Question	Average of Answer (out of 5)
Course objectives were clearly presented.	4.46
Course expectations were clearly stated.	4.46
The course was well-organized.	4.64
The course was difficult.	3.50
The course increased my knowledge and understanding of food safety.	4.59

Short Answer Results

Please describe the course activities that most enhanced your learning in this course.	• The workbook is a big asset. • Biological, chemical, and physical hazards. • Food allergens. • Regulatory overview, preventive controls. • Kept the course filled with great stories. • Have more awareness of all aspects of safety. • Hands on examples.

	• Instructor was excellent and very entertaining and very very intelligent. • The workbook was helpful. • Everything was helpful but a little fast pace. • Working with another person and writing flow chart, hazard, etc. • Preventive controls. • All course activities were exceptional (nothing). • Handbook activities. • Pathogens, allergens, sanitation. • Pertaining to pathogens, allergens, contamination, etc. • The work was very helpful. • Fadi Aramouni – fantastic! Great teacher and storyteller. • Preventive controls • Biological hazards.
Please describe the course activities that were least helpful to your learning in this course.	• More complete samples of forms to help guide in course. • Doing breakouts into groups. Would rather do as an entire group. • Student was nervous and needs to work on her delivery (say "uh" all the time) • Paper work, documentation, review. • Exercises could have been clearer.
Please include any additional suggestions you have about the course structure. Constructive suggestions for improvement are welcome.	• The instructor and his assistant were great. • Instructor was very informative, stayed alert. Very good class. Short period of time, could have been a little longer. Overall, good job! • Presentation (Caitlin) – "uh" and "um" are very distracting, wordy, when listening to a presentation. The atmosphere and keeping light entertainment really helped to keep interested. Great material. (Fadi) You are very knowledgeable and it shows! • Lead instructor was awesome and made it very helpful to learn and understand. • Some slides on slideshow not in book. Might flow better if slide show matched book and had spaces out to the side to make nots instead of at the end of each chapter. • Feel like things went fast but I don't know if it's possible to over everything. • Chapter 16 (Regulatory Overview) should be chapter 1 • Cut program to 2 days, less time on prep for examples, more time discussing as a group. • Make (course) a longer time, short time to have so much. • Not so fast paced. • It was very interesting and enjoyable. • I enjoyed the class. You made it interesting. • Excellent course very pleased to be a part of it.

	• Was pleased to see you add notes for changes but was set up in a logical sequence. Caitlin, please don't be offended but you say "um" a lot. • Was a very interesting course. • Speaker was very good. • Caitlin – Good presentation, use less "um" in presentation it's very distracting. • Fantastic trainer kept us pulled in and interested. Caitlin needs to watch how much she says "um" during her presentation, it makes it a little hard to concentrate on what she is saying, otherwise, enjoyed having her with us. • A lot of material in a short span. Fadi was absolutely great! Informative, humorous, entertaining and made the course interesting and light hearted.

Table 7-3 – Chocolate Company: Location 2 Course Evaluation Summary - June 13–15, 2016

Personal Knowledge Ratings *(Before and After)* **(n = 23)**				
1 = I know nothing	2 = I know a little	3 = I know a fair amount	4 = I know a lot	5 = I am an expert

Topic	Before	After	Difference
Requirements of a food safety plan.	2.37	3.89	+1.53
Good Manufacturing Practices (GMPs) and Prerequisite Programs	3.05	3.89	+0.84
Food Safety Hazards	2.53	3.68	+1.16
Biological Hazards	2.26	3.58	+1.32
Physical Hazards	2.63	3.58	+0.95
Chemical Hazards (including Radiological Hazards)	2.16	3.42	+1.26
Preliminary steps to a food safety plan.	2.21	3.68	+1.47
How to conduct a hazard analysis.	2.16	3.63	+1.47
Preventive Controls	2.47	3.68	+1.21
Process Preventive Controls	2.47	3.74	+1.26
Allergen Preventive Controls	2.42	3.79	+1.37
Sanitation Preventive Controls	2.53	3.74	+1.21
Supplier Programs	1.95	3.47	+1.53
How to perform verification procedures.	2.37	3.63	+1.26
How to perform validation procedures.	2.11	3.53	+1.42
How to properly keep records of food safety activities.	2.47	3.79	+1.32
Recalls	2.16	3.42	+1.26
Standard Deviation	0.253	0.145	
Coefficient of Variance	0.0642	0.0210	

+**Likert Scale Results**	
Question	**Average of Answer (out of 5)**
Course objectives were clearly presented.	4.30
Course expectations were clearly stated.	4.25
The course was well-organized.	4.30
The course was difficult.	2.85
The course increased my knowledge and understanding of food safety.	4.35

Short Answer Results	
Please describe the course activities that most enhanced your learning in this course.	• A lot of information on bio/chemical issues I did not know • Example papers • Going over each item • Workbook activities • I liked the workbook activities • Hands on • Excellent presenter • Worksheets on out products • Workbook activities • Very beneficial information • Food safety-bacteria • Process preventive controls form • All activities were great • The activities help me understand more-hazard analysis • Preventive controls • The exercises • All course activities
Please describe the course activities that were least helpful to your learning in this course.	• Recall info – corporate activity • Lectures • Regulation detail • Recall portion as we don't currently partake in this • Filling out the HACCP forms • Preventive controls • Hazards • GMP lecture
Please include any additional suggestions you have about the course structure. Constructive suggestions for improvement are welcome.	• Job well done. Thanks! • Trainer had a great sense of humor and made training fun.

Table 7-4 - K-State Olathe - Course Evaluation Summary - July 13 – 15, 2016

Personal Knowledge Ratings *(Before and After)* **(n = 23)**				
1 = I know nothing	2 = I know a little	3 = I know a fair amount	4 = I know a lot	5 = I am an expert

Topic	Before	After	Difference
Requirements of a food safety plan.	3.11	4.00	+0.89
Good Manufacturing Practices (GMPs) and Prerequisite Programs	3.50	4.06	+0.56
Food Safety Hazards	3.56	4.17	+0.61
Biological Hazards	3.67	4.17	+0.50
Physical Hazards	3.56	4.17	+0.61
Chemical Hazards (including Radiological Hazards)	3.61	4.17	+0.56
Preliminary steps to a food safety plan.	3.00	3.94	+0.94
How to conduct a hazard analysis.	3.50	4.17	+0.67
Preventive Controls	3.08	3.97	+0.89
Process Preventive Controls	3.22	4.03	+0.81
Allergen Preventive Controls	3.06	4.03	+0.97
Sanitation Preventive Controls	3.06	3.97	+0.92
Supplier Programs	2.94	3.81	+0.86
How to perform verification procedures.	3.06	3.89	+0.83
How to perform validation procedures.	3.06	3.89	+0.83
How to properly keep records of food safety activities.	3.44	4.06	+0.61
Recalls	3.39	3.92	+0.53
Standard Deviation	0.252	0.116	
Coefficient of Variance	0.0633	0.0135	

Likert Scale Results

Question	Average of Answer (out of 5)
Course objectives were clearly presented.	4.50
Course expectations were clearly stated.	4.39
The course was well-organized.	4.39
The course was difficult.	2.39
The course increased my knowledge and understanding of food safety.	4.22

Short Answer Results

Please describe the course activities that most enhanced your learning in this course.	• Preventive controls • Visual aids and anecdotes • Group Discussions • Good overview of 117 • Exercises • Working through the activities • Group exercises help! • Hands on, development of food safety plan

	• Food safety plan exercises • Interaction and exercises • Hands on • Writing out own plans from case exercises • Environmental monitoring/supplier ingredients • Getting up to speed on FSMA. Great interaction with different agencies (FDA and KDA) • Groups activities
Please describe the course activities that were least helpful to your learning in this course.	• About the right length/complexity • Group activities.
Please include any additional suggestions you have about the course structure. Constructive suggestions for improvement are welcome.	• Take 2 or 3 products and make sure everyone has a complete plan with appropriate entries to take with them after the course to refer back to in the future. • When possible, make groups a little bigger and include industry, state, and fed mix. • Use excess time to fully review each group's FS plan • I suggest more tools for discussion between the regulations and the industry during class. Maybe open Q&A sessions after the exercises, where the industry could also ask related questions during the class. • Great class, thank you! • It was great and very educational • Great job, thanks for presenting this info.

After reviewing course evaluations of the training courses conducted, the knowledge acquired in this course is critical to the success of the Food Safety Modernization Act. Participants were asked to rate their knowledge of different aspects of the FCHF final rule before and after the course with an average increase in each topic shown by the decrease in standard deviation shown in *Table 7-2, 7-3,* and *7-4*. Standard deviation is the measure of how widely dispersed the data values are from the average value. The values shown in *Table 7-2, 7-3,* and *7-4* show a decrease in dispersion of values from the mean, showing that knowledge after the course was more uniform across all participants (less widely spread). The increase in knowledge is also shown by the difference in the means of each food safety topic. Instructors also facilitated a workshop for companies in Kansas during each course allowing them to start writing their food safety plans while learning, providing a "hands on" and real-life process to apply the rules to.

7.2 - Conclusion

Overall, the FSPCA's materials have provided a good basis and start to a new food safety era. The biggest advantage to these courses comes from the diversity of the participants. The fact that state and federal investigators, students, industry professionals, and food manufacturing companies were able to not only learn the information in a uniform way but were also able to learn from one another. Students got experience helping companies write their food safety plans, companies were granted help and guidance from both students and investigators, and investigators were able to learn the same materials as the food company participants they could be auditing in the future. Only time can tell if FSMA will be more of a success in preventing foodborne illness outbreaks than regulations in the past and more studies are needed to be conducted in the future to determine if foodborne illness has decreased. Right now, it is important to realize that FSMA's success is related to the quality of the education materials and educators.

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