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Audits and inspections are never enough: a critique to enhance food safety

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Keywords: food safety; audit; inspection; culture
Abstract

Internal and external food safety audits are conducted to assess the safety and quality of food including on-farm production, manufacturing practices, sanitation, and hygiene. Some auditors are direct stakeholders that are employed by food establishments to conduct internal audits, while other auditors may represent the interests of a second-party purchaser or a third-party auditing agency. Some buyers conduct their own audits or additional testing, while some buyers trust the results of third-party audits or inspections. Third-party auditors, however, use various food safety audit standards and most do not have a vested interest in the products being sold. Audits are conducted under a proprietary standard, while food safety inspections are generally conducted within a legal framework. There have been many foodborne illness outbreaks linked to food processors that have passed third-party audits and inspections, raising questions about the utility of both. Supporters argue third-party audits are a way to ensure food safety in an era of dwindling economic resources. Critics contend that while external audits and inspections can be a valuable tool to help ensure safe food, such activities represent only a snapshot in time. This paper identifies limitations of food safety inspections and audits and provides recommendations for strengthening the system, based on developing a strong food safety culture, including risk-based verification steps, throughout the food safety system.

1.0 Introduction

Billions of meals are prepared safely each day throughout the world. The commercial food system relies on audits and inspections to assess the practices and processes used to by food producers at each step in the production chain. Yet when outbreaks of foodborne illness happen, the results can be emotionally, physically and financially devastating to the victims and the businesses involved. Many outbreaks involve firms that have had their food production systems verified and received acceptable ratings from food safety auditors or government inspectors.

Food safety audits and inspections are one activity used to verify that a food producer or individual is following specific guidelines, requirements or rules. Audits involve a “systematic and independent examination to determine whether quality/safety activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives” (ANZFA, 2001; ANZFA was later morphed into Food Standards Australia New Zealand). Planned arrangements, as defined by the Australia New Zealand Food Authority are commonly referred to as standards within the food industry. The difference between inspections and audits is that an inspection evaluates “conformity by measuring, observing, testing or gauging the relevant characteristics” (ANZFA, 2001). Audits are one tool to help ensure adherence to recognized regulations and good manufacturing practices.
An audit of food safety practices, facilities, documentation and written procedures is used to gather information regarding food production and processing practices being followed by a particular producer, identifying areas for improvement and areas that are deficient (ANZFA, 2001). Audit reports, in theory, serve as the “eyes and ears” for an organization buying food from a supplier (Weise, 2010). There are several types of audits, and a variety of audit organizations, each with their own unique or common food safety guidelines.

Self-audits are internal audits performed by a food establishment itself. These businesses usually have a quality assurance team that leads the internal audits. These internal audits may have good potential for reducing risk if the methods followed are those outlined in widely accepted codes and risk assessment guidance documents. The effectiveness of internal audits is also assessed during third-party audits. Second-party audits are audits that a downstream company, or buyer, performs on their supplier. Third-party audits are performed by an outside firm that usually focuses entirely on verification or standard implementation to ensure that a buyer’s rules are being followed (Costa, 2010). Third-party audits examine compliance with laws and codes of practice as well as provide “insight into management controls and supervision” (Costa, 2010).

2.0 The role of audits in food safety

Third-party audits are one part of a multi-factoral approach to food safety. The popularity of third-party audits has increased corresponding to a shift in food safety governance away from government regulation and inspection towards the development of private food safety standards (Busch, 2011).

Standard setting organizations (e.g. International Organization for Standardization (ISO) and the British Retail Consortium [BRC]) include industry consortia, private voluntary associations and buyers. There are many different food safety standards available to food producers and manufacturers even within a single industry segment. While the various standards are voluntary, demand by buyers essentially makes certification or verification under these standards de facto mandatory for food companies that want to continue to sell their product to major retailers (Busch, 2011). This has created a system for enforcing food safety standards without significantly increasing burden on taxpayers.

In addition, if a company such as Walmart wanted specific standards for a product, even if it exceeded U.S. Food and Drug Administration (FDA) standards, the company would demand that from the auditor -- and get it (Prevor, 2009).

While inspectors play an active role in overseeing compliance, the burden for food safety lies primarily with food producers (GAO, 2008). Inspection efforts, even if
doubled, would not be enough to make sure every food item is safe. Third party audits provide the data upon which certification and buying decisions are made, and are now a popular choice for retailers who use them to push the responsibility (and costs) for food safety and quality back on to the supplier (Steir, 2009). Audits are an attempt to move beyond inspections that are point-in-time observations of activities and practices. Audits focus on the procedures in place to achieve food safety outcomes and look for evidence that they are being followed and are appropriate and capable of reducing risk. There is also increasing focus on assessment of food safety culture and management commitment to food safety.

Third-party audits also benefit individual companies and supply chains. It has been argued that the best use of third-party audits is to focus on strengthening self-audit methods and operational controls to achieve safer food (Costa, 2010). For some, it is a genuine desire to improve food safety, quality and sanitation or a way to solve/troubleshoot existing problems (Steir, 2009). For others it is a potential marketing advantage or a customer requirement. The effectiveness of these audits may link to the motivation behind the audit. It has been determined that creating a food safety culture is imperative to an effective food safety risk management system (Powell et al., 2011; Yiannas, 2008). Companies with a strong food safety culture may be more likely to obtain a third party audit because they want to improve operations, not just because of customer demand. Companies with a strong food safety culture are also likely to use audit results as guidance and opportunity to improve their practices. Audits -- first-second- or third-party -- are another tool for companies to enhance safe food production.

What is not clear is the role of third party audits in reducing the risk of contaminated food reaching the marketplace and the ability of auditors to identify problems or high-risk operations. The utility of third party audits has been examined in other industries as well. A 10-year study on workplace safety on U.S. railroads found that high audit scores partially correlated with improved legislative compliance but did not necessarily correspond to improved safety performance (Peterson, 2001). This indicated there were problems somewhere in the system and that the audit process was not necessarily valid for that industry.

3.0 Limitations of audits

Audit systems, in their current form, have limitations in improving food safety. There are no current empirical evaluations that look at the correlation between audit scores and foodborne illness outbreaks but there is a long and storied history of food safety failures involving third-party audits.

Third-party audits are analogous in many ways to regulatory municipal inspections of foodservice operations: the effectiveness of both audits and inspections is driven largely
by observational judgment and consistency of the inspector or auditor. Foodservice
inspection is a cornerstone of local public health, yet inspection scores can be poor
predictors of foodborne illness. Jones and colleagues (2004) examined over 160,000
inspections in Tennessee over seven years and found no difference between scores of
foodservices associated with outbreaks and those that were not. Similar results were
previously found in Miami-Dade county (Cruz et al., 2001). In Massachusetts,
researchers found that jurisdictions had different inspection criteria, and even within a
given jurisdiction, a risk to one inspector may not be a risk to another (DeNucci 2007).

Many foodborne illness outbreaks have been linked to farms, processors and retailers
that went through some form of audit certification. The January 2009 outbreak of
Salmonella Typhimurium linked to the Peanut Corporation of America (PCA) has been
frequently cited as an example of a failure in the third party auditing system (Busch,
2011; Steir, 2009; Moss and Martin, 2009). In January, 2009 PCA recalled over 3,900
peanut butter and other peanut-containing products from more than 350 companies
(FDA, 2009b), 691 people were sickened and nine died across 46 U.S. states and in
Canada (CDC, 2009a).

Moss and Martin (2009) reported in the New York Times that an auditor with AIB was
responsible for evaluating the safety of products produced by PCA. The peanut
company knew in advance when the auditors were arriving. “The overall food safety
level of this facility was considered to be: SUPERIOR,” the auditor concluded in his
March 27, 2008, report for AIB. A copy of the audit was obtained by the Times. AIB was
not alone in missing the trouble at the PCA plant in Blakely, Georgia. State inspectors
also found only minor problems. This outbreak and others highlight some of the
limitations of both third party audits and government inspections which are included in
Table I below.

<table>
<thead>
<tr>
<th>Audit Limitations</th>
<th>Summary</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>A snapshot in time</td>
<td>Audits and inspections remain point-in-time assessments that represent a small fraction of food production time and volume. If conducted properly and the results acted upon, audits can reveal strengths and weaknesses in a food safety program, but cannot guarantee future performance. Further, auditors can only examine what a company provides, although skilled auditors know what to ask for and may be able to identify clues to systemic problems.</td>
<td>PCA outbreak, a federal team of investigators later uncovered a number of alarming signs at the peanut plant including testing records from the company itself that showed Salmonella in its products as far back as June 2007 (Martin, 2009)</td>
</tr>
<tr>
<td><strong>Reliance on an effective standard</strong></td>
<td>The audit is only as effective as the standard against which the practices are being measured. Standards must be evidence-based, designed to address the commodity/product specific risks and practices and responsive to changing industry practices and new science as it becomes available.</td>
<td>Cantaloupe outbreak, July 2011. Previous research had focused on <em>Salmonella</em> and current industry standards may not be robust enough to address risk from <em>Listeria</em>.</td>
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<td><strong>Effective audit tool</strong></td>
<td>The audit tool (or audit checklist) must be valid. There is no scientific basis for certification/validation in audits (Mahshie, 2009). There is high variability in the quality and reliability of audits and many different types of audit tools that vary in length, complexity, and style. A firm may pass some audits but still have a food safety risk factor</td>
<td><em>Salmonella</em> in eggs, Iowa, 2010, lead to 2,000 illnesses and the recall of 500 million eggs. DeCoster received a superior rating from AIB International, despite audit reports that are typically 10-20 pages and consider over 300 elements (AIB International, 2007).</td>
</tr>
<tr>
<td><strong>Auditor competence</strong></td>
<td>Audits require more than just a checklist, they require paying attention and thinking. The individual ability of an auditor has a significant impact on the outcome of the audit, most third-party audits look for objective evidence to assess compliance, but effective auditors must be able to assess risk, particularly in unique situations and synthesize the information provided to determine effectiveness of the food safety management system</td>
<td>In the aftermath of the PCA outbreak, the competency of both the auditor and the auditing firm were criticized. The auditor of the PCA facility was an experienced auditor but was an expert in fresh produce and was not aware that peanuts were susceptible to <em>Salmonella</em> (Moss and Martin, 2009).</td>
</tr>
<tr>
<td><strong>Audit scope</strong></td>
<td>The audit scope must be broad enough to cover all operations, locations and products. When a company is presented with different price quotes they often choose the cheapest one, which is more likely the one with less audit time (Pronk, 2011). This reduces cost for the firm requesting the audit, and reduces the ability of the auditor to see all parts of a complex operation as well as the possibility of the auditor finding instances of non-compliance.</td>
<td>On June 28, 2007, Veggie Booty snack food was linked to an outbreak of <em>Salmonella</em>. The plant that made Veggie Booty had received a rating of “excellent” from AIB International, raising questions about the efficacy of auditors and audits, which, in this case and others, did not extend to ingredient suppliers (Moss &amp; Martin, 2009).</td>
</tr>
<tr>
<td><strong>Conflict of Interest</strong></td>
<td>Almost all food producers/retailers require their suppliers to pay for their own audits. A company receiving a poor audit may be unwilling to hire that auditor again. Even with safeguards in place, auditing bodies still must rely on the honesty of their auditors to declare potential conflicts</td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td>Auditors have no legal authority and cannot demand records, embargo products or close an operation (Costa, 2011). Neither the auditor nor the audited company is required to report non-compliances, even automatic failures, to regulatory agencies. If the buyer does not review the audit report closely, which is often the case (Prevor, 2011a), they may never know that their supplier had a serious non-conformance.</td>
<td></td>
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In response to some of the criticisms around third party audits and standards and the growing number of private standards with no real oversight over their development,
the Global Food Safety Initiative (GFSI) was launched in May, 2000. GFSI is a non-profit foundation managed by the consumer goods forum (GFSI, 2012). GFSI is a benchmarking system where “all recognized schemes have a common foundation of requirements which should provide consistent results, in regard to the common requirements applied during the audit, but the benchmarked schemes cannot be considered as equal” (GFSI, 2012). One objective of the initiative is to reduce costs within the system by reducing the number of different audits a firm requires for their different customers. The success of the GFSI approach has not been evaluated to date.

4.0 Improving audits and inspections

Food safety auditors and inspectors are an integral part of the food safety system, and their use will expand in the future, for both domestic and imported foodstuffs. Supporters of third-party audits argue this type of audit augments the efforts of food regulatory agencies, such as FDA, the Canadian Food Inspection Agency (CFIA), and others.

Auditing can be helpful, in theory. Audit reports, are only useful if the purchaser or food producer them reviews the results, understands the risks addressed by the standards and makes risk-reduction decisions based on the results. From past examples, there appears to be a disconnect between what auditors provide (a snapshot) and what buyers believe they are doing (a full verification of product and process).

Third-party auditing can also assist regulatory agencies by providing the extra assessment and data a regulatory agency might not be able to collect as often as required – but only if the data is shared with regulatory agencies. Audits and inspections can assist in the development of a food safety culture by dictating criteria for the sale of goods (Acheson, 2010). The training component for employees is another use of audits in the daily implementation of food safety practices (AIB International, 2007). Third-party audits also provide “thousands of checks and balances to the food supply system with no direct cost to taxpayers” (AIB International, 2007). However, theory and practice can differ.

Critics see many problems with the general way third-party audits are currently conducted and have described them as the equivalent of “mail-order diplomas” (Moss & Martin, 2009). As far as being the “eyes and ears” for a company buying from the audited supplier, many problems are apparently missed during visits (Weise, 2010). Heavy reliance on prescriptive checklists may increase auditor consistency, allow for cost savings on training but also reduces their ability to assess risk. This ultimately results in a pool of auditors that are poorly qualified to assess the risks associated within individual operations. It is imperative for the food industry to aggressively take
corrective actions and make third-party audits and inspections more meaningful, more accurate, and to fully enhance the safety of consumers.

Good auditors look beyond what is on their checklist and can synthesize the various pieces of information they get to put together a clear picture of whether the operation is doing what they say they are doing. Certification bodies must also embrace a food safety culture, ensuring their auditors have the appropriate training, oversight, knowledge and support.

In an effort to improve the third party audit system, FDA is working to establish accreditation programs under a new food safety law, to insure the quality of audits (Karst, 2011). FDA is also trying to make audit results accessible so they can analyze the results for effectiveness and reliability (Karst, 2011). FDA released guidance for industry in 2009 regarding voluntary third-party certification programs for foods and feeds (FDA, 2009a). In this document, it is clearly stated that industry has the primary responsibility to ensure that food products are safe and meet FDA requirements. The document outlines recommendations for third-party certification programs such as qualifications and training for auditors including coursework and field training. These recommendations, though helpful, are not “legally established responsibilities” and the extensive use of the word “should” in the document infers a recommendation rather than a requirement (FDA, 2009a).

Third-party audits are only one performance indicator and need to be supplemented with microbial testing, second-party audits of suppliers and the in-house capacity to meaningfully assess the results of audits and inspections. Any and all raw product suppliers should be included in the audit scope. More effective audit systems incorporate unannounced visits along with supplemental information into their framework and require extensive documentation of internal audits, regulatory compliance, laboratory results and raw product certifications.

Preventive measures such as instilling and enhancing a food safety culture, where there are shared values throughout the organization that support risk-reduction, may improve the safety of the food supply by supplying daily reminders, incentives and food safety priorities in the absence of inspectors or auditors. Improving and encouraging communication with front-line employees – any food producer is only as good as its worst front-line staff – can help mitigate high-risk situations such as at PCA, where employees said the facility was “a dump,” but did not report their concerns to officials before people became ill and died (Sharp, 2009). Audits, regulatory inspections and testing are an important part of the food safety system, but alone and individually they are not enough.

Education and training are the focus of many food handling behavior interventions. However, research suggests that the impacts of food handler training programs are
often inconsistent, and program evaluation is rarely conducted (Almanza & Nesmith, 2004; Egan et al., 2007; Frash et al., 2005; Roberts et al., 2008). Measuring knowledge change is a poor indicator of changes in practices. Yiannas (2008) points out the limitations of focusing entirely on training as food safety culture indicators and suggests training is just one factor of a good organization. Conscientious proprietors provide training and proper tools, remove barriers, and proceed with a focus on positive food safety behavior. The lack of food safety expertise within an organization to effectively evaluate and interpret audit or inspection results may compound problems. Standards applied by auditing firms and regulatory inspections often include training as a component, but outbreak history suggests that little evaluation of effectiveness is explored.

Researchers have suggested that the only reliable measure of effectiveness of food safety culture-supporting intervention material is through the observation of food preparation practices (Redmond and Griffith, 2003; Anderson et al., 2004; Redmond et al., 2004; Chapman et al., 2010).

In 2010, beef processor JBS started a trial using video cameras as part of their third-party monitoring and auditing efforts (Crews, 2011). Strategically placed cameras recorded footage that could then be observed by auditors around-the-clock and random audits could then be conducted remotely. Not only does this allow for immediate feedback, it has also proven an effective training tool for employees, as they can observe and learn from watching themselves at work (Crews, 2011). Improvement at the pilot plant was seen in days instead of months and compliance rates consistently exceeded 99%. Errors can be addressed almost immediately before problems develop (Crews, 2011).

Assessing food-handling practices of staff through internal observations, externally-led evaluations, and audit and inspection results can provide indicators of a food safety culture. Results of these evaluations can be used to modify interventions and further improve the organization’s culture of food safety (Mitchell et al, 2007).

Since most commercial food establishments are audited or inspected, it remains likely that any food establishment that becomes associated with a foodborne illness outbreak will have had some type of audit in the past. Audits still do not guarantee safe food and have inherent limitations based upon stakeholder involvement, auditor competence, audit scope, and audit system.

In August 2008, Listeria monocytogenes-contaminated deli meats produced by Maple Leaf Foods, Inc. of Canada caused 57 illnesses and 22 deaths (Weatherill, 2009). A panel of international food safety experts convened by Maple Leaf Foods, Inc. to investigate the source of the deli meat contamination determined that the most probable contamination source was mechanical meat slicers that, despite cleaning according to the
manufacturer’s instructions, had meat residue trapped deep inside the slicing mechanisms (Weatherill, 2009). An independent investigative review commissioned by the Canadian federal government concluded that the focus on food safety was insufficient among senior management at both the company and the various government organizations involved before and during the outbreak; that insufficient planning had been undertaken to be prepared for a potential outbreak; and that those involved lacked a sense of urgency at the outset of the outbreak (Mason, 2009).

The specific plant linked to the outbreak received satisfactory marks from federal inspectors for complying with federal regulatory requirements. They appeared to be doing everything right. Employees consistently addressed instances of non-compliance when they were identified. The plant’s management maintained all required records, ensured that staff training took place, and ensured the established quality assurance program was followed. At all plants, the company conducted environmental testing that went beyond regulatory requirements (Weatherill, 2009). Prior to the outbreak, Maple Leaf Foods, Inc. conducted more than 3,000 environmental tests annually at the implicated plant and tested products monthly (McCain, 2009). Although no product tests revealed the presence of *Listeria* spp., a number of environmental samples detected the bacteria in the months before the public was alerted in August to possible contamination (CFIA, 2009; McCain, 2009). However, the company failed to recognize and identify the underlying cause of a sporadic yet persistent pattern of environmental test results that were positive for *Listeria* spp. and was not obliged to report these results.

The use of audits to help create, improve, and maintain a genuine food safety culture holds the most promise in preventing foodborne illness and safeguarding public health. A common thread in all of the outbreaks described above is a clear lack of food safety culture among the implicated companies. In the *E. coli* outbreak in South Wales, a public inquiry into the outbreak by Professor Hugh Pennington (2009) found that, in addition to allowing cross contamination through the operation’s single vacuum packaging machine, butcher William Tudor encouraged ill employees to continue working in establishments and preparing meat for sale. Upon review of statements made by employees and environmental health officers to the police, of video and photographic evidence, and of management documentation, Professor Chris Griffith (2010), head of the food research and consultancy unit at the University of Wales Institute, Cardiff, told the inquiry the culture at the premises was one of little regard for the importance of food safety but where making and saving money was the priority. Health code violations at the abattoir were longstanding, repetitive and widely known among environmental health officers responsible for inspecting the operation. Although foodborne illness may not always be completely preventable, that the risk of a business causing foodborne illness is, to a large extent, a consequence of its own activities. Audit and inspection information must be leveraged into corrective actions to mitigate risk.
Food safety culture, not only within the company but also within a supply chain should also be emphasized. In both the Odwalla and PCA outbreaks, second-party audits were able to identify problems the third party auditors did not. Open communication between suppliers and buyers including expectations and risk management practices is essential. Systems where retailers work with their suppliers to help them achieve objectives have had somewhat better buy-in from suppliers and may achieve better results because they reinforce that culture. (Rains, 2009; Steir, 2009).

Third-party auditing is a business, where an organization or business pays another firm to verify whether a supplier is following agreed-upon standards. While third-party auditors are not in the same position as regulatory inspectors with respect to policing an industry – they can provide information upon which buyers can make decisions. Based on historic examples, audit results have not been well understood by requiring buyers (Griffith, 2010; Schmit, 2009). It is incumbent on auditing firms and food businesses commissioning audits to understand the strengths and limitations of any evaluation process. Companies who blame the auditor or inspector for outbreaks of foodborne illness should also blame themselves.

References


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1.0 Introduction

Billions of meals are prepared safely each day throughout the world. Much of that food is deemed safe by some form of verification of practices, known commonly in the commercial food system as external audits or inspection. Yet when outbreaks of foodborne illness happen, the results can be emotionally, physically and financially devastating to the victims and the businesses involved. Many outbreaks involve firms that have had their food production systems verified and received acceptable ratings from food safety auditors or government inspectors.

Food safety audits and inspections are one activity used to verify that a food producer or individual is following specific guidelines, requirements or rules. Audits involve a “systematic and independent examination to determine whether quality/safety activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives” (ANZFA, 2001; ANZFA was later morphed into Food Standards Australia New Zealand). Planned arrangements, as defined by the Australia New Zealand Food Authority are commonly referred to as standards within the food industry. The difference between inspections and audits is that an inspection evaluates “conformity by measuring, observing, testing or gauging the relevant characteristics” (ANZFA, 2001). Audits may be supplemented with microbiological and quality assurance product testing and process inspections by regulatory agencies or industry to help ensure adherence to recognized regulations and good manufacturing practices.
Reactive investigations based on direct consumer complaints or concerns raised through social media may provide additional information.

An audit of food safety practices, facilities, documentation and written procedures is used to gather information regarding food production and processing practices being followed by a particular producer, identifying areas for improvement and areas that are deficient (ANZFA, 2001). Audit reports, in theory, serve as the “eyes and ears” for an organization buying food from a supplier (Weise, 2010). There are several types of audits, and a variety of audit organizations, each with their own unique or common food safety guidelines.

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2.0 The role of audits in food safety

Third-party audits are one part of a multi-factorial approach to food safety. The popularity of third-party audits has increased corresponding to a shift in food safety governance away from government regulation and inspection towards the development of private food safety standards (Busch, 2011). Standard setting organizations (e.g. International Organization for Standardization (ISO) and the British Retail Consortium (BRC)) include industry consortia, private voluntary associations and buyers. There are many different food safety standards available to food producers and manufacturers even within a single industry segment. While the various standards are voluntary, demand by buyers essentially makes certification or verification under these standards de facto mandatory for food companies that want to continue to sell their product to major retailers (Busch, 2011). This has created a system for enforcing food safety standards with little burden on taxpayers.

Costa (2010) argues that third-party audits should focus on strengthening self-audit methods and operational controls to achieve safer food and maximize benefits. The U.S. Government Accountability Office (GAO) noted in a 2008 report that, while inspectors or auditors play an active role in overseeing compliance, the burden for food safety lies primarily with food producers (GAO, 2008). For example, Prevor (2011b) argues that if a company such as Walmart wanted specific standards for a product, even if it exceeded
U.S. Food and Drug Administration (FDA) standards, the company would demand that from the auditor -- and get it. Doering (2010) has also said responsibility for verification primarily lies with industry, given that inspection efforts, even if doubled, would not be enough to make sure every food item is safe. Third-party audits provide the data upon which certification and buying decisions are made, and are now a popular choice for retailers who use them to push the responsibility (and costs) for food safety and quality back on to the supplier (Steir, 2009).

Third-party audits are relied upon within a single company or supply chain for a number of reasons. For some, it is a genuine desire to improve food safety, quality and sanitation or a way to solve/troubleshoot existing problems (Steir, 2009). For others it is a potential marketing advantage or a customer requirement. The effectiveness of these audits may link to the motivation behind the audit. It has been determined that creating a food safety culture is imperative to an effective food safety risk management system (Powell et al., 2011; Yiannas, 2008). Companies with a strong food safety culture may be more likely to obtain a third party audit because they want to improve operations, not just because of customer demand. Companies with a strong food safety culture are also likely to use audit results as guidance and opportunity to improve their practices. Audits -- first- second- or third-party -- are another tool for companies to enhance safe food production.

What is not clear is the role of third party audits in reducing the risk of contaminated food reaching the marketplace and the ability of auditors to identify problems or high risk operations. The utility of third party audits has been examined in other industries as well. A 10-year study on workplace safety on U.S. railroads found that high audit scores partially correlated with improved legislative compliance but did not necessarily correspond to improved safety performance (Peterson, 2001). This indicated there were problems somewhere in the system and that the audit process was not necessarily valid for that industry.

3.0 Limitations of audits

Audit systems, in their current form, have limitations in improving food safety. There are no current empirical evaluations that look at the correlation between audit scores and foodborne illness outbreaks but there is a long and storied history of food safety failures involving third-party audits and inspections.

Third-party audits are analogous in many ways to regulatory municipal inspections of foodservice operations: the effectiveness of both audits and inspections is driven largely by observational judgment and consistency of the inspector or auditor. Foodservice inspection is a cornerstone of local public health, yet inspection scores can be poor predictors of foodborne illness. Jones and colleagues (2004) examined over 160,000 inspections in Tennessee over 7 years and found no difference between scores of
A foodservice associated with outbreaks and those that were not. Similar results were previously found in Miami-Dade county (Cruz et al., 2001). In Massachusetts, researchers found that jurisdictions had different inspection criteria, and even within a given jurisdiction, a risk to one inspector may not be a risk to another (DeNucci 2007).

Many foodborne illness outbreaks have been linked to farms, processors and retailers that went through some form of audit certification. The January 2009 outbreak of Salmonella Typhimurium linked to the Peanut Corporation of America (PCA) has been frequently cited as an example of a failure in the third party auditing system (Busch, 2011; Steir, 2009; Moss and Martin, 2009). In January, 2009 PCA recalled over 3,900 peanut butter and other peanut-containing products from more than 350 companies (FDA, 2009b), 691 people were sickened and nine died across 46 U.S. states and in Canada (CDC, 2009a).

Moss and Martin (2009) reported in the New York Times that an auditor with AIB was responsible for evaluating the safety of products produced by PCA. The peanut company knew in advance when the auditors were arriving. “The overall food safety level of this facility was considered to be: SUPERIOR,” the auditor concluded in his March 27, 2008, report for AIB. A copy of the audit was obtained by the Times. AIB was not alone in missing the trouble at the PCA plant in Blakely, Georgia. State inspectors also found only minor problems. This outbreak and others highlight some of the limitations of both third party audits and government inspections which are included in Table I below.

The Global Food Safety Initiative (GFSI) is a non-profit foundation managed by the consumer goods forum (GFSI, 2012) and was launched in May 2000 as a response to the growing number of private standards. GFSI is a benchmarking system where “all recognized schemes have a common foundation of requirements which should provide consistent results, in regard to the common requirements applied during the audit, but the benchmarked schemes cannot be considered as equal” (GFSI, 2012). One objective of the initiative is to reduce costs within the system by reducing the number of different audits a firm requires for their different customers. The success of the GFSI approach has not been evaluated to date.

Some auditing companies and standards owners are trying to prevent situations where a company may have a food safety problem but still obtain a passing grade, through the application of mandatory or automatic failures (Steir, 2009). The use of auto-failures in an audit is becoming more common. High-risk activities are identified, such as the quality of water used for washing fresh produce, and if the producer is not compliant with those items, they fail the audit regardless of the final score. Many standards also allow the auditor to suggest an auto-failure if they identify and document any situation they deem to be an immediate food safety risk (CanadaGAP, 2012).
Audit vs Inspections

Government inspectors have also failed to prevent foodborne illness outbreaks. Five-year-old Mason Jones was one of 157 people – primarily children – who became ill in an outbreak in South Wales caused by *Escherichia coli* O157:H7 in September 2005. The outbreak was traced to the consumption of cooked meats provided to schools by John Tudor & Son, a catering butcher business. A packaging machine at the business, used for both raw and cooked meats, was identified as the probable source of contamination – where *E. coli* O157:H7 was most likely transferred from raw meat to cooked meat and was then distributed to four authorities in South Wales for their school meal programs. Ultimately, 31 people were admitted to hospital and, tragically, Mason Jones died.

Following the Wales outbreak, a number of mistakes and shortcomings by environmental health officers were identified – which in no way lessened the primary responsibility on the supplier of contaminated food -- including the failure of one officer to verify claims that all food handlers had food hygiene certificates and the failure by another to insist that steps be taken to prevent cross contamination between raw and cooked meats during vacuum packaging (Pennington, 2009). Brian Curtis, a retired senior U.K. Food Standards Agency official, told the inquiry that the Hazard Analysis Critical Control Point (HACCP) plan reportedly used by John Tudor & Son, and reviewed by Mr. Curtis at the time of the inquiry, would not ensure the production of safe food. Mr. Curtis faulted environmental health officers for failing to identify the deficiencies and weaknesses in the HACCP plan, and for failing to identify and address the poor hygiene and unsafe food handling practices at the facility. In addition, utilizing announced, as opposed to unannounced, inspections allowed the butcher to falsify backlogged cleaning records before such records were due to be viewed by environmental health officers (Pennington, 2009).

In Sept. 2006, 199 people were sickened and at least three died from consumption of bagged spinach contaminated with *E. coli* O157:H7 and produced by Earthbound Farms of California. Samples of river water, wild pig feces, and cattle feces from a nearby grass-fed cattle operation tested positive for the outbreak strain of *E. coli* O157:H7 (California Food Emergency Response Team, 2007). Following the outbreak it was revealed that the suspect facilities had received a third-party audit of their good agricultural practices (GAPs) from auditor Primus Labs that did not raise concerns for the buyer, Dole Foods, to alter any purchasing decisions. This was the 29th documented outbreak of foodborne illness involving leafy greens in the U.S. Despite decades of letters and pleading by regulators to the industry to improve microbiological safety standards, there was no verification that farmers and others in the farm-to-fork food safety system were seriously incorporating and acting on risk reduction messages, especially in production fields rather than just processing facilities (Powell et al., 2009).
4.0 Improving audits and inspections

Food safety auditors and inspectors are an integral part of the food safety system, and their use will expand in the future, for both domestic and imported foodstuffs. Supporters of third-party audits argue this type of audit augments the efforts of food regulatory agencies, such as FDA, the Canadian Food Inspection Agency (CFIA), and others.

Auditing can be helpful, in theory. Audit reports, are only useful if the purchaser who requires them reviews the results, understands the risks addressed by the standards and makes risk-reduction decisions based on the results. From past examples, there appears to be a disconnect between what auditors provide (a snapshot) and what buyers believe they are doing (a full verification of product and process).

Third-party auditing can also assist regulatory agencies by providing the extra assessment and data a regulatory agency might not be able to collect as often as required – but only if the data is shared with regulatory agencies. Audits and inspections can assist in the development of a food safety culture by dictating criteria for the sale of goods (Acheson, 2010). The training component for employees is another use of audits in the daily implementation of food safety practices (AIB International, 2007). Third-party audits also provide “thousands of checks and balances to the food supply system with no direct cost to taxpayers” (AIB International, 2007). However, theory and practice can differ.

Critics see many problems with the general way third-party audits are currently conducted and have described them as the equivalent of “mail-order diplomas” (Moss & Martin, 2009). As far as being the “eyes and ears” for a company buying from the audited supplier, many problems are apparently missed during visits (Weise, 2010). It is imperative for the food industry to aggressively take corrective actions and make third-party audits and inspections more meaningful, more accurate, and to fully enhance the safety of consumers.

In an effort to improve the third party audit system, FDA is working to establish accreditation programs under a new food safety law, to insure the quality of audits (Karst, 2011). FDA is also trying to make audit results accessible so they can analyze the results for effectiveness and reliability (Karst, 2011). FDA released guidance for industry in 2009 regarding voluntary third-party certification programs for foods and feeds (FDA, 2009a). In this document, it is clearly stated that industry has the primary responsibility to ensure that food products are safe and meet FDA requirements. The document outlines recommendations for third-party certification programs such as qualifications and training for auditors including coursework and field training. These recommendations, though helpful, are not “legally established responsibilities” and the
extensive use of the word “should” in the document infers a recommendation rather than a requirement (FDA, 2009a).

Third-party audits are only one performance indicator and need to be supplemented with microbial testing, second-party audits of suppliers and the in-house capacity to meaningfully assess the results of audits and inspections. Any and all raw product suppliers should be included in the audit scope. More effective audit systems incorporate unannounced visits along with supplemental information into their framework and require extensive documentation of internal audits, regulatory compliance, laboratory results and raw product certifications.

Preventive measures such as instilling and enhancing a food safety culture, where there are shared values throughout the organization that support risk-reduction, may improve the safety of the food supply by supplying daily reminders, incentives and food safety priorities in the absence of inspectors or auditors. Improving and encouraging communication with front-line employees – any food producer is only as good as its worst front-line staff – can help mitigate high-risk situations such as at PCA, where employees said the facility was “a dump,” but did not report their concerns to officials before people became ill and died (Sharp, 2009). Audits, regulatory inspections and testing are an important part of the food safety system, but alone and individually they are not enough.

Education and training are the focus of many food handling behavior interventions. However, research suggests that the impacts of food handler training programs are often inconsistent, and program evaluation is rarely conducted (Almanza & Nesmith, 2004; Egan et al., 2007; Frash et al., 2005; Roberts et al., 2008). Measuring knowledge change is a poor indicator of changes in practices. Yiannas (2008) points out the limitations of focusing entirely on training as food safety culture indicators and suggests training is just one factor of a good organization. Conscientious proprietors provide training and proper tools, remove barriers, and proceed with a focus on positive food safety behavior. The lack of food safety expertise within an organization to effectively evaluate and interpret audit or inspection results may compound problems. Standards applied by auditing firms and regulatory inspections often include training as a component, but outbreak history suggests that little evaluation of effectiveness is explored.

Researchers have suggested that the only reliable measure of effectiveness of food safety culture-supporting intervention material is through the observation of food preparation practices (Redmond and Griffith, 2003; Anderson et al., 2004; Redmond et al., 2004; Chapman et al., 2010).

In 2010, beef processor JBS started a trial using video cameras as part of their third-party monitoring and auditing efforts (Crews, 2011). Strategically placed cameras
recorded footage that could then be observed by auditors around-the-clock and random audits could then be conducted remotely. Not only does this allow for immediate feedback, it has also proven an effective training tool for employees, as they can observe and learn from watching themselves at work (Crews, 2011). Improvement at the pilot plant was seen in days instead of months and compliance rates consistently exceeded 99%. Errors can be addressed almost immediately before problems develop (Crews, 2011).

Assessing food-handling practices of staff through internal observations, externally-led evaluations, and audit and inspection results can provide indicators of a food safety culture. Results of these evaluations can be used to modify interventions and further improve the organization’s culture of food safety (Mitchell et al., 2007).

Since most commercial food establishments are audited or inspected, it remains likely that any food establishment that becomes associated with a foodborne illness outbreak will have had some type of audit in the past. Audits provide only a snap-shot of information and have inherent limitations based upon stakeholder involvement, auditor competence, audit scope, and audit system.

In August 2008, *Listeria monocytogenes*-contaminated deli meats produced by Maple Leaf Foods, Inc. of Canada caused 57 illnesses and 22 deaths (Weatherill, 2009). A panel of international food safety experts convened by Maple Leaf Foods, Inc. to investigate the source of the deli meat contamination determined that the most probable contamination source was mechanical meat slicers that, despite cleaning according to the manufacturer’s instructions, had meat residue trapped deep inside the slicing mechanisms (Weatherill, 2009). An independent investigative review commissioned by the Canadian federal government concluded that the focus on food safety was insufficient among senior management at both the company and the various government organizations involved before and during the outbreak; that insufficient planning had been undertaken to be prepared for a potential outbreak; and that those involved lacked a sense of urgency at the outset of the outbreak (Mason, 2009).

The specific plant linked to the outbreak received satisfactory marks from federal inspectors for complying with federal regulatory requirements. They appeared to be doing everything right. Employees consistently addressed instances of non-compliance when they were identified. The plant’s management maintained all required records, ensured that staff training took place, and ensured the established quality assurance program was followed. At all plants, the company conducted environmental testing that went beyond regulatory requirements (Weatherill, 2009). Prior to the outbreak, Maple Leaf Foods, Inc. conducted more than 3,000 environmental tests annually at the implicated plant and tested products monthly (McCain, 2009). Although no product tests revealed the presence of *Listeria* spp., a number of environmental samples detected the bacteria in the months before the public was alerted in August to possible
contamination (CFIA, 2009; McCain, 2009). However, the company failed to recognize and identify the underlying cause of a sporadic yet persistent pattern of environmental test results that were positive for *Listeria* spp. and was not obliged to report these results. Audit and inspection information must be leveraged into corrective actions in order to mitigate risk. However, the use of audits to help create, improve, and maintain a genuine food safety culture holds the most promise in preventing foodborne illness and safeguarding public health.

A common thread in all of the outbreaks described above is a clear lack of food safety culture among the implicated companies. In the *E. coli* outbreak in South Wales, a public inquiry into the outbreak by Professor Hugh Pennington (2009) found that, in addition to allowing cross contamination through the operation’s single vacuum packaging machine, butcher William Tudor encouraged ill employees to continue working in establishments and preparing meat for sale. Upon review of statements made by employees and environmental health officers to the police, of video and photographic evidence, and of management documentation, Professor Chris Griffith (2010), head of the food research and consultancy unit at the University of Wales Institute, Cardiff, told the inquiry the culture at the premises was one of little regard for the importance of food safety but where making and saving money was the priority. Health code violations at the abattoir were longstanding, repetitive and widely known among environmental health officers responsible for inspecting the operation. Although foodborne illness may not always be completely preventable, Griffith (2010) concluded that the risk of a business causing foodborne illness is, to a large extent, a consequence of its own activities.

Food safety culture, not only within the company but also within a supply chain should also be emphasized. In both the Odwalla and PCA outbreaks, second-party audits were able to identify problems the third party auditors did not. Open communication between suppliers and buyers including expectations and risk management practices is essential. Systems where retailers work with their suppliers to help them achieve objectives have had somewhat better buy-in from suppliers and may achieve better results because they reinforce that culture. (Rains, 2009; Steir, 2009).

Third-party auditing is a business, where an organization or business pays another firm to verify whether a supplier is following agreed-upon standards. While third-party auditors are not in the same position as regulatory inspectors with respect to policing an industry – they can provide information upon which buyers can make decisions. Based on historic examples, audit results have not been well understood by requiring buyers (Griffith, 2010; Schmit, 2009). It is incumbent on auditing firms and food businesses commissioning audits to understand the strengths and limitations of any evaluation process. Companies who blame the auditor or inspector for outbreaks of foodborne illness should also blame themselves.
References


Table I – Limitations of Third Party Audits

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<thead>
<tr>
<th>Audit Limitations</th>
<th>Summary</th>
<th>Example</th>
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<tr>
<td>A snapshot in time</td>
<td>Audits and inspections remain point-in-time assessments that represent a small fraction of food production time and volume. If conducted properly and the results acted upon, audits can reveal strengths and weaknesses in a food safety program, but cannot guarantee future performance. Further, auditors can only examine what a company provides, although skilled auditors know what to ask for and may be able to identify clues to systemic problems.</td>
<td>PCA outbreak, a federal team of investigators later uncovered a number of alarming signs at the peanut plant including testing records from the company itself that showed <em>Salmonella</em> in its products as far back as June 2007 (Martin, 2009)</td>
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<td><strong>Reliance on an effective standard</strong></td>
<td>The audit is only as effective as the standard against which the practices are being measured. Standards must be evidence-based, designed to address the commodity/product specific risks and practices and responsive to changing industry practices and new science as it becomes available.</td>
<td>Cantaloupe outbreak, July 2011. Previous research had focused on <em>Salmonella</em> and current industry standards may not be robust enough to address risk from <em>Listeria</em>.</td>
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<td><strong>Effective audit tool</strong></td>
<td>The audit tool (or audit checklist) must be valid. There is no scientific basis for certification/validation in audits (Mahshie, 2009). There is high variability in the quality and reliability of audits and many different types of audit tools that vary in length, complexity, and style. A firm may pass some audits but still have a food safety risk factor.</td>
<td><em>Salmonella</em> in eggs, Iowa, 2010, lead to 2,000 illnesses and the recall of 500 million eggs. DeCoster received a superior rating from AIB International, despite audit reports that are typically 10-20 pages and consider over 300 elements (AIB International, 2007).</td>
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<td><strong>Auditor competence</strong></td>
<td>Audits require more than just a checklist, they require paying attention and thinking. The individual ability of an auditor has a significant impact on the outcome of the audit, most third-party audits look for objective evidence to assess compliance, but effective auditors must be able to assess risk, particularly in unique situations and synthesize the information provided to determine effectiveness of the food safety management system.</td>
<td>In the aftermath of the PCA outbreak, the competency of both the auditor and the auditing firm were criticized. The auditor of the PCA facility was an experienced auditor but was an expert in fresh produce and was not aware that peanuts were susceptible to <em>Salmonella</em> (Moss and Martin, 2009).</td>
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<td><strong>Audit scope</strong></td>
<td>The audit scope must be broad enough to cover all operations, locations and products. When a company is presented with different price quotes they often choose the cheapest one, which is more likely the one with less audit time (Pronk, 2011). This reduces cost for the firm requesting the audit, and reduces the ability of the auditor to see all parts of a complex operation as well as the possibility of the auditor finding instances of non-compliance.</td>
<td>On June 28, 2007, Veggie Booty snack food was linked to an outbreak of <em>Salmonella</em>. The plant that made Veggie Booty had received a rating of “excellent” from AIB International, raising questions about the efficacy of auditors and audits, which, in this case and others, did not extend to ingredient suppliers (Moss &amp; Martin, 2009).</td>
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<td><strong>Conflict of Interest</strong></td>
<td>Almost all food producers/retailers require their suppliers to pay for their own audits. A company receiving a poor audit may be unwilling to hire that auditor again. Even with safeguards in place, auditing bodies still must rely on the honesty of their auditors to declare potential conflicts.</td>
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<td><strong>Follow-up</strong></td>
<td>Auditors have no legal authority and cannot demand records, embargo products or close an operation (Costa, 2011). Neither the auditor nor the audited company is required to report non-compliances, even automatic failures, to regulatory agencies. If the buyer does not review the audit report closely, which is often the case (Prevor, 2011a), they may never know that their supplier had a serious non-conformance.</td>
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