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

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2

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41

42 Keywords: food safety; audit; inspection; culture

43

44 Abstract

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

63

64 *1.0 Introduction*

65

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

73

74 Food safety audits and inspections are one activity used to verify that a food producer
75 or individual is following specific guidelines, requirements or rules. Audits involve a
76 “systematic and independent examination to determine whether quality/safety
77 activities and related results comply with planned arrangements and whether these
78 arrangements are implemented effectively and are suitable to achieve objectives”
79 (ANZFA, 2001; ANZFA was later morphed into Food Standards Australia New
80 Zealand). Planned arrangements, as defined by the Australia New Zealand Food
81 Authority are commonly referred to as standards within the food industry. The
82 difference between inspections and audits is that an inspection evaluates “conformity
83 by measuring, observing, testing or gauging the relevant characteristics” (ANZFA,
84 2001). Audits are one tool to help ensure adherence to recognized regulations and good
85 manufacturing practices.

86

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

94
95 Self-audits are internal audits performed by a food establishment itself. These
96 businesses usually have a quality assurance team that leads the internal audits. These
97 internal audits may have good potential for reducing risk if the methods followed are
98 those outlined in widely accepted codes and risk assessment guidance documents. The
99 effectiveness of internal audits is also assessed during third-party audits. Second-party
100 audits are audits that a downstream company, or buyer, performs on their supplier.
101 Third-party audits are performed by an outside firm that usually focuses entirely on
102 verification or standard implementation to ensure that a buyer’s rules are being
103 followed (Costa, 2010). Third-party audits examine compliance with laws and codes of
104 practice as well as provide “insight into management controls and supervision” (Costa,
105 2010).

106
107 *2.0 The role of audits in food safety*

108
109 Third-party audits are one part of a multi-factorial approach to food safety. The
110 popularity of third-party audits has increased corresponding to a shift in food safety
111 governance away from government regulation and inspection towards the
112 development of private food safety standards (Busch, 2011).

113
114 Standard setting organizations (e.g. International Organization for Standardization
115 (ISO) and the British Retail Consortium [BRC]) include industry consortia, private
116 voluntary associations and buyers. There are many different food safety standards
117 available to food producers and manufacturers even within a single industry segment.
118 While the various standards are voluntary, demand by buyers essentially makes
119 certification or verification under these standards *de facto* mandatory for food
120 companies that want to continue to sell their product to major retailers (Busch, 2011).
121 This has created a system for enforcing food safety standards without significantly
122 increasing burden on taxpayers.

123
124 In addition, if a company such as Walmart wanted specific standards for a product,
125 even if it exceeded U.S. Food and Drug Administration (FDA) standards, the company
126 would demand that from the auditor -- and get it (Prevor, 2009).

127
128 While inspectors play an active role in overseeing compliance, the burden for food
129 safety lies primarily with food producers (GAO, 2008). Inspection efforts, even if

130 doubled, would not be enough to make sure every food item is safe. Third party audits
131 provide the data upon which certification and buying decisions are made, and are now
132 a popular choice for retailers who use them to push the responsibility (and costs) for
133 food safety and quality back on to the supplier (Steir, 2009). Audits are an attempt to
134 move beyond inspections that are point-in-time observations of activities and practices.
135 Audits focus on the procedures in place to achieve food safety outcomes and look for
136 evidence that they are being followed and are appropriate and capable of reducing risk.
137 There is also increasing focus on assessment of food safety culture and management
138 commitment to food safety.

139
140 Third-party audits also benefit individual companies and supply chains. It has been
141 argued that the best use of third-party audits is to focus on strengthening self-audit
142 methods and operational controls to achieve safer food (Costa, 2010). For some, it is a
143 genuine desire to improve food safety, quality and sanitation or a way to
144 solve/troubleshoot existing problems (Steir, 2009). For others it is a potential marketing
145 advantage or a customer requirement. The effectiveness of these audits may link to the
146 motivation behind the audit. It has been determined that creating a food safety culture
147 is imperative to an effective food safety risk management system (Powell et al., 2011;
148 Yiannas, 2008). Companies with a strong food safety culture may be more likely to
149 obtain a third party audit because they want to improve operations, not just because of
150 customer demand. Companies with a strong food safety culture are also likely to use
151 audit results as guidance and opportunity to improve their practices. Audits -- first-
152 second- or third-party -- are another tool for companies to enhance safe food
153 production.

154
155 What is not clear is the role of third party audits in reducing the risk of contaminated
156 food reaching the marketplace and the ability of auditors to identify problems or high-
157 risk operations. The utility of third party audits has been examined in other industries
158 as well. A 10-year study on workplace safety on U.S. railroads found that high audit
159 scores partially correlated with improved legislative compliance but did not necessarily
160 correspond to improved safety performance (Peterson, 2001). This indicated there were
161 problems somewhere in the system and that the audit process was not necessarily valid
162 for that industry.

163 164 *3.0 Limitations of audits*

165
166 Audit systems, in their current form, have limitations in improving food safety. There
167 are no current empirical evaluations that look at the correlation between audit scores
168 and foodborne illness outbreaks but there is a long and storied history of food safety
169 failures involving third-party audits.

170
171 Third-party audits are analogous in many ways to regulatory municipal inspections of
172 foodservice operations: the effectiveness of both audits and inspections is driven largely

173 by observational judgment and consistency of the inspector or auditor. Foodservice
 174 inspection is a cornerstone of local public health, yet inspection scores can be poor
 175 predictors of foodborne illness. Jones and colleagues (2004) examined over 160,000
 176 inspections in Tennessee over seven years and found no difference between scores of
 177 foodservices associated with outbreaks and those that were not. Similar results were
 178 previously found in Miami-Dade county (Cruz et al., 2001). In Massachusetts,
 179 researchers found that jurisdictions had different inspection criteria, and even within a
 180 given jurisdiction, a risk to one inspector may not be a risk to another (DeNucci 2007).

181
 182 Many foodborne illness outbreaks have been linked to farms, processors and retailers
 183 that went through some form of audit certification. The January 2009 outbreak of
 184 *Salmonella* Typhimurium linked to the Peanut Corporation of America (PCA) has been
 185 frequently cited as an example of a failure in the third party auditing system (Busch,
 186 2011; Steir, 2009; Moss and Martin, 2009). In January, 2009 PCA recalled over 3,900
 187 peanut butter and other peanut-containing products from more than 350 companies
 188 (FDA, 2009b), 691 people were sickened and nine died across 46 U.S. states and in
 189 Canada (CDC, 2009a).

190
 191 Moss and Martin (2009) reported in the New York Times that an auditor with AIB was
 192 responsible for evaluating the safety of products produced by PCA. The peanut
 193 company knew in advance when the auditors were arriving. "The overall food safety
 194 level of this facility was considered to be: SUPERIOR," the auditor concluded in his
 195 March 27, 2008, report for AIB. A copy of the audit was obtained by the Times. AIB was
 196 not alone in missing the trouble at the PCA plant in Blakely, Georgia. State inspectors
 197 also found only minor problems. This outbreak and others highlight some of the
 198 limitations of both third party audits and government inspections which are included in
 199 Table I below.

200

201 Table I - Limitations of Third Party Audits

Audit Limitations	Summary	Example
<i>A snapshot in time</i>	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.	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 <i>Salmonella</i> in its products as far back as June 2007 (Martin, 2009)

<i>Reliance on an effective standard</i>	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.	Cantaloupe outbreak, July 2011. Previous research had focused on <i>Salmonella</i> and current industry standards may not be robust enough to address risk from <i>Listeria</i> .
<i>Effective audit tool</i>	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	<i>Salmonella</i> 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).
<i>Auditor competence</i>	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	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 <i>Salmonella</i> (Moss and Martin, 2009)
<i>Audit scope</i>	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.	On June 28, 2007, Veggie Booty snack food was linked to an outbreak of <i>Salmonella</i> . 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 & Martin, 2009).
<i>Conflict of Interest</i>	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	
<i>Follow-up</i>	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.	

202

203

204

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,

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

213

214

215 *4.0 Improving audits and inspections*

216

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

222

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

228

229 Third-party auditing can also assist regulatory agencies by providing the extra
230 assessment and data a regulatory agency might not be able to collect as often as
231 required – but only if the data is shared with regulatory agencies. Audits and
232 inspections can assist in the development of a food safety culture by dictating criteria
233 for the sale of goods (Acheson, 2010). The training component for employees is another
234 use of audits in the daily implementation of food safety practices (AIB International,
235 2007). Third-party audits also provide “thousands of checks and balances to the food
236 supply system with no direct cost to taxpayers” (AIB International, 2007). However,
237 theory and practice can differ.

238

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

247 corrective actions and make third-party audits and inspections more meaningful, more
248 accurate, and to fully enhance the safety of consumers.

249
250 Good auditors look beyond what is on their checklist and can synthesize the various
251 pieces of information they get to put together a clear picture of whether the operation is
252 doing what they say they are doing. Certification bodies must also embrace a food
253 safety culture, ensuring their auditors have the appropriate training, oversight,
254 knowledge and support.

255
256 In an effort to improve the third party audit system, FDA is working to establish
257 accreditation programs under a new food safety law, to insure the quality of audits
258 (Karst, 2011). FDA is also trying to make audit results accessible so they can analyze the
259 results for effectiveness and reliability (Karst, 2011). FDA released guidance for industry
260 in 2009 regarding voluntary third-party certification programs for foods and feeds
261 (FDA, 2009a). In this document, it is clearly stated that industry has the primary
262 responsibility to ensure that food products are safe and meet FDA requirements. The
263 document outlines recommendations for third-party certification programs such as
264 qualifications and training for auditors including coursework and field training. These
265 recommendations, though helpful, are not “legally established responsibilities” and the
266 extensive use of the word “should” in the document infers a recommendation rather
267 than a requirement (FDA, 2009a).

268
269 Third-party audits are only one performance indicator and need to be supplemented
270 with microbial testing, second-party audits of suppliers and the in-house capacity to
271 meaningfully assess the results of audits and inspections. Any and all raw product
272 suppliers should be included in the audit scope. More effective audit systems
273 incorporate unannounced visits along with supplemental information into their
274 framework and require extensive documentation of internal audits, regulatory
275 compliance, laboratory results and raw product certifications.

276
277 Preventive measures such as instilling and enhancing a food safety culture, where there
278 are shared values throughout the organization that support risk-reduction, may
279 improve the safety of the food supply by supplying daily reminders, incentives and
280 food safety priorities in the absence of inspectors or auditors. Improving and
281 encouraging communication with front-line employees – any food producer is only as
282 good as its worst front-line staff – can help mitigate high-risk situations such as at PCA,
283 where employees said the facility was “a dump,” but did not report their concerns to
284 officials before people became ill and died (Sharp, 2009). Audits, regulatory inspections
285 and testing are an important part of the food safety system, but alone and individually
286 they are not enough.

287
288 Education and training are the focus of many food handling behavior interventions.
289 However, research suggests that the impacts of food handler training programs are

290 often inconsistent, and program evaluation is rarely conducted (Almanza & Nesmith,
291 2004; Egan et al., 2007; Frash et al., 2005; Roberts et al., 2008). Measuring knowledge
292 change is a poor indicator of changes in practices. Yiannas (2008) points out the
293 limitations of focusing entirely on training as food safety culture indicators and
294 suggests training is just one factor of a good organization. Conscientious proprietors
295 provide training and proper tools, remove barriers, and proceed with a focus on
296 positive food safety behavior. The lack of food safety expertise within an organization
297 to effectively evaluate and interpret audit or inspection results may compound
298 problems. Standards applied by auditing firms and regulatory inspections often include
299 training as a component, but outbreak history suggests that little evaluation of
300 effectiveness is explored.

301
302 Researchers have suggested that the only reliable measure of effectiveness of food
303 safety culture-supporting intervention material is through the observation of food
304 preparation practices (Redmond and Griffith, 2003; Anderson et al., 2004; Redmond et
305 al., 2004; Chapman et al., 2010).

306
307 In 2010, beef processor JBS started a trial using video cameras as part of their third-
308 party monitoring and auditing efforts (Crews, 2011). Strategically placed cameras
309 recorded footage that could then be observed by auditors around-the-clock and random
310 audits could then be conducted remotely. Not only does this allow for immediate
311 feedback, it has also proven an effective training tool for employees, as they can observe
312 and learn from watching themselves at work (Crews, 2011). Improvement at the pilot
313 plant was seen in days instead of months and compliance rates consistently exceeded
314 99%. Errors can be addressed almost immediately before problems develop (Crews,
315 2011).

316
317 Assessing food-handling practices of staff through internal observations, externally-led
318 evaluations, and audit and inspection results can provide indicators of a food safety
319 culture. Results of these evaluations can be used to modify interventions and further
320 improve the organization's culture of food safety (Mitchell et al, 2007).

321
322 Since most commercial food establishments are audited or inspected, it remains likely
323 that any food establishment that becomes associated with a foodborne illness outbreak
324 will have had some type of audit in the past. Audits still do not guarantee safe food
325 and have inherent limitations based upon stakeholder involvement, auditor
326 competence, audit scope, and audit system.

327
328 In August 2008, *Listeria monocytogenes*-contaminated deli meats produced by Maple Leaf
329 Foods, Inc. of Canada caused 57 illnesses and 22 deaths (Weatherill, 2009). A panel of
330 international food safety experts convened by Maple Leaf Foods, Inc. to investigate the
331 source of the deli meat contamination determined that the most probable contamination
332 source was mechanical meat slicers that, despite cleaning according to the

333 manufacturer's instructions, had meat residue trapped deep inside the slicing
334 mechanisms (Weatherill, 2009). An independent investigative review commissioned by
335 the Canadian federal government concluded that the focus on food safety was
336 insufficient among senior management at both the company and the various
337 government organizations involved before and during the outbreak; that insufficient
338 planning had been undertaken to be prepared for a potential outbreak; and that those
339 involved lacked a sense of urgency at the outset of the outbreak (Mason, 2009).

340
341 The specific plant linked to the outbreak received satisfactory marks from federal
342 inspectors for complying with federal regulatory requirements. They appeared to be
343 doing everything right. Employees consistently addressed instances of non-compliance
344 when they were identified. The plant's management maintained all required records,
345 ensured that staff training took place, and ensured the established quality assurance
346 program was followed. At all plants, the company conducted environmental testing
347 that went beyond regulatory requirements (Weatherill, 2009). Prior to the outbreak,
348 Maple Leaf Foods, Inc. conducted more than 3,000 environmental tests annually at the
349 implicated plant and tested products monthly (McCain, 2009). Although no product
350 tests revealed the presence of *Listeria spp.*, a number of environmental samples detected
351 the bacteria in the months before the public was alerted in August to possible
352 contamination (CFIA, 2009; McCain, 2009). However, the company failed to recognize
353 and identify the underlying cause of a sporadic yet persistent pattern of environmental
354 test results that were positive for *Listeria spp.* and was not obliged to report these results.

355
356 The use of audits to help create, improve, and maintain a genuine food safety culture
357 holds the most promise in preventing foodborne illness and safeguarding public health.
358 A common thread in all of the outbreaks described above is a clear lack of food safety
359 culture among the implicated companies. In the *E. coli* outbreak in South Wales, a
360 public inquiry into the outbreak by Professor Hugh Pennington (2009) found that, in
361 addition to allowing cross contamination through the operation's single vacuum
362 packaging machine, butcher William Tudor encouraged ill employees to continue
363 working in establishments and preparing meat for sale. Upon review of statements
364 made by employees and environmental health officers to the police, of video and
365 photographic evidence, and of management documentation, Professor Chris Griffith
366 (2010), head of the food research and consultancy unit at the University of Wales
367 Institute, Cardiff, told the inquiry the culture at the premises was one of little regard for
368 the importance of food safety but where making and saving money was the priority.
369 Health code violations at the abattoir were longstanding, repetitive and widely known
370 among environmental health officers responsible for inspecting the operation. Although
371 foodborne illness may not always be completely preventable, that the risk of a business
372 causing foodborne illness is, to a large extent, a consequence of its own activities. Audit
373 and inspection information must be leveraged into corrective actions to mitigate risk.
374

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

382
383 Third-party auditing is a business, where an organization or business pays another firm
384 to verify whether a supplier is following agreed-upon standards. While third-party
385 auditors are not in the same position as regulatory inspectors with respect to policing an
386 industry – they can provide information upon which buyers can make decisions. Based
387 on historic examples, audit results have not been well understood by requiring buyers
388 (Griffith, 2010; Schmit, 2009). It is incumbent on auditing firms and food businesses
389 commissioning audits to understand the strengths and limitations of any evaluation
390 process. Companies who blame the auditor or inspector for outbreaks of foodborne
391 illness should also blame themselves.

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

2

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43

44 Abstract

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

63

64 *1.0 Introduction*

65

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

73

74 Food safety audits and inspections are one activity used to verify that a food producer
75 or individual is following specific guidelines, requirements or rules. Audits involve a
76 “systematic and independent examination to determine whether quality/safety
77 activities and related results comply with planned arrangements and whether these
78 arrangements are implemented effectively and are suitable to achieve objectives”
79 (ANZFA, 2001; ANZFA was later morphed into Food Standards Australia New
80 Zealand). Planned arrangements, as defined by the Australia New Zealand Food
81 Authority are commonly referred to as standards within the food industry. The
82 difference between inspections and audits is that an inspection evaluates “conformity
83 by measuring, observing, testing or gauging the relevant characteristics” (ANZFA,
84 2001). Audits may be supplemented with microbiological and quality assurance
85 product testing and process inspections by regulatory agencies or industry to help
86 ensure adherence to recognized regulations and good manufacturing practices.

87 Reactive investigations based on direct consumer complaints or concerns raised
88 through social media may provide additional information.

89
90 An audit of food safety practices, facilities, documentation and written procedures is
91 used to gather information regarding food production and processing practices being
92 followed by a particular producer, identifying areas for improvement and areas that are
93 deficient (ANZFA, 2001). Audit reports, in theory, serve as the “eyes and ears” for an
94 organization buying food from a supplier (Weise, 2010). There are several types of
95 audits, and a variety of audit organizations, each with their own unique or common
96 food safety guidelines.

97
98 Self-audits are internal audits performed by a food establishment itself. These
99 businesses usually have a quality assurance team that leads the internal audits. These
100 internal audits may have good potential for reducing risk if the methods followed are
101 those outlined in widely accepted codes and risk assessment guidance documents.
102 Second-party audits are audits that a downstream company, or buyer, performs on their
103 supplier. Third-party audits are performed by an outside firm that usually focuses
104 entirely on verification or standard implementation to ensure that a buyer’s rules are
105 being followed (Costa, 2010). Third-party audits examine compliance with laws and
106 codes of practice as well as provide “insight into management controls and
107 supervision” (Costa, 2010).

108
109 *2.0 The role of audits in food safety*

110
111 Third-party audits are one part of a multi-factorial approach to food safety. The
112 popularity of third-party audits has increased corresponding to a shift in food safety
113 governance away from government regulation and inspection towards the
114 development of private food safety standards (Busch, 2011). Standard setting
115 organizations (e.g. International Organization for Standardization (ISO) and the British
116 Retail Consortium (BRC)) include industry consortia, private voluntary associations
117 and buyers. There are many different food safety standards available to food producers
118 and manufacturers even within a single industry segment. While the various standards
119 are voluntary, demand by buyers essentially makes certification or verification under
120 these standards *de facto* mandatory for food companies that want to continue to sell
121 their product to major retailers (Busch, 2011). This has created a system for enforcing
122 food safety standards with little burden on taxpayers.

123
124 Costa (2010) argues that third-party audits should focus on strengthening self-audit
125 methods and operational controls to achieve safer food and maximize benefits. The U.S.
126 Government Accountability Office (GAO) noted in a 2008 report that, while inspectors
127 or auditors play an active role in overseeing compliance, the burden for food safety lies
128 primarily with food producers (GAO, 2008). For example, Prevor (2011b) argues that if
129 a company such as Walmart wanted specific standards for a product, even if it exceeded

130 U.S. Food and Drug Administration (FDA) standards, the company would demand that
131 from the auditor -- and get it. Doering (2010) has also said responsibility for verification
132 primarily lies with industry, given that inspection efforts, even if doubled, would not be
133 enough to make sure every food item is safe. Third-party audits provide the data upon
134 which certification and buying decisions are made, and are now a popular choice for
135 retailers who use them to push the responsibility (and costs) for food safety and quality
136 back on to the supplier (Steir, 2009).

137
138 Third-party audits are relied upon within a single company or supply chain for a
139 number of reasons. For some, it is a genuine desire to improve food safety, quality and
140 sanitation or a way to solve/troubleshoot existing problems (Steir, 2009). For others it is
141 a potential marketing advantage or a customer requirement. The effectiveness of these
142 audits may link to the motivation behind the audit. It has been determined that
143 creating a food safety culture is imperative to an effective food safety risk management
144 system (Powell et al., 2011; Yiannas, 2008). Companies with a strong food safety culture
145 may be more likely to obtain a third party audit because they want to improve
146 operations, not just because of customer demand. Companies with a strong food safety
147 culture are also likely to use audit results as guidance and opportunity to improve their
148 practices. Audits -- first- second- or third-party -- are another tool for companies to
149 enhance safe food production.

150
151 What is not clear is the role of third party audits in reducing the risk of contaminated
152 food reaching the marketplace and the ability of auditors to identify problems or high
153 risk operations. The utility of third party audits has been examined in other industries
154 as well. A 10-year study on workplace safety on U.S. railroads found that high audit
155 scores partially correlated with improved legislative compliance but did not necessarily
156 correspond to improved safety performance (Peterson, 2001). This indicated there were
157 problems somewhere in the system and that the audit process was not necessarily valid
158 for that industry.

159 160 *3.0 Limitations of audits*

161
162 Audit systems, in their current form, have limitations in improving food safety. There
163 are no current empirical evaluations that look at the correlation between audit scores
164 and foodborne illness outbreaks but there is a long and storied history of food safety
165 failures involving third-party audits and inspections.

166
167 Third-party audits are analogous in many ways to regulatory municipal inspections of
168 foodservice operations: the effectiveness of both audits and inspections is driven largely
169 by observational judgment and consistency of the inspector or auditor. Foodservice
170 inspection is a cornerstone of local public health, yet inspection scores can be poor
171 predictors of foodborne illness. Jones and colleagues (2004) examined over 160,000
172 inspections in Tennessee over 7 years and found no difference between scores of

173 foodservices associated with outbreaks and those that were not. Similar results were
174 previously found in Miami-Dade county (Cruz et al., 2001). In Massachusetts,
175 researchers found that jurisdictions had different inspection criteria, and even within a
176 given jurisdiction, a risk to one inspector may not be a risk to another (DeNucci 2007).

177
178 Many foodborne illness outbreaks have been linked to farms, processors and retailers
179 that went through some form of audit certification. The January 2009 outbreak of
180 *Salmonella* Typhimurium linked to the Peanut Corporation of America (PCA) has been
181 frequently cited as an example of a failure in the third party auditing system (Busch,
182 2011; Steir, 2009; Moss and Martin, 2009). In January, 2009 PCA recalled over 3,900
183 peanut butter and other peanut-containing products from more than 350 companies
184 (FDA, 2009b), 691 people were sickened and nine died across 46 U.S. states and in
185 Canada (CDC, 2009a).

186
187 Moss and Martin (2009) reported in the New York Times that an auditor with AIB was
188 responsible for evaluating the safety of products produced by PCA. The peanut
189 company knew in advance when the auditors were arriving. "The overall food safety
190 level of this facility was considered to be: SUPERIOR," the auditor concluded in his
191 March 27, 2008, report for AIB. A copy of the audit was obtained by the Times. AIB was
192 not alone in missing the trouble at the PCA plant in Blakely, Georgia. State inspectors
193 also found only minor problems. This outbreak and others highlight some of the
194 limitations of both third party audits and government inspections which are included in
195 Table I below.

196
197
198 The Global Food Safety Initiative (GFSI) is a non-profit foundation managed by the
199 consumer goods forum (GFSI, 2012) and was launched in May 2000 as a response to the
200 growing number of private standards. GFSI is a benchmarking system where "all
201 recognized schemes have a common foundation of requirements which should provide
202 consistent results, in regard to the common requirements applied during the audit, but
203 the benchmarked schemes cannot be considered as equal" (GFSI, 2012). One objective of
204 the initiative is to reduce costs within the system by reducing the number of different
205 audits a firm requires for their different customers. The success of the GFSI approach
206 has not been evaluated to date.

207
208 Some auditing companies and standards owners are trying to prevent situations where
209 a company may have a food safety problem but still obtain a passing grade, through the
210 application of mandatory or automatic failures (Steir, 2009). The use of auto-failures in
211 an audit is becoming more common. High-risk activities are identified, such as the
212 quality of water used for washing fresh produce, and if the producer is not compliant
213 with those items, they fail the audit regardless of the final score. Many standards also
214 allow the auditor to suggest an auto-failure if they identify and document any situation
215 they deem to be an immediate food safety risk (CanadaGAP, 2012).

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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).

259

260 *4.0 Improving audits and inspections*

261

262 Food safety auditors and inspectors are an integral part of the food safety system, and
263 their use will expand in the future, for both domestic and imported foodstuffs.

264 Supporters of third-party audits argue this type of audit augments the efforts of food
265 regulatory agencies, such as FDA, the Canadian Food Inspection Agency (CFIA), and
266 others.

267

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

273

274 Third-party auditing can also assist regulatory agencies by providing the extra
275 assessment and data a regulatory agency might not be able to collect as often as
276 required - but only if the data is shared with regulatory agencies. Audits and
277 inspections can assist in the development of a food safety culture by dictating criteria
278 for the sale of goods (Acheson, 2010). The training component for employees is another
279 use of audits in the daily implementation of food safety practices (AIB International,
280 2007). Third-party audits also provide “thousands of checks and balances to the food
281 supply system with no direct cost to taxpayers” (AIB International, 2007). However,
282 theory and practice can differ.

283

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

291

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

302 extensive use of the word “should” in the document infers a recommendation rather
303 than a requirement (FDA, 2009a).

304
305 Third-party audits are only one performance indicator and need to be supplemented
306 with microbial testing, second-party audits of suppliers and the in-house capacity to
307 meaningfully assess the results of audits and inspections. Any and all raw product
308 suppliers should be included in the audit scope. More effective audit systems
309 incorporate unannounced visits along with supplemental information into their
310 framework and require extensive documentation of internal audits, regulatory
311 compliance, laboratory results and raw product certifications.

312
313 Preventive measures such as instilling and enhancing a food safety culture, where there
314 are shared values throughout the organization that support risk-reduction, may
315 improve the safety of the food supply by supplying daily reminders, incentives and
316 food safety priorities in the absence of inspectors or auditors. Improving and
317 encouraging communication with front-line employees – any food producer is only as
318 good as its worst front-line staff – can help mitigate high-risk situations such as at PCA,
319 where employees said the facility was “a dump,” but did not report their concerns to
320 officials before people became ill and died (Sharp, 2009). Audits, regulatory inspections
321 and testing are an important part of the food safety system, but alone and individually
322 they are not enough.

323
324 Education and training are the focus of many food handling behavior interventions.
325 However, research suggests that the impacts of food handler training programs are
326 often inconsistent, and program evaluation is rarely conducted (Almanza & Nesmith,
327 2004; Egan et al., 2007; Frash et al., 2005; Roberts et al., 2008). Measuring knowledge
328 change is a poor indicator of changes in practices. Yiannas (2008) points out the
329 limitations of focusing entirely on training as food safety culture indicators and
330 suggests training is just one factor of a good organization. Conscientious proprietors
331 provide training and proper tools, remove barriers, and proceed with a focus on
332 positive food safety behavior. The lack of food safety expertise within an organization
333 to effectively evaluate and interpret audit or inspection results may compound
334 problems. Standards applied by auditing firms and regulatory inspections often include
335 training as a component, but outbreak history suggests that little evaluation of
336 effectiveness is explored.

337
338 Researchers have suggested that the only reliable measure of effectiveness of food
339 safety culture-supporting intervention material is through the observation of food
340 preparation practices (Redmond and Griffith, 2003; Anderson et al., 2004; Redmond et
341 al., 2004; Chapman et al., 2010).

342
343 In 2010, beef processor JBS started a trial using video cameras as part of their third-
344 party monitoring and auditing efforts (Crews, 2011). Strategically placed cameras

345 recorded footage that could then be observed by auditors around-the-clock and random
346 audits could then be conducted remotely. Not only does this allow for immediate
347 feedback, it has also proven an effective training tool for employees, as they can observe
348 and learn from watching themselves at work (Crews, 2011). Improvement at the pilot
349 plant was seen in days instead of months and compliance rates consistently exceeded
350 99%. Errors can be addressed almost immediately before problems develop (Crews,
351 2011).

352
353 Assessing food-handling practices of staff through internal observations, externally-led
354 evaluations, and audit and inspection results can provide indicators of a food safety
355 culture. Results of these evaluations can be used to modify interventions and further
356 improve the organization's culture of food safety (Mitchell et al, 2007).

357
358 Since most commercial food establishments are audited or inspected, it remains likely
359 that any food establishment that becomes associated with a foodborne illness outbreak
360 will have had some type of audit in the past. Audits provide only a snap-shot of
361 information and have inherent limitations based upon stakeholder involvement,
362 auditor competence, audit scope, and audit system.

363
364 In August 2008, *Listeria monocytogenes*-contaminated deli meats produced by Maple Leaf
365 Foods, Inc. of Canada caused 57 illnesses and 22 deaths (Weatherill, 2009). A panel of
366 international food safety experts convened by Maple Leaf Foods, Inc. to investigate the
367 source of the deli meat contamination determined that the most probable contamination
368 source was mechanical meat slicers that, despite cleaning according to the
369 manufacturer's instructions, had meat residue trapped deep inside the slicing
370 mechanisms (Weatherill, 2009). An independent investigative review commissioned by
371 the Canadian federal government concluded that the focus on food safety was
372 insufficient among senior management at both the company and the various
373 government organizations involved before and during the outbreak; that insufficient
374 planning had been undertaken to be prepared for a potential outbreak; and that those
375 involved lacked a sense of urgency at the outset of the outbreak (Mason, 2009).

376
377 The specific plant linked to the outbreak received satisfactory marks from federal
378 inspectors for complying with federal regulatory requirements. They appeared to be
379 doing everything right. Employees consistently addressed instances of non-compliance
380 when they were identified. The plant's management maintained all required records,
381 ensured that staff training took place, and ensured the established quality assurance
382 program was followed. At all plants, the company conducted environmental testing
383 that went beyond regulatory requirements (Weatherill, 2009). Prior to the outbreak,
384 Maple Leaf Foods, Inc. conducted more than 3,000 environmental tests annually at the
385 implicated plant and tested products monthly (McCain, 2009). Although no product
386 tests revealed the presence of *Listeria* spp., a number of environmental samples detected
387 the bacteria in the months before the public was alerted in August to possible

388 contamination (CFIA, 2009; McCain, 2009). However, the company failed to recognize
389 and identify the underlying cause of a sporadic yet persistent pattern of environmental
390 test results that were positive for *Listeria spp.* and was not obliged to report these results.

391
392 Audit and inspection information must be leveraged into corrective actions in order to
393 mitigate risk. However, the use of audits to help create, improve, and maintain a
394 genuine food safety culture holds the most promise in preventing foodborne illness and
395 safeguarding public health.

396
397 A common thread in all of the outbreaks described above is a clear lack of food safety
398 culture among the implicated companies. In the *E. coli* outbreak in South Wales, a
399 public inquiry into the outbreak by Professor Hugh Pennington (2009) found that, in
400 addition to allowing cross contamination through the operation's single vacuum
401 packaging machine, butcher William Tudor encouraged ill employees to continue
402 working in establishments and preparing meat for sale. Upon review of statements
403 made by employees and environmental health officers to the police, of video and
404 photographic evidence, and of management documentation, Professor Chris Griffith
405 (2010), head of the food research and consultancy unit at the University of Wales
406 Institute, Cardiff, told the inquiry the culture at the premises was one of little regard for
407 the importance of food safety but where making and saving money was the priority.
408 Health code violations at the abattoir were longstanding, repetitive and widely known
409 among environmental health officers responsible for inspecting the operation. Although
410 foodborne illness may not always be completely preventable, Griffith (2010) concluded
411 that the risk of a business causing foodborne illness is, to a large extent, a consequence
412 of its own activities.

413
414 Food safety culture, not only within the company but also within a supply chain should
415 also be emphasized. In both the Odwalla and PCA outbreaks, second-party audits were
416 able to identify problems the third party auditors did not. Open communication
417 between suppliers and buyers including expectations and risk management practices is
418 essential. Systems where retailers work with their suppliers to help them achieve
419 objectives have had somewhat better buy-in from suppliers and may achieve better
420 results because they reinforce that culture. (Rains, 2009; Steir, 2009).

421
422 Third-party auditing is a business, where an organization or business pays another firm
423 to verify whether a supplier is following agreed-upon standards. While third-party
424 auditors are not in the same position as regulatory inspectors with respect to policing an
425 industry – they can provide information upon which buyers can make decisions. Based
426 on historic examples, audit results have not been well understood by requiring buyers
427 (Griffith, 2010; Schmit, 2009). It is incumbent on auditing firms and food businesses
428 commissioning audits to understand the strengths and limitations of any evaluation
429 process. Companies who blame the auditor or inspector for outbreaks of foodborne
430 illness should also blame themselves.

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Table I - Limitations of Third Party Audits

Audit Limitations	Summary	Example
<i>A snapshot in time</i>	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.	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 <i>Salmonella</i> in its products as far back as June 2007 (Martin, 2009)

<i>Reliance on an effective standard</i>	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.	Cantaloupe outbreak, July 2011. Previous research had focused on <i>Salmonella</i> and current industry standards may not be robust enough to address risk from <i>Listeria</i> .
<i>Effective audit tool</i>	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	<i>Salmonella</i> 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).
<i>Auditor competence</i>	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	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 <i>Salmonella</i> (Moss and Martin, 2009)
<i>Audit scope</i>	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.	On June 28, 2007, Veggie Booty snack food was linked to an outbreak of <i>Salmonella</i> . 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 & Martin, 2009).
<i>Conflict of Interest</i>	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	
<i>Follow-up</i>	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.	