

Collaborative Food Safety Forum (CFSF)

Workshop on Root-cause Analysis: Workshop Summary

October 17 & 18, 2016

Washington, D.C.

Background

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the [Collaborative Food Safety Forum](#) (CFSF or Forum). Invited representatives from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), state agencies, industry, consumer advocacy groups, and academia attended a workshop on October 17-18th, 2016 to discuss root-cause analysis, its role in promoting food safety, and strategies for extracting maximum value and learning from the practice. This workshop is a continuation of the Forum's efforts to put in place structures and practices to enhance food safety and protect public health, with a particular focus on successfully implementing the Food Safety Modernization Act (FSMA). Root-cause analysis was one of several topics discussion of which the CFSF identified as intrinsic to achieving enhanced food safety, but also expands beyond FSMA.

Welcome and Opening of Workshop

This workshop opened with a welcome and remarks from Sandra Eskin and Karin Hoelzer (Pew), followed by a review of the workshop's goals, outcomes, and agenda by Abby Dilley (RESOLVE) and a brief round of introductions. Audience was then given to representatives from the major government agencies in attendance as they shared their perspectives on the value of root-cause analysis and iterated their goals and expectations of the discussion.

Setting the Stage: Opening Thoughts from FDA, CDC and USDA

Per the agenda, Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at FDA, Michael Jhung and Michael Beach of the Division of Foodborne, Waterborne and Environmental Diseases at CDC, David Goldman from Food Safety and Inspection Service (FSIS) at USDA, and Thomas Gomez with Animal and Plant Health Inspection Service (APHIS) at USDA provided introductory remarks on the value of root-cause analysis and their expectations for the discussion to follow. On behalf of their respective agencies, these senior leaders thanked participants for attending, noting the wealth of experience and expertise in the room, and spoke to root-cause analysis' capacity to catalyze system improvement, prevent illness, drive research, improve regulatory decision-making, and ultimately promote safe food and protect public health. Of note, CDC representatives expressed hope for their agency to move further into the prevention arena, and saw a role for CDC in root-cause analyses as part of a tri-agency cooperative to fully leverage the utility of this tool. Goldman and Gomez referenced the recent [FSIS/APHIS MOU](#) to collaborate on root-cause analysis, particularly when a root cause is suspected pre-harvest. It was noted that lessons and processes from both water-related investigations conducted by the CDC and livestock

epidemiology and on-farm investigations conducted by APHIS could be brought to bear on the discussion of improving root-cause analysis in food production.

Root-Cause Analysis and Food Safety: Historical Use and Case Examples

Following these introductory remarks, John “Jack” Guzewich, an independent food safety consultant of the CDC and FDA, provided a brief overview of the evolution of food safety analysis, beginning with the five primary contributing factors associated with foodborne outbreaks identified by the CDC in 1973 and expanded thereafter, and the concurrent rise of systems analysis, hazard analysis and critical control point (HACCP) thinking in the regulatory sector. Guzewich explained how contributing factors, systems analysis and environmental antecedents were incorporated into the environmental assessments the National Center for Environmental Health (NCEH) at the CDC began conducting in 2005 and the FDA later adopted in 2010. However, the problem, as Guzewich described it, is that contributing factors and inspection violations – the traditional focuses of FDA analyses – are often only symptomatic of underlying root causes, explaining how an outbreak or contamination occurred without fully uncovering why. In order to move food safety to the “next level,” Guzewich posited the need to leverage behavioral science and consider the “people factor” more thoroughly when analyzing potential threats to food safety. He noted that, in many respects, industry has taken the lead in this area and suggested government agencies could learn from the private sectors’ example. Guzewich left participants to consider how root-cause findings could and should be used, and how to encourage wider information-sharing to improve food safety while ameliorating producers’ concerns related to enforcement and liability.

Root-cause Analysis Case Example Presentations

Representatives from industry and government presented brief case examples of root-cause analyses conducted by their organizations – either independently or as part of a broader, multi-party investigation. These examples were intended to stimulate discussion and provide participants with a shared frame of reference and an understanding of the diverse ways in which root-cause analyses are conducted and to what extent and at what stage various sectors are involved.

Presenters were asked to touch on: how the decision to initiate the root-cause analysis was made; the actions, if any, which were taken as part, and/or as part of a result, of the root-cause analysis; and any other insights and information that were gained from the analysis. Each presentation was followed by a brief period of Q&A. Links to the presentation materials are provided below (where available).

- [Tim Jackson, Nestlé: 2009 Cookie Dough](#)
- [Ian Williams, CDC: 2016 Multistate Outbreak of Shiga toxin-producing Escherichia coli Infections Linked to Flour](#)
- De Ann Davis, Earthbound and Will Daniels, Consultant: 2006 Spinach
- [Kathleen Gensheimer, FDA: DELMARVA Project Initiative Fresh Produce](#)
- David Goldman, FSIS, USDA: 2015-16 Luau Pigs
- Angie Siemens, Cargill: Animal Food Safety
- [Thomas Gomez, APHIS, USDA: Veterinary Services Approach to Epidemiologic Investigations](#)

Tim Jackson, Nestlé: 2009 Cookie Dough

Tim Jackson, Director of Food Safety for Nestlé North America, presented on the 2006 outbreak of *E. coli* associated with raw cookie dough. He explained Nestlé's interactions with CDC and FDA during the first 72 hours after the outbreak was identified and how Nestlé responded to the information provided, including a near-immediate recall of all refrigerated raw cookie dough products and a production halt to allow for FDA inspection of their facility from which they released an investigation brief summarizing their findings. Jackson noted that, while the CDC's brief was helpful, it was not disclosed until weeks after the investigation began, which complicated Nestlé's own on-site analysis since the facility conditions at that point differed from the time of contamination. Jackson recounted the array of root-cause hypothesis Nestlé developed and the steps they took to evaluate each theory including, swabbing, visiting suppliers, and interviewing disgruntled and ill plant employees and farm workers. Jackson also highlighted critical confounding factors such as pressure to get product back to market, managing FDA expectations and inquiries while conducting internal analysis, and workers' personal concerns for job security. Ultimately, investigations did not definitively uncover a "smoking gun" root cause; however, they did reveal a number of potential contributing factors and production system vulnerabilities all of which Nestlé addressed in its corrective action plan, improving its systems across the board. Jackson believes open communication with suppliers, customers and government agencies was a key to making the analysis successful and acknowledged the importance of Nestlé's in-house counsel championing transparency throughout the process.

In response to questions regarding the corrective actions Nestlé took post-analysis and in combination with additional investigation into the contribution of contaminated flour, Jackson explained that Nestlé implemented a full redesign of its cookie products, including examining the possibility of superheating flour to eliminate contaminants. And that during its analysis - which included examination of: its milling processes; products that relied on consumer involvement, such as baking them per the package instructions, to make them safe; and ingredients to look for potential new food vehicles and vulnerabilities - Nestlé identified and addressed 30-40 other risk factors potentially affecting its food safety.

One participant asked whether the FDA's arrival was helpful or hindered Nestlé's internal investigation. Initially, Jackson replied, the FDA was distracting because they requested Nestlé delay its investigation so the FDA could conduct its own. However, once Nestlé communicated its desire to collaborate in the investigatory process, their relationship with regulators shifted and both entities were able to be an asset to the other.

Some participants raised concern that root-cause analysis could be used to delay action on problem-solving and corrective actions. They asked how Nestlé determined the point at which it had sufficient information to implement interventions, even when the root-cause remains unknown. Jackson said Nestlé was able to balance both impetuses by implementing interventions mid-investigation while still looking for underlying causes. Because a true root cause wasn't identified, Nestlé had to determine the best corrective actions without complete information, in this case meaning it addressed a broad range of potential causes, which was costly, but also in the best interest of the business.

Ian Williams, CDC: 2016 Multistate Outbreak of Shiga toxin-producing Escherichia coli Infections Linked to Flour

Ian Williams, Chief for the Outbreak Response and Prevention Branch of the Division of Foodborne, Waterborne and Environmental Diseases National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention (CDC), talked participants through an investigation of a multi-state outbreak of Shiga Toxin-producing *Escherichia coli* (STEC) in 2016. Williams explained how epidemiologic, laboratory, and traceback evidence indicated that flour produced at a General Mills facility in Kansas City, Missouri was the likely source of this outbreak. Once notified, General Mills issued a recall on May 31, 2016 and initiated a root-cause analysis. In June 2016, laboratory testing by the US Food and Drug Administration (FDA) isolated STEC O121 in open samples of General Mills flour collected from the homes of ill people in Arizona, Colorado, and Oklahoma. Whole genome sequencing (WGS) showed that the STEC O121 isolates from the flour samples were closely related genetically to the STEC O121 isolates from ill people. The flour collected in Oklahoma was not included in the initial General Mills recall. The other flour samples that were tested came from lots of flour included in the initial recall announced by General Mills. In July 2016, laboratory testing by General Mills and FDA isolated STEC O26 from a sample of General Mills flour. WGS showed that the STEC O26 isolated from the flour sample was closely related genetically to isolates from an ill person in the PulseNet database. The flour tested was not included in the earlier General Mills recalls. As a result of these findings, General Mills expanded its recall on July 1, 2016 and again on July 25, 2016 to include more production dates. This was the first time flour was definitively implicated in any STEC outbreak. General Mills could not determine an exact root cause. Williams noted this analysis and agency investigations resulted in several important consumer messages (i.e., cook the cookies!) and research questions. As a raw product which is known to have the potential to be contaminated with STEC, what can farmers and producers do to improve safety around flour? What can consumers do? Should there be separate production streams for home cooking flour (which might be more likely to be eaten raw) and factory flour? Williams also emphasized how this case study exemplifies how critical collaboration between state, local and federal public health and regulatory bodies is essential to thorough food safety investigations.

Although there are contamination risks associated with wheat agriculture practices, participants discussed how many large producers mix and store flour in silos which makes tracing contaminated flour upstream to a specific supplier and identifying a root cause nearly impossible. Given this, the group asked how industry and regulators might implement downstream solutions to flour safety. Williams indicated that consumer education is a critical component of such interventions.

Noting that the FDA performed testing over several months before isolating STEC in certain products, a participant asked how the CDC and FDA determine the trustworthiness of their test results. Epidemiology results and trace backs, Williams explained, can often be used to check laboratory tests and vice versa. If the epidemiology strongly points to an association that testing does not confirm agencies are more likely to persevere in testing and it may indicate a need to change the test method. During this discussion, several participants highlighted that testing for the presence of generic *E. coli* is not a good indicator for the presence of pathogenic *E. coli* (like STEC) in flour.

DeAnn Davis, Earthbound and Will Daniels, Consultant: 2006 Fresh Cut Spinach

De Ann Davis, Vice President of Quality Assurance and Food Safety at Earthbound Farm, and Will Daniels, Consultant, and at Earthbound from 1999 - 2014, presented on the 2006 spinach outbreak at Earthbound. Earthbound's situation occurred amidst a rash of produce-related outbreak across the industry in early 2006. Unable to immediately isolate the responsible products, the FDA pulled all fresh, canned and frozen spinach from shelves, speculating the outbreaks could be a terrorist event. When further investigation isolated fresh cut spinach, Earthbound voluntarily recalled its products and initiated a root-cause analysis of its facility. It also employed a third-party organization to conduct an independent investigation. Neither revealed any glaring facilities issues, however, indicating the problem was likely related to overwhelming (i.e., several factors overwhelming the usual food safety control measures in place). These analyses helped Earthbound enhance its overall systems as it examined potential contamination risks at all production stages – raw materials leaving the field, transport to the facility, final products and distribution. The analysis also revealed consumers were eating products well past their expiration date, assessing produce quality qualitatively (i.e. if it looks okay) which is not atypical for food subject to visible spoilage. Such consumer behaviors affected the recall's scope and duration. This prompted Earthbound to modify its on-package consumer messaging, using "best buy" versus a "packaged on" date. Though Davis acknowledged this change may have only minimal effect on consumer behavior.

Though several of Earthbound's partners had previously undergone produce-related outbreaks and investigation, they did not communicate their findings or lessons learned in a way that could have informed or expedited Earthbound's analysis. As such, Daniels relayed, Earthbound made concerted efforts to be transparent throughout its investigatory process and share take-aways with other producers. Davis added, continual root-cause analysis is inherent to the company's safety assurance process, and this constant "check-and-change" approach (i.e., check to see that an action improves food safety and if it does not, change the action to one that does) to standards has helped it implement preventive measures at the agricultural production (or on farm) level.

A participant asked what contributing factors Earthbound identified beyond its plant, as its investigation extended upstream to farms and agricultural practices. Davis listed a number of potential contamination sources the analysis revealed, including streams, bird and cattle feces and wild pig invasion. She noted, however, a combination of factors is responsible and correcting for any one may have no or negligible impact on risk reduction.

While many large suppliers and producers have the time and resources to perform regular systems analysis and implement dozens or hundreds of preventive actions, this may not be viable, or even a reasonable expectation, for smaller operations. Participants agreed data from root-cause analysis would likely be most useful to (and used by) small growers if it were translated into the three or four priority safety measures with most relevance to their unique setting and most likely to have impact, especially if growers are expected to invest in addressing these concerns. Daniels saw a role for large companies as beacons for small growers, helping identify the critical safety risks or factors to watch in their areas, and potentially provide resources to do so.

Participants were also curious about how the short shelf-life of leafy greens affects root-cause analysis. Daniels acknowledged it's a significant barrier. Implicated leafy green products are usually

off the market by the time an outbreak is identified and the on-farm conditions have changed. Rapid response is critical in leafy green investigations, he said, and even then root causes are often elusive. Because of this, Davis added, Earthbound's focus is process-based, continually evaluating its systems for vulnerabilities.

Kathleen Gensheimer, FDA: DELMARVA Project Initiative Fresh Produce

Kathleen Gensheimer, Director of Outbreak Investigation and Response for the FDA's Coordinated Outbreak Response and Evaluation Network (CORE), commented on the FDA's collaborative efforts working with public health, agriculture, regulatory authorities in the DELMARVA States (Delaware, Maryland and Virginia) to address the recurrent *Salmonella* Newport 061 outbreaks reported since 2002, tracing back to produce harvested and produced in the DELMARVA region. The three states have reached out to involve Cooperative Extension and Academia within their states to engage them in addressing the issue. CDC has worked with public health partners in the mid-Atlantic States to utilize a standardized epidemiologic surveillance tool for interviewing case patients in real time. Tracing the source of produce contamination is complicated by a compendium of factors, including the relatively intermittent, widespread and low attack rates, supply chain intricacies, the disease's slow onset, and resource allocation. Environmental surveys have identified this unique *Salmonella* strain in pond sediment locations in Virginia. It's unknown how this particular strain of *Salmonella* is transmitted to crops, but since identifying the environmental risk, the Center for Food Safety and Applied Nutrition (CFSAN) has teamed with DELMARVA States to continue research into this issue. Gensheimer called this partnership a model for information sharing and with such a model in place, she noted public health and regulatory authorities are well positioned to respond in real time in the event of another outbreak. She added that such collaboration promotes preventive action in addition to quality response.

Participants mentioned this case is of particular interest to researchers because the *Salmonella* type involved is unique to the DELMARVA region and therefore in theory more trackable and susceptible to targeted prevention measures. The members of the DELMARVA initiative hope to solve questions such as how *Salmonella* in the environment contaminates crops. Participants acknowledged environmental pathogens are ubiquitous, and the goal of interventions is risk reduction, not elimination. More challenging, many agreed, is introducing the concept of acceptable risk in a palatable way to consumers and the public. One participant raised the question of whether acceptable risk levels should be developed for produce as they have been for water, and how to communicate the consumption risks and benefits of produce to the public.

David Goldman, FSIS, USDA: 2015-16 Luau Pigs

David Goldman, Assistant Administrator of the Office of Public Health Science at FSIS, discussed the coordinated effort of FSIS, CDC and Washington State Health Department to address the 2015 and 2016 *Salmonella* outbreaks associated with luau pigs. The initial, larger outbreak was traced back to one producer where systems analysis revealed pathogens in pre-operation samples surviving through production. Halting production stymied the 2015 outbreak and allowed the plant to address its systems issues. However, when the facility was associated with a smaller outbreak the following year, FSIS did not find problematic conditions, systems issues or practices as it had previously, causing investigators to consider possible farm-level contributions. APHIS was brought

into the investigation per its [MOU](#) with FSIS to apply the epidemiological principles of animal illness analysis to uncover possible connections to the outbreak in humans. This was the first case to leverage the MOU, Goldman explained, and agencies and industry are interested to see what information will be disclosed and how it will be used given the data sharing parameters set forth in the memorandum.

Several participants had questions about the [FSIS/APHIS MOU](#), how APHIS becomes involved, how agency resources and responsibilities are allocated, and if and how information from on-farm investigations will be shared. APHIS Veterinary Services (VS) representative Thomas Gomez explained the process APHIS uses to assess whether it will engage in an FSIS-requested root cause investigation which takes into consideration resource availability, potential costs and benefits, the political environment and other factors. He added that APHIS does not have authority to go on to farms for food safety reasons, so on-farm investigations, under the MOU, are voluntary on the part of the producer or company, are non-regulatory; and, are confidential (though the MOU includes language that information may be shared if an outbreak is ongoing). While producers and companies regularly invite APHIS to conduct animal disease investigations, there's been some pushback on food safety investigations from some concerned with brand protection and confidentiality. Gomez hoped success stories will promote further participation from industry. Gomez elaborated on the FSIS/APHIS MOU later in the session during his [presentation](#).

Angie Siemens, Cargill: Animal Food Safety

Angie Siemens, Vice President of Technical Services at Cargill, affirmed industry's interest in the FSIS/APHIS MOU in her presentation, noting further farm-level analysis and some mechanism for sharing information cross-industry could help producers learn from other settings and product groups (e.g., similar to steps taken to prevent *E. coli* in beef). She added it could help delineate where responsibility for food safety starts and ends as products move through the supply chain. Currently, companies like Cargill which only own a fraction of their livestock must assume some level of contamination when supply comes into their facilities because there is little they can do to prevent exposure on farms or identify problematic practices.

Drawing on root-cause analyses Cargill performed in response to outbreaks associated with both raw beef and turkey products, Siemens highlighted several challenges and questions facing producers, including the difficulty of identifying the small percentage of positives that pose a public health risk. Individual cows carrying high levels of *Salmonella*, though not showing symptoms, can be coincidentally concentrated in batches and overwhelm the system. Though root-cause analysis surfaced this risk, how to address it remains less clear. Similarly, one turkey flock tested at the farm can test positive for the presence of *Salmonella* and pose no public risk, while another that also tests positive poses a risk, and producers are still searching for the distinguishing factor or factors. Siemens noted Cargill is working with the Agriculture Research Service (ARS) at USDA to further research and address such issues.

Responding to questions about the steps Cargill has taken to lower the risk of *Salmonella*-related outbreaks, Siemens explained Cargill has done enumerations for *Salmonella* across all its food items to assess the dose-response relationship it should target. In doing so, Cargill seeks to keep "high-risk products from the market."

Thomas Gomez, APHIS, Veterinary Services Approach to Epidemiologic Investigations

Thomas Gomez, APHIS Veterinary Services (VS) Liaison to CDC, presented on APHIS Veterinary Services' approach to epidemiologic investigations and how VS' on-farm epidemiologic investigation capability and resources can be leveraged to promote pre-harvest food safety. He described the four types of epidemiologic investigations VS conducts beyond established legacy programs, focusing primarily on investigations initiated by public health concerns associated with foods of animal origin. Gomez again touched on the [FSIS/APHIS MOU](#), emphasizing that VS' on-farm investigations under this memorandum are voluntary on the part of the producer or company, are non-regulatory, and data collected are intended to be confidential. He also outlined the VS' mission and mapped its role in supporting pre-harvest food safety, including the establishment of best practices to improve food safety as an expected outcome from on-farm investigations. Gomez noted that since VS does not have authority to go on-farm for food safety purposes, VS needs to continue to partner with industry and producers in a collaborative non-regulatory manner and VS believes its on-farm investigations will be most effective when the producer or company choose to participate on a voluntary basis. Lastly, as a historic example of how root-cause analysis has been used and the associated value, Gomez reviewed the Pennsylvania *Salmonella* Enteritidis pilot project the APHIS/VS collaborated on with the poultry industry.

A participant asked, when animal analysis is done on-farm to determine if livestock is carrying potentially harmful bacteria, who owns the livestock? Another participant answered it depends on the animal, and agreed, along with others, that the question of ownership could be critical to voluntarily engaging farmers in the process. The issues of livestock testing provoked others to wonder if carrier animals would be deemed contaminated and therefore unusable in production and what, if any, legal ramifications this could have?

Improving the Effectiveness of Root-Cause Analysis for Food Safety

Drawing on the case example presentations and pursuant discussion, the group worked to articulate and gain alignment and understanding around the value of root-cause analysis; how root-cause analyses vary by context; and the challenges to implementing root-cause analysis or barriers to maximizing their full benefit. Key themes and areas of alignment from these discussions are captured below.

Variations in Context

Participants discussed how the method and purpose of root-cause analysis sometimes varies depending on the setting or industry in which it's conducted, who conducts it, and at what time. Capturing these variations helped participants note areas for clarification and where there were opportunities for alignment.

Closed facilities vs. open facilities – The group iterated that a relatively contained system, like a plant or processing facility, lends itself to more systematic and compressive root-cause analysis; while in an open and dynamic farm setting, the sheer number of environmental and other contributing factors overwhelms this type of approach.

Participants emphasized that product type usually dictates the extent to which a root cause can be identified. Processed products with longer shelf-lives can be more easily recalled, tested and traced,

while raw products are usually off the market by the time an outbreak is evident. The complexity of a product's supply chain also affects investigators' ability to trace contamination to its source, participants added. Different authorities, and therefore agencies, also are associated with different products – whether fresh or processed produce, meat and poultry.

Participants agreed many smaller and mid-sized farmers and producers lack the necessary resources to perform root-cause analysis with the same frequency or thoroughness as larger operations. So while analysis of every incident and near miss may be the expectation at some levels, it is not realistic for others.

The group also discussed how one's approach to and expectations of root-cause analysis are necessarily influenced by one's affiliation and the function and goals of his or her organization or operation. To industry, root-cause analysis serves to enhance the safety of production, is an integral part of systems management, and keep products on shelves (or return them if recalled) and protect consumers' trust in the brand. Regulatory inspectors, by trade, bring an eye for non-conformance and violations to root-cause analysis. Other, non-regulatory agencies have more interest in driving research and increasing public awareness of potential health risks. While making these distinctions, participants also acknowledged the considerable number of objectives shared across sectors.

Values of Root-Cause Analysis

Root-cause analysis can help farmers, producers, regulators and other agencies understand why a process went, or almost went, awry, and this extends to understanding what went right (i.e., where safety measures and other aspects of the production system operated as intended) and what almost went wrong, revealing vulnerabilities before they cause harm. As participants indicated, the ability to say why something happened, and show sound evidence to support the associated conclusions, is powerful and can catalyze positive change across sectors.

Root-cause analysis informs what can be done to prevent process vulnerabilities and enhance food safety. Once safety threats are identified, companies can take corrective action to minimize or eliminate those vulnerabilities. While some corrective actions may be company-specific, participants emphasized many have industry-wide, or cross-industry applicability and can result in sweeping safety improvement if shared. It was also noted that well-researched, well-communicated causes and interventions have the potential to replace “urban legends” and ineffective preventions.

From a business perspective, root-cause analysis helps companies prioritize and strategically utilize their resources to target interventions at the junctures likely to maximize risk reduction.

Disseminating lessons and effective interventions learned from root-cause analyses can spare companies from conducting redundant analysis, further increasing the practice's economic value to industry. Participants also noted that data gathered from large-scale root-cause analyses initiated in response to an outbreak or near miss can be leveraged by small and mid-size operations without the financial means to conduct routine analysis to make systems safety enhancement viable.

Root-cause analysis provides an opportunity for broad scrutiny of food production processes. As demonstrated by the case examples, root-cause analysis compels companies to evaluate all hypothetical explanations for the system(s) failure until (and ideally after) the underlying cause is

identified. Companies are able to address the multitude of other “non-root” problems or vulnerabilities and contributing factors that invariably emerge from this process.

Root-cause analysis can foster collaboration, trust, knowledge-sharing and food safety culture between and among producers, regulatory and non-regulatory agencies, and consumers. As mentioned in several presentations, cooperation and mutual curiosity between industry and government agencies during root-cause analyses has the potential to shift the practice (and surrounding relationship) from an exclusively regulatory exercise to a joint, problem-solving venture. Participants acknowledged the opportunity for FDA and CDC investigators, who are not food production experts, to learn from industry during this process and building their capacity to conduct richer analyses in other cases. Transparency around why and how an analysis was conducted and the issues and insights it uncovered can help maintain and restore consumer trust during and after an outbreak. And intra-organizational information sharing can help institutionalize knowledge and preserve best practices through leadership regimes.

Challenges Implementing Root-Cause Analysis and Barriers to Maximizing Analyses’ Full Benefit Communication – or lack thereof - was perhaps the most reiterated barrier to extracting value from root-cause analysis. As listed previously, participants identified numerous ways in which broader dissemination of data collected from root-cause analysis could improve food safety, reduce costs and lower burdens on small operations, and support cross-sector collaboration. However, participants also identified communication breakdowns at several levels.

- Industry and agencies and third-party organizations often conduct parallel analyses of the same outbreak, but findings are not always shared or compared.
- Findings from root-cause analyses are often used to develop corrective actions internal to an organization, and sometimes shared (often informally) with partners in the same market; but findings are less often translated into high-level learnings with broader applicability for various reasons (lack of time/resources, unawareness that other industries are interested in/could use the information, lack of communication channels).
- Consumers, government officials and production workers, are often critical players in implementing corrective action, but it’s challenging to communicate the results of root-cause analyses in a way accessible to non-experts.
- Industry representatives expressed difficulty articulating the value of root-cause analysis to organizational leadership, particularly absent a pressing outbreak or business concern.
- Lack of consistent mechanisms or forums for sharing information was raised, as well as those targeted to the more hard to reach audiences (i.e., small to mid-size operations).
- Participants also mentioned lack of audience can dis-incentivize information sharing. Even when data are made available, sometimes they are not used (or not apparent they are being used) by other entities possibly because companies want to disassociate themselves from a problem or don’t have resources to act on the information.

Related to communication, participants raised the *issues of liability, confidentiality and brand protection*. One of the major reasons cited for withholding or delaying the release of root-cause analysis results was fear and/or uncertainty of the backlash of disclosing that information in real

time. Sometimes companies do not understand what questions are asked for what reasons and this can breed reservations about broader information sharing. While general sentiment supported the notion of greater information sharing, this is complicated when information-gathering and problem-solving efforts are done in tandem with regulatory bodies and conflated with inspection. Beyond regulatory concerns, public disclosure could expose companies to consumer litigation. Involvement of the Department of Justice (DOJ), some said, further affects companies' disposition to participation and openness. Though others responded the DOJ is usually only involved when intentional misconduct is suspected, some remained concerned businesses could be prosecuted for decisions made in good faith based on faulty information. It was noted legal parameters also limit the information government agencies can make public, and that Freedom of Information Laws (FOILS) sometimes prevent state agencies from communicating findings to federal bodies.

The lack of a regulatory agency mandate or external requirement to perform root-cause analyses also presents a challenge. As one participant put forth, impetus and oversight for root-cause analysis, at this point, derives from industry, which can limit their use when there's no immediate political pressure or business incentive. Business considerations also drive how far root-cause analyses are pursued and how the resultant information is used. It was suggested that some companies too regularly perceive root-cause analysis conducted across a food supply chain and involving multiple public and private entities as a "one-off" exercise when really it should be considered an ongoing, iterative process, like all scientific review, and is fundamental to systems quality assurance and improvement.

On a similar note, the group surfaced as another barrier *uncertainty around who's involved at which stages of a root-cause analysis and how far responsibility extends for each entity*. Participants discussed how this raises legal questions related to due diligence and frustrates communication as organization try to determine where to "hand-off" information.

It was noted that given the *large amount of time and resource* root-cause analyses sometimes require, smaller organizations can perceive conducting them as a "big-man's" game, suited to operations of a certain scale – and particularly when they involve multiple entities and over a long duration of time. Participants agreed increased participation of small-operations in the analysis process would improve food safety, and acknowledged the challenge of including them in a way that does not become cost-prohibitive or a "check-box" exercise.

The group recognized *a general leadership void* in the cross-sector root-cause analysis arena, and connected it to many of these challenges – dissemination of lessons/ best practices, role uncertainties, etc.

Ideas for Addressing Challenges and Creating Conditions to Support Root-Cause Analysis

Throughout this discussion, participants proposed a number of potential steps to improve value derived from root-cause analysis for food safety. Preliminary ideas suggested are captured below.

- Delineate root-cause analysis from regulatory inspection and separate these processes. This separation would promote information sharing and help level competing priorities

(e.g., implementing quick solutions to get product back to market and uncovering root causes).

- Make root-cause analysis a truly multi-disciplinary initiative, particularly for the larger more complex situations, by expanding the team involved to include food engineers, scientific experts, health professionals and others.
- Develop some sort of contamination indicator test for supply coming off farms that does not necessarily lead to regulatory action. Many companies are contractually obligated by suppliers not to test their products in order to avoid Reportable Food Registry (RFR) requirements.
- Implement an animal identification system that would help producers trace contaminated livestock back to the farm and be more likely able to identify a root source.
- Conduct research to demonstrate the economic value of root-cause analysis to motivate resource allocation at the business level.
- Develop a mechanism(s) or forum(s) for sharing data collected during root-cause analysis. Consider multiple forums for different audiences (e.g., experts v. laymen, industry insiders v. outsiders, a forum for workers/ product handlers). Participants suggested this could be done by leveraging or adapting existing forums/tools such as the Global Food Safety Initiative (GFSI), trade associations, USDA Agricultural Research Service (ARS), or as part of a university extension.
- Build on current IFORC discussions around liability and confidentiality and include private sector, NGOs and other expertise.
- Implement a coaching program that pairs food safety managers with newcomers to the field and or with individuals at smaller farms/ supplier operations, without a dedicated safety division, looking for guidance.
- Develop an after-investigation summary template for the FDA that can be posted publically, a template that includes key findings but is short and high-level enough to avoid confidentiality concerns. Some participants noted a summary of remaining questions, current thinking and research needs would be useful, even when there don't seem to be "key" findings, or an identified root cause.

Root-Cause Analysis in Other Sectors: What can be learned?

The group turned next to how root-cause analysis is performed and used in other sectors, building discussion around presentations from three participants:

- [Karin Hoelzer, Pew - Root cause analysis \(RCA\) of accidents: Lessons learned from 6 case studies](#)
- [Laura Brown, National Center for Environmental Health \(NCEH\) - Identifying environmental factors contributing to foodborne illness outbreaks](#)
- Leon Bruner, Grocery Manufacturers Association (GMA) – Lessons from medical devices

Drawing from these presentations participants were asked to consider: What has worked well in other sectors and can some aspects be transferred to the food sector? What are common challenges

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to root cause analysis that are shared across sectors, and what solutions have other sectors found? What solutions in other industries may be transferrable to the food sector?

Karin Hoelzer, Pew - Root cause analysis (RCA) of accidents: Lessons learned from 6 case studies

Karin Hoelzer, Officer of Health Programs at Pew, presented findings from case studies Pew researched to determine how organizations in other sectors conduct root-cause analyses, how they disseminate and use key data, and what seems to be working well and not working well in those examples from diverse sectors. Pew researched six organizations - National Transportation Safety Board (NTSB), Chemical Safety Board (CSB), Nuclear Regulatory Commission (NRC), Consumer Product Safety Commission (CPSC), Occupational Safety and Health Administration (OSHA), and Divers Alert Network (DAN) – and Hoelzer briefly explained the approach each takes to conducting root-cause analysis and to developing recommendations for corrective action. Hoelzer compiled a list of ten key findings about root-cause analysis across sectors. These findings reflected both differences across sectors, such as the way in which root-cause analysis is defined and that root-cause analyses are conducted by organizations with and without regulatory oversight function, as well as similarities, including the types of evidence used in root-cause analysis, the broad factors considered, and certain common challenges. Hoelzer’s presentation also highlighted factors interviewees identified as key to successful root-cause analysis, and common themes that emerged from the case studies.

One participant asked if there was any difference between the implementation rates of recommendations made by organizations with regulatory authority and those without. Actually, Hoelzer explained, their research indicated recommendations were not especially well implemented across the board. She noted that non-regulatory recommendations were easier to dismiss, but some industries have been successful in leveraging other means (such as peer or public pressure) to integrate proposed changes.

Referencing the group’s earlier discussion about the challenge of pushing root-cause data and insights across the industry, another participant asked whether Pew’s research uncovered any interesting solutions to this in other sectors. Hoelzer cited the model in diving, where DAN both conducts root cause analysis of accidents and offers a hotline for distressed or injured divers through their referrals for treatment, as well as specialized insurance program. In this way, DAN collects information from nearly every diving accident which drives research they publish online – increasing its visibility and accessibility.

One participant asked how other sectors demonstrate the value of root-cause analysis. In the airline industry, Hoelzer said, the value is driven by the public’s risk aversion. The industry understands that people are tolerant of virtually no perceived risk when flying, and so investing in root-cause analysis when accidents do occur helps the whole industry recover.

Participants were curious about how the decision to conduct an analysis is made in other sectors and who makes that decision. By its governing laws, the NTSB is required to investigate every accident, although this requirement is self-imposed and not a regulatory mandate. However, Hoelzer continued, the NTSB uses a recently established triage system to determine whether a full a

root-cause analysis is warranted based on whether the accident was attributed to a known or unknown cause (a judgement made first by a senior investigator and then verified by a more junior investigator).

Finally, participants asked about where funding comes from for root-cause analysis in other sectors. Hoelzer supplied that several organizations are funded by annual appropriations from congressional committees, but added funding presented a challenge across the board given recent budget cuts. The one exception may be DAN which is funded by its insurance sales.

Laura Brown, NCEH, CDC - Identifying environmental factors contributing to foodborne illness outbreaks

Laura Brown, Acting Safe Food Team Lead for the Environmental Health Services Branch of the Division of Emergency and Environmental Health Services, NCEH, described how foodborne illness outbreaks are analyzed from an environmental health perspective, using environmental assessments. Brown explained that environmental assessments attempt to describe how the environment in a particular setting contributes to the introduction and transmission of illness agents, and involve identifying both contributing factors (i.e., reasons how illness occurred) and environmental antecedent (i.e., reasons why). Brown then described the two-tiered initiative to improve identification of environmental factors contributing to foodborne illness outbreaks launched by CDC's Division of Emergency and Environmental Health Services (DEEHS). DEEHS has developed an environmental assessment training module for state and local health program staff to improve programs' competency in this area. In addition, DEEHS launched the National Environmental Assessment Reporting System (NEARS) to collect and analyze assessment data reported by state and local health programs. Brown expressed hope that NEARS data will help identify: investigation characteristics that lead to identification of environmental antecedents and contributing factors; links between specific contributing factors and environmental antecedents; and policies and practices to prevent outbreaks. This initiative has been in place for two years and currently focuses primarily on retail food establishments, but Brown said DEEHS aims to move further into other settings.

Participants had several questions about NEARS, including whether it linked to the National Outbreak Reporting System (NORS), if data from NEARS were shared with epidemiologists, and whether and how multijurisdictional outbreaks are captured. Brown confirmed NEARS does connect with NORS and that DEEHS' intention is to make the two system complementary without collecting redundant data. She also said DEEHS, as part of its environmental assessment program, encourages environmental health workers to collaborate with epidemiologists. With regard to multi-jurisdictional outbreaks, Brown acknowledged so far NEARS does not contain many such reports, the majority of data coming from single-setting outbreaks.

Participants also had questions about the reporting process. One person mentioned NORS is struggling with incomplete reports and asked what steps DEEHS is taking to fill in reporting gaps. Brown replied that training (like DEEHS module) is one step toward encouraging environmental health specialist to collaborate with epidemiologists to collect a full dataset. DEEHS also has metrics to measure state and local programs' success at reporting as well as a quality assurance process to

check the data reported and follow up with additional on-site questions when necessary. Another participant asked whether the report questions were standardized. Brown stated that the reports include both standardized questions and space to capture unique information.

Several participants expressed interest in using DEEHS' training and reporting system for staff in their production facilities. Brown encouraged this, but noted currently their training is modeled toward restaurant assessment, although new courses geared toward production facilities are in development.

Participants were also interested in how NEARS data would be compiled and presented and whether they have yet revealed any trends or common sources of outbreak. The CDC is currently in the distillation process, Brown said, and is assessing how much the program has impacted restaurant outbreaks, though this data have not been released yet.

Some participants lamented the slow release of government-collected data. They pointed to process examples from the previous presentation, like at NTSB, where data and recommendations can be released at any point during the investigatory process, even before data are fully analyzed, and asked whether NEARS might emulate this model, or release raw data more quickly so the industry could see at least high-level trends. Representatives responded that the tri-agencies have taken strides to be more transparent and make information public more quickly, although in some cases there are legal limitations to what data can be reported. Others pointed out there's some risk associated with allowing non-experts to interpret raw data, as they could more likely arrive at incorrect conclusions. Additional encouragement was stated for releasing data and/or high-level trend analyses in order to share more potentially useful and relevant information.

Leon Bruner, Grocery Manufacturers Association (GMA) – Lessons from medical devices

Leon Bruner, Executive Vice President for Scientific and Regulatory Affairs at GMA presented on root-cause analysis in the context of medical devices, drawing from his experience in product safety at The Gillette and Procter & Gamble. Bruner described root-cause analysis as one part of a more comprehensive safety management system, rather than a stand-alone tool. Referencing a slide from Hoelzer's presentation, which differentiates predictive (before operations), operational (during operations) and investigational (after accident) investigations, Bruner tracked the development of medical devices and described how these three phases of investigation map onto management systems. Predictive investigations are used at the R & D stage to ensure a device's design allows it to do exactly as intended. Operational investigations, Bruner said, are component to the management systems set in place during manufacturing under which employees are encouraged to expect problems, report and correct them, thereby supporting quality assurance. Finally, after incident investigations (e.g. root cause analyses) are used in response to reported problems to determine what caused the failure and to define the corrective actions that will be implemented in order to prevent a reoccurrence of the problem.

The most effective management systems, according to Bruner, are driven through the culture of an organization and implemented from the top-down and bottom-up. He provided examples of how this can be done, including writing product safety metrics into the performance reviews for senior

leadership, encouraging a rich exchange of problems and solutions across business lines, and bringing in experts from other sectors to discuss critical safety concepts with staff. Emphasizing preventive and operational analysis and corrective action such as these is a strength Bruner believed the food industry could use to prevent the emergence of problems. Preventing outbreaks in the first place is always better than trying to determine causes after an outbreak has occurred.

Participants agreed a robust food safety program is built on employee vigilance and transparency, and asked how companies successfully create working conditions in which employees feel safe reporting problems. In some cases, Bruner replied, reporting is directly incentivized and employees are rewarded for speaking up when procedures are not followed and for spotting situations when products are out of specification.

Development of a Working Definition of Root-Cause Analysis for the Forum

As reflected earlier in the discussion and in pre-session interviews with participants, the term “root-cause analysis” is used variably between sectors, settings and organizations. The group agreed jointly developing a definition of root-cause analysis for the Forum deliberations would be of value to increase alignment and ensure participants are referring to the same concept during deliberations. The purpose of a working definition is not to replace current, established definitions. The group agreed their working definition would need to convey:

- Confidence in the rigor of process and data/information that is collected to do the analysis.
- Analysis is related to, but distinct from, the risk management or actions taken based on the analysis (risk assessment, risk management, and risk communication).
- Analysis results in actionable items (tailored appropriately to those taking action).
- Analysis is iterative, a tool used on an on-going basis and not solely in response to outbreaks.

Given these considerations, they arrived at the following working definition:

“Investigation methods are used to identify the “who, what, where, when, why, and how” a problem (*or non-compliance*) occurred. The goal is to determine underlying reason(s) that caused a problem and what actions can be done to eliminate the problem and reduce risk.”

This working definition combines language from existing definitions of root-cause analysis from APHIS and the American Society for Quality as well as language derived from participants. Some discussion and questions that arose during definition development are:

Root-cause analysis and “hot wash” are distinct. The CDC conducts an after-accident review colloquially know as a “hot wash.” A CDC representative explained this type of review is an assessment of the investigatory process and how it could be improved. A root-cause analysis is one type of investigatory process a hot wash may review.

Should the definition include implementation of corrective action? Participants agreed that while root-cause analysis implies the need for action and should result in actionable steps,

implementation of those steps is not part of the analysis process. In the broader context of management systems, implementation would fall under risk management, not risk assessment.

Should the definition emphasize root-cause analysis is “evidence-based” or “data-driven”? While some argued the term “evidence-based” should be included in the definition, others countered this qualification could make their definition inaccessible to certain groups (e.g., those without resource to conduct research). The group agreed the results of root-cause analyses need to be dependable and that an element of scientific rigor is implied through the description, “investigation methods.” Investigators need to be able to account for the premises that led to their conclusions.

Should the definition include the term “non-conformance”? The original definition put forth included the term “non-conformance,” but some participants believed this carried too heavy a regulatory connotation. Others pointed out that not all root causes are necessarily related to non-conformance, especially outside of a contained production system. Non-conformance, others pointed out, assumes a standard with which to conform, and root-cause analysis may identify a problem not previously taken into consideration. Although there was not complete resolution on point, participants agreed to move forward using the broader word “problems” which includes non-conformance.

Outcomes and Next Steps

The group generally agreed the opportunities and challenges highlighted in this session warranted further examination and follow-up for the overall goal of increasing the value of root-cause analysis and its contribution to improving or enhancing food safety. The group identified two challenges as priorities 1) sharing and communication of lessons learned from root-cause analysis within and between industry, agencies and the public, and 2) overcoming legal barriers with regard to information sharing. The group then preliminarily and developed short- and long-term objectives for addressing these issues.

Communication

Near-term

- Pilot an information sharing forum that brings together 5-10 representatives from industry and other sectors to exchange lessons learned in outbreak prevention and food safety related to the topic of *Listeria*, and from this forum, produce a high-level summary or key themes document to be distributed across different sectors, including the industry, agencies, and posted publically.

Long-term

- Assess the value and sustainability of the information sharing pilot.
- Develop pilot into a regularly standing practice (possibly housed in an association or the CDC or other organization).

Legal Considerations

Near-term

- Develop a project group to identify who would need to be involved in future, problem clarification and solving conversations and what the essential questions would be.
- Reach out to identified stakeholders to determine feasibility/interest of discussion

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Long-term

- Convene a meeting with the appropriate expertise to discuss the legal considerations of sharing information derived from root-cause analysis, identify barriers, and explore possible approaches to navigating legal boundaries.

Note: The Pew Safe Food Project staff, in particular Karin Hoelzer (khoelzer@pewtrusts.org), Ben Kessler (bkessler@pewtrusts.org), and Carol Conroy (cconroy@pewtrusts.org), will be leading the organization of these pilot project and any other follow-up activities to the root-cause analysis workshop, including the development of the meeting agendas, outreach to presenters and participants, and meeting logistics.

Participation Gaps

The group identified several industry groups and sectors not represented at the sessions who they believed should be involved in further discussion of this topic

- Attorneys (to discuss liability and confidentiality concerns related to RCA)
- Representation from broiler industry
- Representation from dairy industry
- Representation from insurance industry

The meeting adjourned at 12:30 pm.