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FoodSafety™ magazine

APRIL/MAY 2023

Culture and Food Safety Management Systems in Foodservice

Is CEA a Safer Way to Grow and Process RTE Vegetables?

Using Frontline Feedback to Nudge Food Safety Culture Improvements

Third-Party Gap Assessment for a Food Safety Management Program

A bnp media Publication

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FoodSafety magazine

APRIL/MAY 2023
Vol. 29, No. 2

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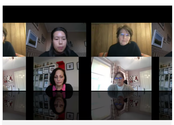

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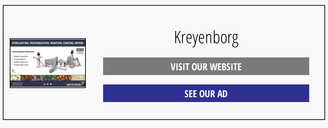

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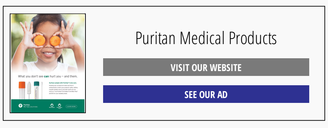

Puritan Medical Products

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SCROLL DOWN

Celebrating 25 Years of the Food Safety Summit, Your Must-Attend Event for 2023

Next month, the Food Safety Summit, the premier event for food safety professionals, will celebrate its 25th anniversary with an outstanding education program and exhibition at the Donald E. Stephens Convention Center in Rosemont, Illinois.

The Summit will take place May 8–11 and showcase three days of certificate/certification courses, workshops, education sessions, an opening Keynote with senior executives, a Town Hall Q&A with regulators, and a Closing Keynote with an all-attorney panel. The Summit's esteemed Educational Advisory Board has worked hard to craft an education program that stays on top of current issues in food safety, caters to the needs of our expanding attendee base, and keeps the demand for practical, actionable insights at the forefront.

Every educational offering on the agenda is a standout, but I'd like to highlight a few of the sessions here to whet your appetite. The Summit kicks off with certificate/certification courses on **Monday, May 8** that explore topics including food fraud prevention, Certified Professional—Food Safety (CP-FS) credentials review, and training for HACCP, among others. On **Tuesday, May 9**, our workshops series will kick off with an expertly guided session on root-cause investigations, and continue with a workshop on how to establish a robust traceability program to comply with FDA's Traceability Rule. Tuesday evening will conclude with a welcome reception on the Exhibit Hall floor, offering attendees the chance to network and enjoy beverages and small bites.

The education program on **Wednesday, May 10** will start with morning community discussions for foodservice, manufacturing and distribution, and retail. Afterward, the opening Keynote Presentation will explore how to balance risks for the safety of consumers, employees, and the environment, and feature senior executives from Wawa Inc., Maple Leaf Foods, and OSI Group. Attendees who are newer to the food safety space may wish to join the later session on "Pathogen Genomics—What Makes an Organism a Pathogen," to understand more about these organisms and their fundamental importance to food safety.

For attendees who are interested in understanding the traceback mechanisms used during a foodborne illness outbreak and how food companies fit into the picture, Wednesday's "Outbreak Investigation for Food Safety Professionals" session, led by representatives from CDC, FDA, USDA, and industry, will share profound insights. Later in the afternoon, one session will take a regulatory look forward at *Salmonella* in poultry, while another will take a look back at the lessons learned from the 1992–1993 Jack in the Box *E. coli* outbreak. The day's events will conclude with the "Food Safety Summit Gives Back" Networking Reception to benefit Stop Foodborne Illness. **Thursday, May 11** will offer a wealth of options for attendees to advance their knowledge. Morning sessions will explore the respective challenges of PFAS in food packaging, the incorporation of *Cannabis* in the food industry, and the rise of social media in food safety—all topics of increasing focus and concern. Following the morning sessions, the Town Hall with Regulators and Advisory Groups will feature a conversation and audience Q&A with top officials and representatives from FDA, USDA, CDC, and AFDO. Join this popular session for a riveting discussion with regulators and advisors on the most pressing food safety concerns of today and tomorrow.

Thursday afternoon sessions will take a look at the reality of food safety culture in retail foodservice operations, sanitary design in restaurants, and reducing food loss and waste. Also, Stop Foodborne Illness and FDA will host the seventh webinar in their food safety culture series live from the Summit on Thursday afternoon. The webinar will be livestreamed online, and Summit attendees are invited to be part of the onsite audience. The day's Closing Keynote session will feature an all-star attorney panel, moderated by yours truly. The panel will impart practical, helpful advice to attendees on how to sharpen their food safety focus at the plant and corporate levels, and stay out of the courtroom. Make sure to check out the full Summit agenda to view *all* of the great courses, workshops, and education sessions we're offering this year!

But that's not all the Summit has to offer. The **Exhibit Hall**, open from 10:30 a.m.–2:30 p.m. on May 10–11, will feature Tech Tent and Solutions Stage Presentations, interviews with select speakers live from the *Food Safety Magazine* booth, and numerous solutions and demonstrations from exhibiting companies. Lunch will also be served in the Exhibit Hall, so stop by for some sustenance and explore all of the options available to make your afternoon an exciting and informative one. Also, since there are no Summit education sessions during Exhibit Hall hours, you won't have to worry about missing anything on the agenda!

So, now that I've got you hyped up for this year's program, I'd like to let you know that registration is open—it takes just a few minutes to complete. For convenience, you can also book your hotel online. We look forward to welcoming back our returning attendees and greeting this year's new faces.

See you in Rosemont!

Regards,

Adrienne Blume,
Editorial Director

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Taylor to Receive *Food Safety Magazine* Distinguished Service Award

Michael R. Taylor, J.D., is the winner of Food Safety Magazine's Distinguished Service Award for 2023. The award will be presented at the 2023 Food Safety Summit, taking place May 8–11 in Rosemont, Illinois.

Mr. Taylor has held leadership roles in public health and food safety in government, academia, and the private sector, with a major focus on modernizing the U.S. food safety system to prevent foodborne illness. He led the U.S. Food and Drug Administration's (FDA's) role in the legislative enactment of the Food Safety Modernization Act (FSMA), the U.S. Department of Agriculture's Food Safety and Inspection Service, a consumer organization supporting and representing the victims of foodborne illness and their families.

From 2010–2016, he served as the Deputy Commissioner for Foods and Veterinary Medicine at FDA. In addition to his work on FSMA, he oversaw FDA's other food-related activities, including its nutrition, labeling, food additive, dietary supplement, and animal drug programs. Previously, Mr. Taylor was appointed Administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) FSIS in 1994, where he overhauled the agency's food safety inspection system, which was based on outdated technology to ensure that meat and poultry with pathogenic bacteria, particularly E. coli O157:H7, would be detected and killed before they reached consumers. From 1991–1994, where he worked on the implementation of the Nutrition Labeling and Education Act of 1990.

Prior to joining FDA in 2009, he spent nearly a decade in academic consulting food safety, food security, and public health policy research, second to George Washington University's School of Public Health. Mr. Taylor is a graduate of Davidson College and the University of Virginia School of Law.

Past recipients of the *Food Safety Magazine* Distinguished Service Award include Reginald Bonnett, M.Sc., Dave Bernard, M.Sc., Larry Brasher, Ph.D., Robert L. Buchanan, Ph.D., Frank Busta, Ph.D., John W. Betts, Ph.D., Darin Detwiler, Ph.D., Alan Kaminsky, Ph.D., Mark Kaysen, Ph.D., Sam N. Lacy, Ph.D., Hugh Lefferts, Barbara Martens, D.V.M., Ann Marie McNamara, Ph.D., Theodora Mueller Hinds, M.Sc., William Sperber, Ph.D., Joe Stout, R.S., Steve Tarlas, Ph.D., David Theno, Ph.D., Bruce Tompkin, Ph.D., and Dave L. Zink, Ph.D.

Food Safety Magazine
Distinguished Service Award
Presented to
Michael R. Taylor, J.D.
Deputy Commissioner for Foods and Veterinary Medicine
Food and Drug Administration
Food Safety Magazine
Distinguished Service Award
Presented to
Michael R. Taylor, J.D.
Deputy Commissioner for Foods and Veterinary Medicine
Food and Drug Administration

FDA Announces Vision for Restructuring Human Foods Program; Stakeholder Groups Levy Criticism

FDA U.S. FOOD & DRUG ADMINISTRATION

At the end of January 2023, the U.S. Food and Drug Administration (FDA) announced a reorganization plan for the agency's Human Foods Program, as well as for the Office of Regulatory Affairs (ORA), to better support FDA as a whole. The plan includes creating a unified Human Foods Program under a single leader who reports directly to the Commissioner of FDA, removing redundancies and enabling the agency to oversee human food in a more effective and efficient way.

The agency's decision comes after reviewing the findings and recommendations from an external evaluation conducted by the Boston Global Foods Institute, as well as a separate internal review of the agency's food activities sought shortly after Congress instituted last year. Under the new plan, the functions of the Center for Food Safety and Applied Nutrition (CFSAN) will be divided among the Office of Food Safety (OFS), and Nutrition functions will be unified into a newly established organization called the Human Foods Program. FDA's OFS will conduct a competitive national search for a Deputy Commissioner for Human Foods who will oversee the program. Other key elements of the proposed reorganization include:

- The **creation of a Center for Excellence in Nutrition** that prioritizes FDA's ongoing efforts to help American consumers make more informed food choices. FDA proposes to establish an Office of Critical Foods, as directed by the 2021 Consolidated Appropriations Act, within this center.
- The **establishment of an Office of Integrated Food Safety System Partnerships** that will focus on strengthening partnerships with state, local, tribal, and territorial food safety regulatory and public health partners, which have been critical to the rollout of an Integrated Food Safety System, as mandated in FSMA.
- To help support the agency's scientifically-grounded decision-making activities, a **Human Foods Advisory Committee will be established** and consist of external experts to advise FDA on challenging and emerging issues in food safety, nutrition, and human food technology.
- There will be **an emphasis on strengthening FDA's enterprise information technology and analytical capabilities** to fulfill the promises made in the New Era of Smarter Food Safety and support the improvement in workflow that will accompany these changes.
- As part of the program of restructuring, ORA's operating structure will be transformed into an enterprise-wide organization that supports the Human Foods Program and all other FDA regulatory by focusing on its critical activities—inspections, laboratory testing, import, and investigations. The change is anticipated to improve risk prioritization and the public health impact of FDA's field activities, modernize FDA's field laboratory footprint, and better integrate FDA's laboratory, data, and information technology systems. The plan has the priorities and budget for human foods related activities will be the direct responsibility of the new Deputy Commissioner of Human Foods.
- While the FDA Center for Veterinary Medicine (CFVM) will continue to operate as a standalone center, the relevant food safety activities will be closely coordinated between the CFVM Center Director and the Deputy Commissioner for Human Foods.
- FDA has formed an Implementation and Change Management Group that will develop a detailed plan to ensure the successful execution of the new structure.

On February 28, FDA announced a national search for a new Deputy Commissioner for Human Foods and provided an update on the current status of the program. Deputy FDA has taken a lead over the new vision for the program, including:

- Assessing specific functions of FDA, CFSAN, and OFPR to be unified into a new Office of Integrated Food Safety Systems Partnerships that will engage with state, local, tribal, and territorial food safety regulatory partners, looking to coordinate and harmonize best to enhance connectivity with international food safety partnership programs.
- Assessing regulatory and compliance functions that sit within both ORA and program offices across the agency to determine opportunities to streamline operations and clarify decision-making authority at each step of the inspection process, as well as to integrate new automation and information technology support.
- Determining how best to empower the Deputy Commissioner for Human Foods and leaders of other programs, along with the Associate Commissioner for Regulatory Affairs, to oversee program and field resource allocation, including publicly mapping the budget to functional activities to provide clarity on resource allocation.
- Ensuring coordination across FDA and state-operated food laboratory operations by evaluating the food laboratory programs, including the relationships, roles, and responsibilities among CFSAN, CVM, ORA, and state-operated laboratories.
- Improving FDA's risk-based inspection risk prioritization by performing an evaluation of how the Human Foods Program accomplishes risk management, particularly risk prioritization, given the multitude of demands and the scarce resources, and how this can be used to guide domestic work planning and resource allocation.
- Planning for greater enterprise transformation of certain ORA IT functions, which will be coordinated with the Human Foods Program, including the Office of Food Safety, to an enterprise-wide to create an enterprise-wide platform for inspectional and laboratory activities.
- Evaluating training programs, including for FDA investigators, to see how they can best serve the needs of FDA, regulatory partners, and industry.

Following the announcement, organizations representing consumers, industry, and state and local regulators expressed their concerns. The coalition of stakeholder groups representing Consumer Reports, Consumers Union, the Center for Science in Public Interest, Food Safety First, Food Safety Officials (AFDO), Food Safety Illinois, Consumer International Food Protection Association (IAFP), the Environmental Working Group, and the American Tinnitus Foot Institute (ATFI)—has been asking FDA to strengthen leadership at the agency by appointing a fully empowered Deputy Commissioner for Human Foods and direct her authority over the elements of the Foods Program, as recommended in the Reagan-Udall Foundation's report. The coalition of stakeholder organizations believe that FDA's plan rejects the Reagan-Udall Foundation's recommendations that the agency appoint an experienced, single leader of the Human Foods program. Coalition representatives shared their concerns in a media briefing attended by *Food Safety Magazine* on February 28.

Overall, the stakeholder representatives expressed that they have not felt included in effective dialogue about the restructuring of FDA thus far. When asked what the next steps are for the stakeholder groups, Roberta Wagner, Vice President of Regulatory and Technical Affairs at the Consumer Brands Association, stated that they would have "no choice but to wait and see." Sarah Sorscher, Deputy Director of Regulatory Affairs at CSPI, stated that

Codex Publishes Guidance on Managing Microbiological Foodborne Illness Outbreaks

Codex Alimentarius, the Food and Agriculture Organization and World Health Organization's joint food standards program, has published a detailed mapping and checklist of steps that authorities can take when a foodborne illness outbreak is suspected, as an established, and a detailed mapping and checklist of staff from the current to new organization.

The Codex Alimentarius Commission on Food Hygiene (CCFH) has released a proposed draft guidance on the management of foodborne illness outbreaks associated with microbiological hazards. The draft guidance is intended to assist Codex Alimentarius Commission member organizations in the management of outbreaks of microbiological origin, including on communication with international networks like the International Food Safety Authorities Network (INFOSAN) and notification to the World Health Authority (WHO) under the International Health Regulations (2005). The draft guidance includes "preliminary preparedness, detection, and response to limit the extent of outbreaks as much as possible. It also recommends the appropriate use of new analytical technologies, such as genomic typing methods, during an outbreak investigation.

Also described in the guidance are the roles of food safety authorities at the local, national, and international levels, and the collaboration among authorities in official network meetings. Guidelines are included for collaboration and communication with food business operators and other stakeholders before and during foodborne illness outbreaks, as well as during post-outbreak activities and outbreak management reviews. Maintenance of structures and training methods to strengthen network response are also addressed.

USDA-FSIS Strategic Plan for 2023–2026 Focuses on Innovation, Reducing Foodborne Illness

USDA Food Safety and Inspection Service

The U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) has released its Strategic Plan for Fiscal Years (FY) 2023–2026. The FSIS Strategic Plan is the foundation document for both the long-range and day-to-day operations of the agency.

Goal 1: Prevent Foodborne Illness and Protect Public Health

The first goal aims to prevent adulteration and misbranding, as well as to limit foodborne illnesses that occur because of FSIS-regulated products. Objectives identified by FSIS under Goal 1 include:

- Strengthen compliance with food safety statutes and regulations
- Achieve pathogen reduction
- Ensure labeling is truthful and not misleading
- Strengthen food safety practices throughout the supply chain
- Enhance collaborative response to foodborne illness outbreaks and other public health incidents
- Raise consumer awareness of food safety.

Goal 2: Transform Inspection Strategies, Policies, and Scientific Approaches to Improve Public Health

The desired outcomes of Goal 2 are to improve food safety through the adoption of innovative approaches and technologies, and to optimize data use at every level of agency decision-making. Objectives identified by FSIS under Goal 2 include:

- Advance and adopt innovative regulatory approaches and technologies
- Foster the adoption of advanced scientific techniques
- Improve the integrity, accessibility, and utility of data
- Strengthen data analyses and evaluations
- Optimize the agency workforce to prepare for decision-making.

Goal 3: Achieve Operational Excellence

The desired outcomes of Goal 3 are to sustain and advance an adaptable, high-performing, and engaged workforce, as well as to optimize service delivery. Objectives identified by FSIS under Goal 3 include:

- Expand recruitment and increase retention for mission-critical positions
- Enhance employee training and professional development
- Ensure equal opportunity, civil rights, diversity, equity, inclusion, and accessibility in the work environment
- Enhance effectiveness and efficiency of key business procedures
- Improve customer service
- Transform business infrastructure and information technology.

FSIS will implement the Strategic Plan by using its performance management framework, which includes developing and reporting processes approved by the agency's executive governance process. FSIS will regularly track and monitor progress, ensure FSIS meets intended targets, and make timely and necessary adjustments to best optimize or remediate.

FDA Sets Action Levels for Lead in Baby Foods as Part of Closer to Zero Initiative

FDA has announced new recommended action levels for lead in certain processed baby foods. The proposed action levels support the Closer to Zero initiative to continually reduce babies' and young children's exposure to toxic heavy metals from food.

The FDA draft guidance, titled, *Action Levels for Lead in Food Intended for Babies and Young Children*, covers processed foods such as product packaged in jars, pouches, tubs, and boxes—intended for babies and children less than two years of age. Lead may be present in the aforementioned foods because the agricultural commodities the products are derived from—fruits, vegetables, grains, and animals—take up contaminants in the environment, as well as nutrients.

The draft guidance sets the following action levels:

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards and puddings, and single-ingredient meats
- 20 ppb for single-ingredient root vegetables
- 20 ppb for dry cereals.

FDA estimates that the new action levels could reduce babies' and young children's exposure to lead from the current levels by 24–72 percent. Action levels are not intended to set the tolerable limit for industry to adhere, but are meant to cause manufacturers to implement agricultural and processing measures to lower lead levels in food products.

Although not binding, FDA can reference proposed action levels when considering whether to bring enforcement action in a particular case. For all foods, with or without action levels, the agency will take action when it finds that the level of lead in a food is unsafe, which may include working with the manufacturer to resolve the issue and removing product from the U.S. market. FDA will monitor industry's progress in reducing the lead levels in the foods identified in the draft guidance, while ensuring that manufacturers are putting in place any needed preventive controls to minimize or eliminate the presence of lead in products.

USDA-FSIS Updates Generic Label Approval Regulations

USDA's FSIS has expanded its generic label approval regulation to include certain categories of meat, poultry, and egg products, beginning March 19, 2023. The final rule, published on January 18, 2023, also responds to comments received on the September 2022 proposed rule.

The final rule expands generic approval to the labels of products that are only intended for foreign consumers, even if such labels deviate from U.S. labeling requirements; labels of products that receive voluntary FSIS inspection; labels with "geographic landmarks"; labels with "negative" claims that identify the absence of certain ingredients or types of ingredients; and labels with "organic" claims. In the proposed rule's statement, FSIS will continue to require prior approval of labels that display "organic" claims outside the ingredients statement, including those verified and produced as organic. FSIS to educate business leaders on food safety, and we would only have great things from all students, many of whom were business leaders. Peter could teach just about anything in a way that the knowledge could be applied. He established a successful business based on this gift, and we are sure that his training indeed a significant reduction in food safety risk in many restaurants across the nation.

Hal King, Ph.D.
Author Food Safety

Steven A. Lyons, Ph.D.
Chick-fil-A Inc.

People & Places

Hargrove's L. Sunshine, Ph.D., has been appointed President of the Canadian Food Inspection Agency (CFIA).

Frank Hanson, original co-chair/co-founder of Food Safety and Response at FSR on February 24, 2023. **Donald Prater, Ph.D.**, is serving as Acting Director of Office of Food Policy and Response at the time of publication.

International Food Protection Association's (IFPA) Chief Food Safety and Regulatory Officer, **Jennifer McEntire, Ph.D.**, will step away from her role with the association on May 31, 2023.

The National Association of State Departments of Agriculture (NASDA) Foundation has hired **Chris Jones** as Senior Director of the NASDA Foundation. Also, NASDA has announced Shannon Dougherty of Agriculture **Wayne Archer** as Vice President of the organization.

Mike Bastian President and Chief Executive Officer of the Cypress Foods Group of companies has joined the board of directors of the Cincinnati-founded Innovative Center for U.S. Dairy. He replaces Schreiber Foods Chair **Mike Hedahl**, who served as the Innovation Center's chair for five years.

Brandon Voelker has been promoted to Senior Director of Food Safety at Conagra Brands.

Church Brothers Farms has appointed **Victor Soto** as Food Safety Manager and **Maria Chavarria** as Food Safety Specialist.

Food Safety Consultants, Inc. has hired Jeff Rosenberg, Ph.D., as Senior Food Safety Scientist.

Katerina Kimmerling, Ph.D., has been named Deputy Executive Director and Chief Science Officer at AOAC International.

Marine International Inc., a member of the Ecovate family of operating companies, has appointed **Sean Emerson** to President.

PPC named **Pelissa Wiens** as its new Packaging Systems Global Technical Director in January 2023.

JBS, an organization supplier specializing in value-adding specialty fat and oil, has hired **Rod Roy** as Product Manager.

Cindy Farm Fresh Foods has promoted **Mark Kaunitz**, former Chief Operating Officer and Senior Vice President of Dairy Farm Fresh Foods, at the subsidiary's new President. Kaunitz's promotion follows the previous appointment of **Samuel Dudas** in the new CEO of Cindy. The parent company of Dairy Farm Fresh Foods.

IFT Board President, **Chris Downs, Ph.D.**, has assumed a new role as Director of the Food and Beverage Accelerator (Eddie) Tasklayer program funded by the Australian Government Department of Education and hosted by The University of Queensland.

BizTracks

Radylaxion Could Replace Pasteurization, Uses UV for Microbial Inactivation of Liquids

Radylaxion, a technology that uses UV light to inactivate microbes in liquids in a radiation system from Danish company Jurs Sensor Technology, has been commercialized in the United States. Radylaxion's technology is a radiation system that uses UV light to inactivate microbes in liquids such as tofu whey, juice, and soy and meat broth. Radylaxion's new radiation system will be able to treat 40,000 liter of industrial scale liquid per hour. Radylaxion is a non-thermal treatment technology based on UV that inactivates microorganisms but is gentle on enzymes, proteins, amino acids, and vitamins. Radylaxion provides higher quality, increased yields, improved production flow, less cleaning and waste, and better energy efficiency.

Technology Achieves Pathogen Reduction Milestone in Wheat Flour

Energis Solutions™ has released results from a recent validated study confirming its pathogen reduction technology, GuardiAn™, which is highly effective in reducing common pathogens found in the wheat milling environment. The study showed that GuardiAn™ achieved 5.25 percent logs of kill rate on dry-inoculated samples, without leaving chemical residues or altering the functionality of wheat flour. As part of the study, Food Safety Net Wheat was inoculated with Salmonella and E.coli O157:H7 and was then treated using Energis Solutions' GuardiAn treatment technology. Results showed an average 5.0 log reduction of E.coli and an average 5.50 log reduction of Salmonella when analyzed against the non-treated control samples.

Sabert Commits to Eliminating PFAS from All Products by End-2023

Food packaging manufacturer Sabert Corporation has pledged to remove its intentionally added PFAS (per- and polyfluoroalkyl substances) from all products by the end of 2023. The company's resolution follows a recent announcement from its competitor Dart that it will remove and discontinue all intentionally added PFAS, including more than 40 that are verified by the Biodegradable Products Institute. More than 75 percent of Sabert's fiber products already meet this criteria, and the company is actively working to eliminate PFAS from all products in the upcoming 18 months. Sabert is headquartered in Greenville, Texas, which is developing exclusively PFAS-free packaging products for the North American market and beyond.

ONLINE & OF NOTE

Online Produce Safety Handbook for Northeastern Buyers

The Northeast Center to Advance Food Safety (NECAFS) recently announced its new online Produce Safety Handbook for Buyers. The handbook is formatted as an interactive website that clarifies the complex landscape of food safety regulations and standards across 12 different states in the U.S. Northeast. The Produce Safety Handbook for Northeastern Buyers is a resource for produce buyers and food safety professionals. The site provides an interactive regional map, farm production statistics by state, a glossary of terms with common audit and inspection language, state inspection and audit information displayed with simple charts and tables, and regional content in a step-by-step display.

Buyers included in the handbook are Maine, Massachusetts, New Hampshire, Vermont, New York, Rhode Island, Connecticut, Delaware, New Jersey, Pennsylvania, West Virginia, and Maryland. Presently, NECAFS published an online version of the handbook, but based on comments, tailored to small and very small producers that are required to comply with FDA's Preventive Controls for Human Food Rule under FSMA.

By John Butts, Ph.D., Principal, Food Safety by Design LLC; Gina Flores, M.B.A., Vice President of Food Safety, Rust Foods, and Bob Lipna, M.Sc., Food Safety and Quality Assurance Consultant

Image Credit: Eric Tucker, Cal Poly, SLO

Transferring Needed Experience and Skills to the Next Generation

Generational changes, as part of normal turnover in a company, catalyze the need for knowledge transfer—but how can this best be accomplished?

"That's how we've always done it!" may actually be a much better rallying cry than we might be willing to credit. Let us use that paradigm to lend some context to ensuring that the right food safety behaviors and practices are properly transferred from "those who know" to "those who need to know" (whether they know they need it or not). Understanding how and why something is "done that way" goes a long way toward driving positive change while simultaneously minimizing risk to public health.

This article will provide many proven lessons in this regard, particularly for when a long-tenured subject matter expert (SME) leaves an organization. How is that person replaced? The suggestions and tenets shared in this article are founded on proven scientific principles and actions, and on instincts honed by long-term experiences in the food business. We share best practices, not just opinion, to increase the organization's effectiveness at planning for and executing a transfer of experience and skills from one generation to another.

The Need for Skills Transfer

All companies run across the need to replace their revered SMEs. When the person who knows "everything" and has been around "forever" decides to retire or leaves the business, companies must find a way to replace this lost knowledge. Odds are that this expert holds significant "legacy knowledge" inherent to a long-tenured career, and the expert has learned it, and can apply it, at all levels of the organization. The SME is typically equally comfortable on the production floor as in the executive suite, and on any work shift. The SME is involved in many integral touchpoints, and legacy knowledge transfer occurs almost seamlessly.

Generational changes, as part of normal turnover in a company, can also catalyze the same need for knowledge transfer. This seems particularly germane these days with such a large percentage of "boomers" leaving the workforce, along with the effect the COVID-19 pandemic has had on workers.

Take the example of the "spice room person," the revered SME of their space. They are usually highly tenured and experienced, and run their domain (the spice blending room) with the proverbial iron fist. All batches are correct, all of the time, and all audits are passed. However, when this person is on vacation, all kinds of problems occur. Is that their fault? Is it due to a lack of training? Is it due to a lack of accountability on the part of their management? Or are the underlying food safety processes and food safety culture not supportive of this kind of "generational" transfer?

What are the benefits the "spice room person" has been bringing, and therefore need to be replicated, captured, and engrained in the organizational fabric? These may relate to preventive controls, risk analysis, and problem solving, all essential for the handling of "special causes" (i.e., mistakes), as well as "common causes" (addressed by strong, established processes).

In many companies, the revered SME patrols the frontline and the production floor at will, and with ease. Since this SME is likely in regular communication with senior management, this means that the SME is a great communication conduit between the senior leaders and the frontline workers. As two-way communication with the frontline is often one of the weakest links in driving change management, this is a "gap" that will need attention once the SME leaves.

Also, the SME is likely the "keeper of the why." The SME has been around long enough to have a thorough knowledge of how and why processes and practices have been changed over time. When the SME leaves, the organization needs a gatekeeping system to ensure that existing systems and processes are not changed without an understanding of the underlying reasons why they exist in their current forms. The underlying conditions and inherent assumptions may indeed have changed, but these need to be recognized and understood before straying too far from "we always do it that way." Gatekeepers can be, for example, mid-level managers who approve process changes before they are implemented—and who make changes only with a complete understand of the "why."

Why is "why" so important? Legacy solutions are *real*. If they are discarded or given too little attention, then the organization is likely not to notice for quite some time—and, when it does notice, it may be too late to prevent a costly recall or product loss. That insidious result can be unrecoverable. It is always worth remembering that changes to systems and cultures are journeys, not single events. For example, when the food industry develops a best practice process, it usually takes years, if not decades, for it to become the "norm" across many organizations and involves trial and error. Literature provides examples of why we end up with specific best practices; therefore, it is important to have a system in place for transferring knowledge in the organization, particularly as a revered SME is exiting. We are sharing these approaches to provide a contrast later in this article with other, better methods:

Write It Down

- Report files, corrective and preventive action (CAPA) files, third-party audit reports, standard operating procedures (SOPs), and sanitation SOPs—all are incident and data captures that can be useful for comparison in the face of a problem
- Established protocols, work instructions, ways to execute tasks on the manufacturing floor (as opposed to relying on someone who "should know")—all can help ensure proper practices, even when the food industry evolves
- Formal reports, scientific reviews, after-action reports, process-based manufacturing operating procedures—these might include the historical basis and the "why" (but typically do not), and can serve as effective pattern captures for application to new problems.

Shadow the SME

- Meet and connect with the SME's network outside of the company
- Ask the SME to give webinars and seminars
- Take gemba walks with the SME around the plant
- Invite the SME to share stories (e.g., over Friday lunches or seminars on key subjects).

Hang on to the SME as Long as Possible

- The organization should expect (and hold accountable) the SME to continue to communicate with the frontline, and the organization should recognize and reward this
- One of the downsides to hanging on is that it avoids the inevitable, and reinforces the belief that the SME is the source of all solutions to food safety issues (which likely reinforces that 'senior management' is the source of all solutions also).

These approaches can be somewhat beneficial, but reading through reports and listening to long-winded stories may not be the most appealing methods of knowledge transfer for some people. Also, ego has a tendency to get in the way of successful knowledge transfer. Many people believe they can do better, or would rather not be 'biased' by the past, or do not take the time to reflect, a paradigm shift in thinking is needed. The truth is that losing a revered SME is a burden for an organization, and a company must be ready for this inevitable scenario.

> **"Effective use of root-cause determination within the organization can catalyze transformational and trans-generational information flow and solve problems."**

The Fundamentals of Risk Assessment and Problem Solving

The essence of generational transfer (e.g., losing a revered SME) is actually all about risk management. Food safety risks to an organization continue to evolve as new ones arise. The organization must be capable of identifying and managing these risks. The culture of the organization must be conducive to problem solving.

What are key characteristics of good problem solving? In general, the best solution is likely not solving the problem at the level of the problem itself. Problems also differ in their makeup—some are logic-based, some are algorithm-based, some involve troubleshooting, and some involve design.[1] Effective use of root-cause determination within the organization can catalyze transformational and trans-generational information flow and help solve problems.

Keep in mind that technology (e.g., whole genome sequencing) is a driver of change and, hence, new problems. New technology does not change the underlying food safety need for public health protection, however.

Recognize that the SME is likely extremely adept at identifying food safety risks to the business. These include current and real risks, as well as new and emerging risks. Risk identification and management are business-critical functions. When a revered SME leaves, it should be a reminder of the need to abandon the view that decisions should be made by a single authority (e.g., the SME or even the CEO). Rather, the sources of solutions must include a broader lenses.

A Paradigm Shift

We began this article with the admonition that the claim, "That's how we've always done it!" may deserve more credit. Consider Sisyphus, the Greek king forever forced to push a rock uphill, only to have it roll back down again. Suppose that this rock represents the legacy knowledge of a revered SME. Might the fact that it is difficult to get rid of that collective food safety knowledge be a good thing?

The company evolves, as does the "why we do what we do." Establishing why doing things 'the way we always have' helps set fundamental principles; it does not need to be a reason for change. A transparent understanding of why and how we got here is crucial to examine why some long-ingrained practices should remain in effect.

Technicians and Supervisors

Often underestimated in their impact on knowledge and generational transfer are the floor-level employees and middle managers. They are the ones who can (and are expected to) execute a strong CAPA program, and they affect cost of poor quality (COPQ). Empowering this frontline is critical. All levels must have the same sense of pride, ownership, and responsibility to address matters that are out of process control. Seemingly small practices, such as daily huddles for enhancing communication and ongoing education to increase skills and knowledge, can go a long way.

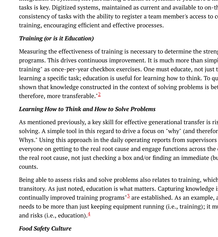
The Value of Data

Risk assessment and problem-solving absolutely should be predicated on data. There is a need to be data-driven, with the right sense of urgency, the ability to obtain and acquire data, and the ability to assess and communicate learnings from this data. The CAPA process and COPQ data help define patterns and identify root causes. Process improvement and process control are critical. "Data can drive… a predictive state where actions are taken in advance of… a high-risk situation."[2]

Best Practice Technology to Capture Information and Learning

Thanks to improvements in electronic data collection, machine learning, and overall software capabilities, best practices for food safety operations now include using connected worker platforms. These platforms enable information to be literally at the fingertips of the on-the-floor team member. Think of the many points that individuals can access information by way of a tablet, phone, scanner, etc. The connected worker merely needs a "hook" to capture it from the source. Once yet, to scan a QR code that provide all of the required information

FIGURE 1. Example of a Tablet-Based Connected Worker Platform



The 'connected worker' has ease of system access for immediate availability of information to the team; this also has huge benefits in limiting the need for off-floor time in training. Look at this as a means of preserving 'why' and as the creation of a centralized digital library that includes work instructions, videos, and troubleshooting solutions, all easily viewed on the floor using tablets.

The integration of data from disparate sources is the critical step in creating a 'connected worker.' It is about integration of systems, not just having a bunch of systems. If you have a multi-plant operation, standardization of tasks is key. Digitized systems, maintained as current and available to on-the-floor team members, ensure consistency of tasks with the ability to register a team member's access to content and register on-premise training, encouraging efficient and effective processes.

Training (or is it Education)

Measuring the effectiveness of training is necessary to determine the strengths and weaknesses of the training program. This drives continuous improvement. It is much more than simply having 'GMP training' or 'HACCP training' as once-per-year checkbox exercises. One must educate, not just train. Training may be useful for learning a specific task; education is useful for learning how to think. To quote David Ionassen, "Research has shown that knowledge constructed in the context of solving problems is better comprehended, retained, and therefore, more transferable."[2]

Learning How to Think and How to Solve Problems

As mentioned previously, a key skill for effective generational transfer is risk identification. Its cousin is problem solving. A simple tool in this regard to drive a focus on 'why' (and therefore, root cause) is the use of the 'Five Whys.' Using this approach in the daily operating reports from supervisors and key operators can help educate everyone on getting to the real root cause and engage functions across the company to create solutions. Getting to the real root cause, not just checking a box and/or finding an immediate (but unsustainable) solution, is what counts.

Being able to assess risks and solve problems also relates to training, which in and of itself is fleeting and transitory. As just noted, education is what matters. Capturing knowledge is useless unless 'effective, robust, and continually improved training programs'[3] are established. As an example, a preventive maintenance program needs to be more than just keeping equipment running (i.e., training); it must also prevent food safety hazards and risks (i.e., education).[4]

Food Safety Culture

It is also critical to have the structure, practices, and motivation to build the right food safety culture, independent (yet inclusive of) revered SMEs. Having the right food safety culture creates engagement with team members. It involves reporting relationships, especially to define tasks and expectations, and holding the right people accountable. It includes identifying best practices and bringing them in from outside the organization when necessary, as well as the value of wide and diverse engagement and proactive and continual improvement. The best system can be undercut if the underlying culture is poor. Culture eats strategy for breakfast!

Teamwork

Teamwork is the deployment vehicle for the transformation of culture. Teams can go beyond a given individual's knowledge, experience, and skills. Teams can be more creative than individuals. Teamwork can be a great way to develop people and managing risk, and having the organizational skills to solve problems with a team-based approach. Help keep the legacy knowledge rock from being pushed over the cliff. Butts, John. "The Journey to a State of Control." *Food Safety Magazine*, February/March 2019. https://www.foodsafetymagazine.com/article/982-the-journey-to-a-state-of-control.

> **"Best practices now involve becoming data-based, identifying risks, and managing risk, and having the organizational skills to solve problems with a team-based approach."**

The Generational Transfer

If handled properly, generational transfer is not a single event, nor even an event itself. "That's how we've always done it!" can become a very effective rallying cry—for not changing without identifying 'how we got here.' Hence, migrating from current practices can be accomplished with eyes wide open, knowing there is risk. Checking ego at the door facilitates this process.

Note that the above tools and principles will never truly take the place of a revered SME. If an organization has another SME, then that person should be provided with support and resources. The above tools and principles will also never replace the 'human element'—i.e., a SME personally connecting with other employees. This is both valuable and honorable.

Generations will continue to move out, and in, within the workforce and the workplace. How can this inevitable process be made most effective? If you do not have a systems-based approach to adjusting to a new generation coming in as reversed SMEs leave, then you are at risk of COPQ costs, higher turnover, and higher salaries. These issues may not be noticed for some time, making recovery more difficult. This is why it is beneficial to make the right investments sooner rather than later.

What can an organization do to succeed? Keeping the standard data-capture and report-writing in place and working with the SME to tap as much knowledge as possible is a start. Then, get independent of all of that. Best practices now involve becoming data-based, identifying and managing risk, and having the organizational skills to solve problems with a team-based approach. Help keep the legacy knowledge rock from being pushed over the cliff. ■

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By Richard Brouillette, Director of Food Safety, Commercial Food Sanitation
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SCROLL DOWN

Image credit: ardenre79 - via Getty Images

The Cost of Hygienic Design: Considering Total Cost of Ownership

The total cost of ownership, and not only the price tag, is critical to consider when evaluating the hygienic design of equipment

'Hygienic design is expensive!' This sentence has often been used as an argument against purchasing equipment with improved hygienic design—but is letting the initial purchase price drive purchase decisions the right choice? Frequently, the rebuttal against the higher cost with some hygienic designs is that cost can be avoided. After all, the cost of a recall is estimated to be around €1.67 million (or about $1.8 million[1]), and recent recalls have been estimated to cost companies even more. In this article, the authors present a different way of looking at the cost of equipment. The total cost of ownership (TCO) should be considered when purchasing hygienically designed equipment. Methods for applying hygienic design to legacy equipment are also included.

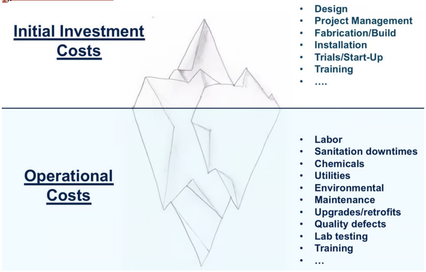
It is common for equipment to be purchased as part of a project, so we will use a project framework to discuss the cost of hygienic design. First, the project team should begin by identifying criteria it expects to meet with the equipment. Examples of those criteria are:

- **Product risk.** We often think about the food safety hazard an equipment may pose—e.g., a foreign material contamination risk from metal parts coming into contact with one another. The assessment should also include damages that products may cause to the equipment—e.g., product with low pH may prematurely damage the material of construction of the equipment. When equipment is expected to last years and decades, risk can be an important factor to consider.
- **Cleaning.** This should include not only the types of detergents and sanitizers that will be used to clean the equipment, but also the cleaning window and resources needed to clean the equipment. Resources to clean equipment should also include the resources needed during changeover, especially if some level of cleaning is expected to take place during production. The time needed for periodic equipment cleaning (PEC) tasks will also need to be considered.
- **Location.** This aspect refers to the materials of construction and design of equipment and the equipment's location in the facility. For example, a case packer made of painted soft metal may not last long in a wet environment where 'harsher' detergents and sanitizers are used. In a situation like this, equipment made of stainless steel will last longer and may not present the microbiological risk of rusted equipment.
- **Maintenance.** Similarly to PEC, preventive maintenance tasks should also be considered. Equipment with simpler designs and fewer parts are likely to require less periodic tasks.
- **Other.** Companies may also have their own additional criteria based on past experience.

Once all of the criteria are established, the team can utilize equipment design checklists to help assess the designs of different options available. Such checklists include the 2021 NAMI Equipment Design Checklist and the CBA (GMA) Equipment Design Checklist.

The next factor to consider is the price tag of equipment or different models of the same equipment. Given the criteria mentioned above, it is important to remember that price is only one aspect. It is often only the tip of the iceberg or only a portion of the TCO. Cross-functional teams are well-positioned to assess the total cost (Figure 1).

FIGURE 1. Initial Investment Costs vs. Operational Costs

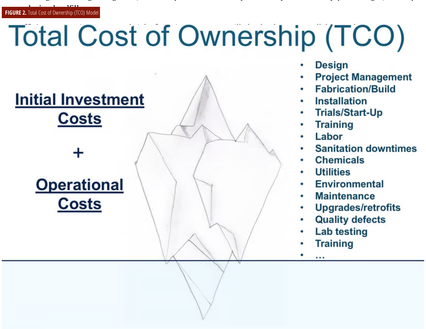


The investment costs include the price of the equipment, as well as other costs such as project management, installation, contingency, and trials (which may be considered a one-time cost). Other costs included in the original project that are not truly one-time costs but rather reoccurring costs may include training costs for the initial training of operators, sanitors, technicians, etc. As Figure 1 shows, there are many operations costs, or ongoing costs, required to run the equipment. When making decisions between different models of equipment vs. the cost of improving the hygienic design of equipment, these other operational costs should be considered. As shown in Figure 2, when considering the operational costs over the lifespan of the equipment, the additional investment in a better design may be justified. Conversely, considering these other factors, a more expensive model may have lower operational costs and be a better option.

Examples of operational costs include:

- **Sanitation windows.** A simpler, better hygienic design is likely easier to clean. Not only does 'easier to clean' mean more effective cleaning, but it also usually means faster cleaning. Shorter cleaning windows mean more products can be produced, which translates into increased profitability.
- **Time and resources required for training.** New operators, sanitors, and maintenance technicians must be trained on the equipment. More complex equipment models will require more training time.
- **Downtime.** Regardless of whether this is for planned downtime, such as routine and periodic cleaning and maintenance, or for unplanned downtime, it allows less time for production, thereby affecting revenues and profits.
- **Sustainability.** In the sense of environmental impact, an equipment may require less chemical and water for cleaning and during changeover, but it may also have less replacement parts and simply last longer, thereby

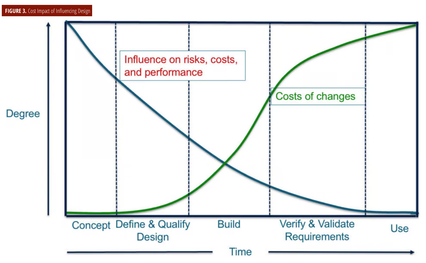
FIGURE 2. Total Cost of Ownership (TCO) Model



TCO will consider the overall cost throughout the lifecycle of equipment. Amongst other benefits, it will help guide the right decisions.

As shown in Figure 3, it is also important to highlight that hygienic design must be considered early in the project (concept and design stages) to keep the cost impact of required design changes low. In an initial project stage (in the design phase), the influence on hygiene or food safety risks, costs, and performance is high, while the cost impact of changes will be low. The more the project progresses, the lower the degree of influence will be as the cost impact increases—in particular, after equipment is built.

FIGURE 3. Cost Impact of Influencing Design



One of the most important deciding factors should be the opportunity presented by a design that will require less time to clean, fewer periodic tasks, less time to start up, etc., thus allowing more time for production (i.e., making sellable products). The revenues and profits that could be generated by optimizing the design of the equipment will help reduce unplanned downtime, quality defects, and the amount of resources required to accomplish the different tasks that will justify the higher price tag a piece of equipment may have.

The same concept applies to legacy equipment. While it may not be necessary to replace a piece of equipment, it may be time to hire the original equipment manufacturer (OEM) to rebuild it after years of operation. This is a good time to discuss design modifications with the OEM to reduce operational costs. Many OEMs will have made design modifications that could be considered for legacy equipment.

Another approach for managing the hygienic design of legacy equipment is for the plant to use a continuous improvement process to make small, incremental changes. These small hygienic design improvements add up over time and can reduce the food safety risk in a food manufacturing plant. While there are many ways to accomplish this task, a best practice is to leverage an internal food safety team.

If a plant does not have a cross-functional food safety team, then one should be assembled. That team can review food safety data each week—items like pathogen environmental monitoring results, sanitation pre-operation success rate, APC or other microbiological results, PEC tasks, and many others. The cross-functional team will react to out-of-specification results and be a go-to team for food safety. It is a natural fit to leverage this team for hygienic design improvements. Many of the problems they will be correcting have roots in poor design. This team should be trained on what hygienic design is and how to apply it to legacy equipment. They can use hygienic design checklists to rate the equipment already in place. From these evaluations, the team can create a list of hygienic design improvements to tackle. Hygienic design improvements will then become a weekly agenda item. It is important that the team understands that it cannot fix all design flaws. By staying focused on what *can* be improved, this team will be able to reduce food safety risks by improving the design of legacy equipment.

In summary, having a cross-functional team that agrees on the criteria the equipment will need to meet early in the project will help prevent costly modifications later, or will lead to lower operational costs. The TCO, and not only the price tag, of a piece of equipment is critical to consider when making decisions that will lead to changes in operation. Hygienic design is not only considered when purchasing new equipment; it should also be applied to legacy plant equipment to reduce overall food safety risk.

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Controlling Foreign Object Hazards in Food

The reliability of control systems should align with the criticality of the process they control. Learn how implemented the right level of control has helped food processors.

Foreign objects (FO) contact in the food industry requires never-that-one-perfect-product-or-the-end-of-the-world. Unacceptable contamination of FO impact product quality, customer satisfaction, and brand reputation. Food processors must take every precaution to prevent FO from entering their products. Some FO are inadvertently introduced into the product during ingredient, and packaging or the complete manufacturing process. Some FO are deliberately introduced into the product, and the rest are unknowns.

Food processors have a vested interest in the food manufacturing supply chain. Food processors are responsible for the manufacture of the food, the quality, and the safety of the product. Food processors are responsible for the food, the quality, and the safety of the product. Food processors are responsible for the food, the quality, and the safety of the product. Food processors are responsible for

By John E. Haugh, Founder and Managing Principal, Sheinbridge Inc. and Professor of Practice, McCoy College of Business, Texas State University, Dr. Dwight Smith, Professor of Supply Chain Management, Texas State University and Lawrence Pitts, Professor of Sustainable Agri-Food Systems, University of Lincoln

Global Food Chain Traceability—Reflections on the Past, Present, and Insights into Future Directions

Traceability is developing and maturing, but much remains to be tackled

Traceability determines how materials, packaging, products, processing aids, and so forth have moved through the supply chain. Often broken down into two aspects, track and trace, traceability systems underpin food safety, food quality, sustainability claims, and food transformation initiatives to prevent food fraud and deliver benefits.

Tracing in the ability to follow a product backward from the retail shelf to the manufacturer, the ingredient supplier, and farm origins. Tracking means following material from suppliers, such as a carton, through to the spice nuts and then all the finished products and their destinations where the spice nuts was used as an ingredient and/or during material. The practicality of traceability is also essential—i.e., the level of detail to which we can determine traceability. Granularity reflects the time element of the traceable unit—e.g., production for one week, one day, one shift, one production line, one batch, one specific product, one pack. Traceability is also dependent on zone which the traceability operates from 'one step forward, one step back' (OFOB) through to entire 'field to fork' (F2F) traceability. Traceability underpins information sharing in supply chains and characteristics of the data and the systems developed. The characteristics discussed in this article include visibility, transparency, and trust.

Global Drivers for Traceability

Figure 1 captures the many drivers of traceability in today's global food supply chains. Of note, the GS1 standards organisation does not mandate traceability for product traceability and recall potentially and specifically for food safety purposes. Instead, GS1 states that "GS1 standards are used by companies, industry associations, organisations, and implementation groups. Adoption requirements are established by buyers, data pools, pool, brick-from and repositories, eggs, wines, and more. The traceability standard also details examples of the fast-evolving need for organisations to connect with traceability systems (TTS), and to share data with TTS. Food safety regulations, for instance the U.S. Food and Drug Administration (FDA) Food Food Traceability Rule* anticipates the need for CTEs and KDEs for certain products, with full compliance mandated by January 20, 2026. The Rule is a part of the FDA's New Era of Smarter Food Safety blueprint and implement Section 204(d) of the FDA Food Safety Modernization Act (FSMA).

Regulations
Food Safety
Food Quality
Product Origin
Product Authenticity
Product Quality
Product Safety
Product Recall
Product Withdrawal
Product Recall Effectiveness
Product Traceability
Product Transformation
Product Sustainability
Product Provenance
Product Provenance
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Current States of Food Safety Cultures in Food Safety Management Systems in Food Establishments

Results from a survey of food safety professionals in food establishments in the United States

by Mark E. Mishler, CP-FS, Advisory Partner, Active Food Safety; Elizabeth A. Bell, RD/LD, Retired Food Safety Consultant; Jeffrey Gunzenhauser, Ph.D., Associate Professor, Food Science, Rutgers University; Jeffrey Hutsell, Senior Research Scientist, Ecolab; Jeff Kornacki, Ph.D., Principal, Food Safety Consultants; Jeffrey Lenz, Ph.D., Senior Director of Technical & Market Development, Ecolab; Jeff Stewart, Principal, Food Safety Consultants

Although Ecolab had sought to conduct one of the safety culture surveys in the world, there are an estimated 9 million establishments in the United States each year.[1] Additionally, Southern Illinois is estimated to cause more than 15,000 illnesses annually in the United States.[2] Ecolab's mark was low. Ecolab's survey would be a pilot study with a small sample.

Food producers, distributors, handlers, and vendors are primarily responsible for the safety of food. The role of regulatory authorities is primarily focused on ensuring food safety. A prerequisite for a successful program is the daily operation of a food establishment, the responsibility of food safety lies with management. Management has responsibility for the daily operation of food establishments and ensuring food safety. Food safety is a shared responsibility between Ecolab, Rutgers, and Food Safety Consultants, who envisaged, are that employees a more human-centered technical focus on food safety culture.[3]

Food safety culture is a fourth part of an organization's larger culture, has been defined in several ways. Frank Yiannas, Food Safety Consultants Representative Food Safety Culture Survey, Food Safety Culture Survey, Food Safety Culture Growing a Behavior Based Food Safety Management System, that it should not be viewed as a food safety program but rather be a set of ideas, beliefs, and behaviors that are a recognizable culture. Food safety is the culture. Food safety culture. It is critical to have a systems thinking approach to food safety culture. Thinkers. Thinkers emphasize their values and behaviors. Food safety culture is a sub-culture of the larger culture of the food establishment.

Having to more, Kathryn Sommers, the most frequently cited example is the recently published FDA study, Food Safety Culture Sponsors Lectures Diversity, is from Griffith, Lindsay, and Clayton. They define food safety culture as "the sum of the attitudes, beliefs, perceptions, and values that affect food safety behaviors, values, and beliefs contributing to the behaviors and attitudes with a particular food handling environment.

Purpose Statement

Researchers have suggested that an organization's food safety culture should incorporate its food Safety Management System, and that it should be a part of the overall organizational culture. Food establishments have been asked to implement and develop food safety culture. Food safety culture has been conducted by the U.S. to understand the state of food safety culture and FSMS currently practiced among the nation's leading brands.

The purpose of this study, as described in the Research Questions section of the Methodology section, Action Plan, was to understand the current state of food safety culture among U.S. food establishments, including restaurants, retailers, and food manufacturers. Ecolab, Rutgers, and Food Safety Consultants, who envisaged, are that employees a more human-centered technical focus on food safety culture. Food safety culture has been conducted by the U.S. to understand the state of food safety culture and FSMS currently practiced among the nation's leading brands.

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Survey Methodology

Survey methodology, as defined in online survey, summarized has been conducted and pilot testing was conducted. Invitee response or functional food safety professionals (directors, vice presidents, and senior vice presidents) and professionals (QA manager, food safety manager, food safety specialist, food safety technical specialist).

The survey was distributed to two constituencies. The first included questions about food safety culture and management practices and

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Using Frontline Feedback to Nudge Food Safety Culture Improvements

The objective for an organoleptic warning to improve its food safety culture is to find ways to nudge and make incremental improvements

By Lewis Jagannath, Ph.D., Founder and Principal Consultant, Nimisha Raja, Founder, Nim's Fruit Crisps Ltd., Luci Russell, Group Technical Director, New England Seafood International Ltd., Sophie Tongyu Wu, Ph.D., Senior Research Assistant, University of Central Lancashire and Project Coordinator, Cultivate, and Carol Wallace, Ph. D. Professor of Food Safety Management Sciences, University of Central Lancashire

Focusing on frontline team members is critical for improving the food safety culture of an organization. This includes tapping into their collective experience around procedures and products, ensuring effective two-way communication with their middle managers and senior leaders, making sure food safety remains top of mind, and providing everyone with the meaningful recognition that we all require for driving change. Engaging with frontline team members is particularly powerful because they are the ones who make food safety decisions and put them into action in real time.

A proven tool to improve frontline employee engagement and education is the concept of 'nudging.' In this context, nudging is any aspect of the choice architecture (the way in which choices are presented) that alters human behavior in a predictable way without forbidding any options or significantly changing their economic incentives.[1] Nudging is not asking employees to respond to questions from management teams (sometimes dressed up as 'asking for feedback'). True nudging separates the questions from the hierarchy.

'Nudges' are an extremely effective way to identify when a process may be getting out of control or when a behavior is difficult to act on consistently, and to assess whether knowledge and training are effective. This article will share real-life examples of nudging, including successful examples from a smaller company and a larger company, to provide practical learning. The examples are adapted from a *Food Safety Magazine* webinar[2] held on January 19, 2023.

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Frontline Employees: An Overview

In many industries, the frontline team members are those who interact directly with the customers or consumers (e.g., in sales or marketing). In the food industry, they are directly involved in making product, from formulation to manufacturing to packaging and to shipping. Frontline managers and supervisors must meet or communicate directly with the frontline team members.

Frontline managers make up about 60 percent of the company's management ranks, and they directly manage 80 percent of the people.[3] The frontline, therefore, constitutes an extremely large contingent of a company's workforce, far exceeding the proportion of senior leaders and senior management. Frontline team members are typically expected to manage the daily work, drive the mission of the company on the floor, and make sure that processes and products perform as intended. Thus, the main, day-to-day, lived experience of food safety culture happens on the frontline. With that in mind, when Cultivate SA has studied (in over 150 companies to date) how different hierarchical levels rate their company's level of maturity, they regularly find that frontline team members tend to rate their company's food safety culture as 68 percent *less* mature than do their senior managers.

In addition to the gap between perceived maturity levels between frontline and senior leaders, Cultivate SA has also found that the biggest gap in food safety maturity levels across many organizations (up to 78 percent) is in 'adaptability.' Adaptability reflects a company's ability to react, prepare, and respond to unexpected disruptions and crisis situations. A key to closing this gap is to get all employees engaged with each other (e.g., frontline and senior leaders). Having a good 'people system' assists in this regard by its open communication of risks and near-misses and its people-centered approach, especially when it involves frontline employees.

Why Focus on Frontline Employees?

The fact that a significant gap exists in how frontline teams and leaders view the maturity of their company's food safety culture should raise an urgent concern, as well as opportunities. Harvard Business School Professor Bill George has rightly stated, "…frontline workers are making the greatest difference in… product quality… yet they're commonly treated as a cost to be managed, rather than an asset to empower and support."[4] CEO Anthony Tjan also observed, 'Relying on the insights and observations of your frontline folks is good business.'[5]

The frontline makes up the majority of a large group, are closer to the business, directly control work processes and products, and make significantly more decisions as a group than any other group in the company. Hence, their impact on food safety culture is tremendous.

> "Another definition of nudging is a regular cadence of small, easily controlled, and easily taken actions to make a change process more effective, manageable, and sustainable."

Nudging: What It Is, and Why Use It?

Another definition of nudging is a regular cadence of small, easily controlled, and easily taken actions to make a change process more effective, manageable, and sustainable. A good treatise on this subject is the book, *Nudge*.[1] The examples in the book are taken from many industries, and the scientific concepts are directly applicable to the food industry. These concepts are founded on behavioral economics, which bridges psychology and economics to explain why people behave the way they do. Behavioral economics has been successfully applied to non-finance businesses.

Examples of different types of nudges include:

- Physical markings (e.g., arrows on floors and walls)
- Posters and signage representing daily actions
- Social interactions (e.g., handwashing stations in public so that everyone sees)
- Social normative changes (e.g., "9 out of 10 of your colleagues do this…")
- Social recognition (e.g., time off 'bank accounts').

Note that 'social' appears frequently. This is by design, as social phenomena are what set culture apart from individual behavior. Hence, effective nudging addresses and leverages the social sciences for optimal effectiveness.

Framing the Project

The webinar on which this article is based was intended to share the value of nudging in improving food safety culture from an applied food safety culture improvement project. To facilitate nudging in a company, Cultivate SA developed a tool, Cultivate Pulse, a real-time proprietary data-gathering and behavior-influencing tool that uses immediate feedback from frontline team members submitted via electronic notebooks. It makes use of machine learning, behavioral economics, and social science principles (such as nudging), and engages the frontline directly in food safety on a daily basis. It is built on social science principles to build regular interactions, with the aim of building food safety habits to improve food safety culture. Pulse nudges frontline team members to act daily and provides weekly feedback and suggested actions, which allow everyone to see their feedback in action through their managers' and organization's subsequent decision-making and actions. Cultivate SA teamed up with researchers from the University of Central Lancashire, UK, and eight food businesses to test nudging in the UK food manufacturing context. Two of these businesses participated in the webinar.

The objective for an organization wanting to improve its food safety culture is to find ways to nudge and make incremental improvements, regardless of the techniques used to do so. With nudging as a proven technique across so many industries, and the size and impact of frontline team members being paramount to the output of the company, it makes sense to 'nudge' that group of employees for better food safety and quality outcomes.

Learnings from a Smaller Company: Nim's Fruit Crisps

Nim's Fruit Crisps Ltd. produces and sells fruit and vegetable crisps that are single-ingredient, 100 percent natural, have a long shelf life, and provide a healthy everyday snack. Since its beginning, Nim's has gone from kitchen to garage to commercial factory, with the last change driving a recognition of the importance of being BRC certified. Nim's has one owner with many roles, and its change process tends to be relatively quick and straightforward in execution.

Nim's immediately saw a need to have the frontline employees engaged rather than just using a 'top-down, prescriptive, 'checkbox' approach. The company has utilized Pulse to fulfill its vision, finding ways to nudge that fit with the company culture. These nudges have been extremely effective and show that the program is an ongoing process, if implemented correctly. Although the benefits take some patience to manifest, nudging has shaped a communication rhythm by involving everyone on a daily basis. Through this improved communication and discussions about food safety, the people at Nim's realized that many of their food safety posters had become 'wallpaper,' as employees had ceased to notice them. Nim's used its employee feedback to create an ongoing conversation with its team members. As a small company, Nim's now has many more team members taking action to change and improve food safety.

In addition to measurable improvements in food safety culture metrics (an over 50 percent increase in the food safety culture maturity score), an interesting series of culture changes took place over a few months. Nim's employees are expressing less irritation with repeat errors, and in fact are handling them with humor and a sense of camaraderie. They are also enjoying a more positive vibe during meetings with the incorporation of regular recognition programs.

Learnings from a Larger Company: New England Seafood International

New England Seafood International Ltd. (NESI) is a major supplier of premium fresh and frozen fish in the UK, with about 600 employees across three sites. As is typical of a larger company, its employees tend to have specialized roles, and the company's change process can be relatively time-consuming, requiring patience as changes are identified and implemented.

Although NESI deals with many different types of processes, using the daily nudging approach for approximately 18 months taught the company that there can be many common approaches to culture changes across the company, regardless of the specific type of work involved. They have also learned that seemingly small gestures (e.g., giving out chocolate bars) can be perceived as rewards or incentives. Nudging has driven a significant amount of communication, including slogan competitions, ideas for posters, and the recognition that food safety messaging must be regularly updated to be noticed. Nudging also has supported combining food safety and personnel safety (i.e., health and safety) for approaches to improving their respective yet shared cultures, and has helped define roles at all levels for communication responsibilities.

Additional progress to date is that 85 percent of questions are answered on a daily basis, customers appreciate the approach, the program is driven by different owners at different times, and QR codes are being used to keep the program moving, especially for remote workers.

> "Changing culture at the frontline takes effort, patience, a regular rhythm of changes, and consistency over time. Stick with it."

Questions and Answers

The following are some of the questions that were addressed at the end of the webinar. We are sharing these for the additional perspective that they provide.

How can senior leaders be engaged? Believe it or not, the senior leaders and executive team also need rewards and recognition, so take advantage of this. Also, have them sign off on key performance indicators and other important metrics. Even though getting them on board to begin with can be hard, it is essential.

Why should health and personnel safety be brought on board with food safety? There is often an inherent bias that food safety is 'technical,' and hence different from personnel safety. Creating a culture that links these two silos helps reduce this barrier. In addition, having two different 'customers' creates extra work, especially when so much is shared from a culture point of view (i.e., keeping people and food safe). In that regard, 'together' offers synergies.

How can gaps in external audits be reduced? Auditors love the 'nudging' approach, so make sure that nudging efforts are communicated to them. Keep everyone informed by communicating 'nudge' learnings forward to the organization.

How should employers handle a multicultural/diverse work force? Language is of course key, so make sure that nudging questions are clear, can be understood, and can be answered honestly and accurately. Use imagery more than words. Take into account how different generations prefer to communicate (e.g., social media vs. experienced know-how), and keep iterating to improve how questions are asked and answered.

Summary

Nudging is an extremely effective way to improve food safety culture by highly engaging the frontline. Nudging through recognition, social normative messaging, and consistent rhythms and habits is a great way to achieve frontline engagement, and is proven to be correlated to food safety culture maturity improvements. Changing culture at the frontline takes effort, patience, a regular rhythm of changes, and consistency over time. Stick with it.

Three for Tomorrow

Below are three suggestions that you can immediately apply to your business:

1. Identify three people who should receive a small reward or recognition
2. List three ways that your frontline team members affect the safety of the final food product
3. Identify three simple 'nudges' that you might use to improve food safety practices.

Acknowledgment

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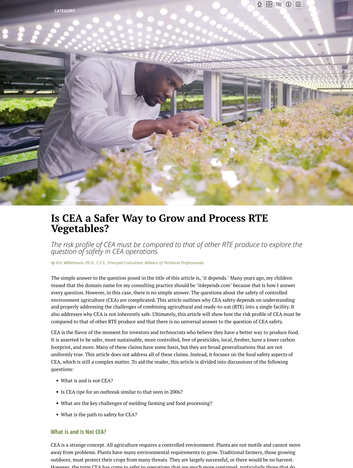

Is CEA a Safer Way to Grow and Process RTE Vegetables?

The risk profile of CEA must be compared to that of other RTE produce to explore the question of safety in CEA operations

By Eric Wittenhouse, Ph.D., C.F.S.S., Contributing Editor, Alliance of Technical Professionals

The simple answer to the question posed in the title of this article is, "It depends." Many years ago, my children teased that the domain name for my consulting practice should be "ildepends.com" because that is how I answer every question. However, in this case, there is no simple answer. The questions about the safety of controlled environment agriculture (CEA) are complicated. This article outlines why CEA safety depends on understanding and properly addressing the challenges of combining agricultural and ready-to-eat (RTE) into a single facility. It also addresses why CEA is not inherently safe. Ultimately, this article will show how the risk profile of CEA must be compared to that of other RTE produce and that there is no universal answer to the question of CEA safety.

CEA is the flavor of the moment for investors and technocrats who believe they have a better way to produce food. It is asserted to be safer, more sustainable, more controlled, free of pesticides, local, fresher, have a lower carbon footprint, and more. Many of these claims have some truth to them, but they are broad generalizations that are not uniformly true. This article does not address all of these claims. Instead, it focuses on the food safety aspects of CEA, which is still a complex matter. To aid the reader, this article is divided into discussions of the following questions:

- What is and is not CEA?
- Is CEA ripe for an outbreak similar to that seen in 2006?
- What are the key challenges of combining farming and food processing?
- What is the path to safety for CEA?

What Is and Is Not CEA?

CEA is a strange concept. All agriculture requires a controlled environment. Plants are not mobile and cannot move away from problems. Plants have many environmental requirements to grow. Traditional farmers, those growing outdoors, must protect their crops from pests. They must fertilize their crops because the soil is never fertile enough. However, the term CEA has come to refer to operations that are much more contained, particularly those that do not use soil and are in a building. Some CEA operations use peat, coconut fiber, or other inert media to replenish use water-delivered nutrients. Some traditional farmers use water to convey nutrients, too. Some CEA operations provide artificial light, and some provide enhanced carbon dioxide. Traditional agriculture must cope with weather, but this leads to various climates being selected for specific crops.

Weather elimination and enclosed buildings are probably the most distinctive feature of CEA efforts. The intent is to yield year-round crops. Enclosure of the operation is also the belief among many proponents that CEA prevents interaction with pests and human pathogens to provide a 'safer' (as opposed to 'safer') product.

The vision consumers have of CEA is often more like that of a biodome than a simple greenhouse. A biodome is a closed habitat that is built to represent a particular environment and the community of organisms that live there. Ideally, a biodome will require no inputs except light or energy for artificial light and have no outputs. This level of containment is impossible for a CEA operation. CEA operations generally have soil substitutes and nutrients as inputs in addition to light or energy to power artificial light sources. The product is clearly an output, but there are usually byproducts such as the used substitute soil and semi-consumable supplies such as gutters or floats, which are used to support the plants. Even the most automated CEA operations require some people, which limits the achievable degree of closure (Figure 1). Human intervention will be part of both farming and processing operations in CEA facilities. Foot traffic has been shown to track *Salmonella* into a CEA greenhouse.

Figure 1. Is this the future of CEA? Operators Bryan Chen Poole, left, and Jim Ko, Nobody's Farm, in their Vertical Farm, Chicago. Photo by Lynn Trapp

The level of control that is achieved in agriculture generally, and in CEA in particular, is quite variable. The range of control starts with open fields placed for some measure of control and extends to hoop houses, to greenhouses with windows that open, and then onto more closed environments, as are often found in vertical farms where all of the lighting is artificial. Ultimately, the marketplace will establish the value of the various levels of control or control based on the perceived value of the product. The safety of products will play into this valuation. A partial list of different types of CEA categories includes the following:

- Greenhouses
- Hydroponics
- Aeroponics
- Vertical farms
- Aquaculture
- Aquaponics.

Given that CEA operations are inherently partially open, it is important to consider what is necessary to mitigate potential hazards to maximize safety. This maximization of safety will require risk assessment on an operation-by-operation basis. The categories of vectors to be controlled are surprisingly similar for CEA and traditional farming when viewed in the light of the claims made about CEA. All farming operations need to consider water, wildlife, environmental factors, workers, and others as potential vectors. This list can be parsed in many ways, but a high-level examination of some categories will illustrate the similarities.

Traditional farming must properly place fields to partially mitigate air as a vector. If there is a known hazard, it is often better to relocate to a different field. Air exchange in CEA operations can make air a vector. It would be possible to use clean room technology to eliminate air as a vector, but the costs could render CEA impractical. Potentially, there is a middle ground. Risk assessment analysis is required to identify the hazards and risks associated with air as a vector for both CEA operations and traditional farming.

Water is another potential vector. Traditional farming is moving toward better control of this input with greater use of drop-with and water treatment. Agricultural water has been linked to multiple outbreaks including those associated with CEA. In the process environment, water chemistry is critical for safe operation. The control of process water chemistry has evolved with many automated dosing and control systems allowing high levels of performance and verification of performance. CEA will need water inputs. The quality of the water needed to grow nutrients to the plants is of concern. The recirculation of this water presents its own challenges with the potential to allow pathogen growth. Incidental contact with edible portions of the crops is of concern. At present, there is much discussion regarding whether and how to wash CEA product. Ultimately, these concerns must be addressed as part of a complete risk assessment profile. This assessment will need to be carried out for each operation to the extent that operations are different. Again, water must be considered as a vector for both CEA and traditional farming operations.

Amendments and seed are other vectors that both traditional farming and CEA must address in their risk assessments. Seeds are difficult to sanitize. Sterilization of seeds to prevent inoculating doses of undesirable pathogens will damage germination rates or, in some cases, prevent germination. The microbiological conditions on seeds are largely a fact of life for all agriculture. The other types of additives are largely specific to the type of agriculture. In CEA, soil substitutes are an important potential source that must be examined. Traditional farming is increasingly focused on soil amendment quality. Compost, chicken pellets, and fish emulsions have and are receiving scrutiny. Clearly, all agriculture operations must assess the risks associated with these materials and take appropriate precautions.

The impact of animals is probably the area of greatest difference between traditional farming and CEA. A building will provide better control than fences and isolation. Traditional farming continues to work on this area with various tools including outhacks, relocation, restricted product, and greater vigilance. These methods will never be perfect. Birds are the biggest remaining challenge. CEA has an advantage of the enclosed building; however, the impact of large animals can be mediated by air, where CEA is still vulnerable. CEA operations must consider their land neighbors.

CEA operations are trying to appear more 'wholesome' than traditional organic, presenting themselves as chemical and pesticide free. Insects are challenges for all agricultural operations, including CEA. There are benefits to infestations to CEA operations. Insects can be carriers of plant pests and human pathogens and can do direct damage. It appears that CEA operations must implement some manner of insect control, as CEA is not closed enough to exclude the mitigation of hazards associated with insects.

Although not a safety concern, the nutrient formulations will, in general, contain chemical components that are not on the U.S. Department of Agriculture's National Organic Program (NOP) list. At some point, consumers will become aware of the use of these chemicals and may feel deceived. Eventually, the marketplace will render judgement.

Bottom line, the vectors for CEA are largely the same as for traditional agriculture, with some differences. These challenges are not insurmountable, but planning and execution are required. CEA operations must build on the foundations of traditional agriculture. As they say, there is no 'free lunch.' Safety can be achieved only with attention to the details.

> **"The CEA industry needs to absorb the learnings of more than 30 years of traditional farming related to RTE foods in a short time to avoid problems."**

Is CEA Ripe for an Outbreak?

One would like to think that the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) would take a more targeted approach to a produce outbreak and not shut down an entire sector of the ready-to-eat (RTE) marketplace, as was done in the fall of 2006. However, in 2018, an outbreak event was attributed to romaine lettuce, and the market sector was essentially shut down. One can only speculate about the potential for CEA to be excluded from a general shutdown of a product category. Given the current state of affairs, one can also speculate about FDA shutting down the entire CEA category if outbreaks continue. FDA does seem to have moved away from this type of response. However, FDA has also pointedly asserted, in its assessments of the CEA-related outbreaks that have occurred, that CEA is not inherently safe.

Returning to our question, in 2006, the RTE spinach industry was shuttered because of contamination with pathogenic *E. coli*. Hundreds of people got sick with the outbreak provided hundreds of millions of servings. The increased consumption of raw spinach clearly played a role. The whole story is much too long to rehash here; however, three aspects stand out as relevant enabling factors for this outbreak that may apply to CEA. First, enough illness occurred to provide enough product type-specific tracback that the regulators felt compelled to act. Second, prevailing consumer attitudes were that washed spinach was safe as long as the dirt was removed. Third, the product volume was large. I am sure some would say this is a naive analysis and point out that many more technical factors were in play. However, I would ask that they bear with me for a moment while I expound on these ideas.

It is probable that commodity spinach has always caused illness at some low level when consumed raw. However, such illnesses disappeared into the background as 'unexplained foodborne illnesses.' The rise of branded RTE products made the product carriers a target and revealed the linkage of multiple cases together to identify at least a partial source or cause of the illnesses. The ability to trace back has continued to improve in the intervening years. CEA product seeks to be distinctive and, therefore, will be readily identified in tracback efforts. Outbreaks and recalls associated with particular CEA products have already occurred.

As part of its outbreak investigation, FDA concluded that many contamination risk factors for CEA are similar to those found in traditional, open-field agriculture. FDA highlighted the following requirements and recommendations for CEA growers:

- Assess and understand potential sources and routes of contamination within and around operations
- Implement effective sanitation procedures and sampling plans
- Apply the Food Safety Modernization Act (FSMA) Produce Safety Rule and Good Agricultural Practices (GAPs)
- Maintain proper temperature
- Ensure that all water used in the operation is of adequate water quality
- Perform root cause analysis (RCA) and implement appropriate preventive measures.

Unfortunately, my experience with CEA practitioners is not encouraging with regard to risk mitigation efforts. In my view, CEA growers assume that because they do not dirt and are enclosed, they are safe. This attitude seems similar to the prevailing attitudes in 2006. The CEA industry needs to absorb the learnings of more than 30 years of traditional farming related RTE foods in a short time to avoid problems. This is a large, aggressive characterization of CEA. Some CEA players are probably well down this path; time will tell. However, the blanket characterization of CEA as safe is unfounded. There are a number of confirmed risks that need to be mitigated.

With CEA growers continuing to grow, CEA remains a small portion of the RTE industry. Given that large outbreaks are primarily a numbers game, CEA is unlikely to be the focus of an industry-wide outbreak. Small RTE labels are off when there is an 'oops' moment and someone seriously increases the risk of illness. However, having undesirable acts of commission or omission, the numbers do not support the idea of CEA shutting down a portion of the RTE industry. It might be instructive to examine the number of reported illnesses from a serving side—this would normalize the comparison. Unless CEA operations can turn the corner on profitability, they are unlikely to achieve enough volume to affect entire sectors of the RTE marketplace.

CEA probably cannot cause a 2006-like event. However, CEA needs to do better as it expands. The marketplace will forgive some early mistakes as CEA gets started, however, it is probable that continuing problems would swamp the influence of marketing claims and stifle the growth of CEA.

Key Challenges of Melding Farming and Food Processing

The biggest challenge for CEA operations in melding farming and food processing is that they still have all the same challenges associated with traditional, more separate operations. As discussed above, many of the same vectors need to be considered in each half of the operation that are found in their traditional counterparts. These challenges are made more difficult by proximity. CEA business models that rely on reduced human labor may come up short. CEA operations do not have the same advantages of scale to spread overhead costs as do their larger cousins in the traditional RTE production system.

Having both farming and processing operations under one roof leads to challenges related to proximity and the need for separation. Processing safety devolves into having a high-care area where clean product is packaged. This requires traffic control. People traffic should be highly restricted. In traditional processing plants, this separation is often achieved by using the wash system to transport product from the receiving side into the high-care area. If the wash system is installed, then some other 'one-way' door is needed to act as pass-through. If intact product from the farming operation is transported into the high-care area, then the potential for contamination increases. Some operations may use a cordoned-off area of the high-care room for the initial processing of the fresh-from-farm product. This separation must be carefully examined as part of the risk assessment.

Having a farming operation onsite does not eliminate the general requirements for the processing side of the operation. Traditional plants have recognized the need to treat their operations as food processing facilities. Food processing plants have developed aggressive environmental monitoring problems where potential problem areas are sampled by swabbing on a regular basis. CEA processing will need to follow a similar path and consider many details:

- Highly third-shift sanitation
- Self administered Good Manufacturing Practice (GMP) audits
- Washing, wash chemistry control, and drying of product
- Verification and validation of sanitation practices
- Sanitary design and maintenance of equipment
- Material handling, especially packaging, to protect the high-care area
- Employee-related sanitation concerns.

Most, if not all, traditional RTE operations are cold, wet environments. *Listeria monocytogenes* is of particular concern. *Salmonella* is generally of greater concern in drier operations. Given that CEA operations can have both wet and dry areas, it is reasonable to consider the development of tailored environmental monitoring programs that address both hazards.

Control of the wash system is a traditional RTE processing facility is an important focus of the food safety program. Washing value-added product has reduced illnesses. CEA, however, has largely bypassed the washing step. Some CEA operations are grappling with the decision to wash or not wash. A handful of operations are washing as a point of differentiation. Since 2006, the science and technology behind washing RTE product have advanced tremendously. Each CEA operation must consider how the safety of its system compares to the current standards of the RTE industry as a whole to support its claims of safety.

CEA farming presents some unique food safety challenges that traditional operations do not face. The recycling of nutrition solutions as part of irrigation has the potential to contaminate an entire production facility. Given the tendency toward continuous production, there are no clean-outs or clean breaks when a problem occurs. Food safety needs to be designed into operations. The current designs of CEA operations are tailored for optimum operational performance. These designs will evolve in the same way that traditional process plants evolved. Traditional operations are no longer packing sheds. This evolution has taken time. However, given the achieved safety in traditional operations, CEA operations will need to evolve faster and make fewer mistakes.

The bottom line is that bringing the farm and the processing plant together changes the problems, but does not radically simplify the challenges of safe operation.

> **"With CEA operations clawing their way to profitability, cost-cutting is the name of the game. It is important that food safety be considered a fundamental foundation of the business and not a luxury insurance program."**

What's the Path to Safety for CEA?

The path to safety for CEA looks a lot like the path for traditional operations. In the three discussions above, risk analysis is presented as the panacea for all of the food safety challenges. Unfortunately, the ability to execute a complete risk assessment is still evolving. The standards for risk assessments for traditional RTE vectors are soft. Third-party audits are very prescriptive and often focus on minor details without addressing the fundamentals that must be improved to advance food safety. Given the developmental stage of CEA, it will be difficult to execute a complete risk assessment of CEA operations at present. I expect someone will attempt a risk assessment of a farm in an RTE plant in the near future. It will probably be denounced and attacked, however, it will provide a starting point for a much-needed effort.

If such an assessment is completed, it is probable that many fundamentals in the operation will be found lacking and require costly changes. The ability to perform these risk assessments will improve if the CEA industry can develop a working knowledge and acknowledge that CEA is not inherently safe. The various approaches to CEA will be tried and scrutinized by the marketplace. The best processes, and those that evolve in the most cost-profitable manner, will survive.

With CEA operations clawing their way to profitability, cost-cutting is the name of the game. It is important that food safety be considered a fundamental foundation of the business and not a luxury insurance program. The traditional RTE sector invests heavily in food safety and continues to seek improvement. CEA operations need to invest in food safety to survive. They must gather the necessary technical expertise to achieve the known risks. Every food company is just one or two outbreaks away from failure. CEA operations face all the difficulties of small farms and small food processing operations, requiring expertise of capable people to overcome the challenges.

Without the benefit of a complete risk assessment, it is possible to identify a few large opportunities for the CEA sector to move down the path of safety:

- Either employ washing, or demonstrate that washing does not enhance consumer safety
- Develop and implement ways to prevent pathogen proliferation in recycled nutrient systems
- Implement a lot system with clean breaks in the farming operations
- Treat pathogen events as learning opportunities by performing root cause analysis and developing improved processes to prevent similar events
- Go to school on traditional food safety programs and implement the appropriate programs.

CEA represents an exciting, potential compliment to the existing offerings of the fresh, RTE world, but CEA is far from mature. There will be growing pains. Consumers seem willing to pay premium prices for these products, but growth will be sustained only by delivering against the promised and perceived benefits. Any agriculture is only as safe as the food safety programs associated with it. FDA made the point that CEA is not inherently safe. It will fall to the practitioners to ensure that consumers receive the promised value. ■

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The Importance of Third-Party Gap Assessments for a Food Safety Management Program

An unbiased gap assessment of a foodservice business' FSMP should be performed by a third party, using a defined set of standards for each business function

By Hal King, Ph.D., Managing Partner, Active Food Safety

The food safety management program (FSMP) in a foodservice business should be established and staffed to ensure that all food safety risks are properly managed. This FSMP should periodically be benchmarked against the most current regulatory requirements and best-in-class industry food safety program standards. The foodservice industry uses these regulations and standards to maintain food safety risk management of the three biological, chemical, and physical hazards associated with foodservice. It is especially important to review a FSMP during a significant change in operations (e.g., increases in off-premises dining, new menu items, new equipment). In addition, significant changes in food ingredient suppliers, or a significant increase in sales volume per location facility (i.e., expansion), should trigger a review of the program.

A gap assessment should be performed by a third party, using a defined set of standards for each business function to ensure an unbiased assessment of each. It should include a review of the program management team's responsibilities and corporate governance, all operating procedural documentation related to systems and specifications for both supply chain and foodservice operations, and training/indoctrination, facilities design, and executions/compliance measurements of the operations. The third-party gap assessor should review, evaluate, coordinate and review all deficiencies identified. The team should also develop an action plan that is prioritized by level of risk, and use this plan as a road map for continuous improvement of the FSMP. A gap assessment should provide the foodservice operation's business leaders with a measurement of the FSMP's effectiveness. This is most effective early in the growth of a business after the FSMP has been well established. It helps ensure that a mature FSMP is being properly executed to prevent food safety hazards within the business.

Determine the Standards to Be Used for the Gap Assessment

The work of the FSMP in a corporate foodservice business function should define all food safety specifications and manage food safety risk associated with the supply chain, distribution, and foodservice operations, and the foodservice operations. Therefore, the standards chosen for gap assessment should be FSMP elements that are based on foodservice business management, and food safety management teams should choose the specific standards that will be used in the gap assessment. These standards should include program elements used by best-in-class foodservice businesses and recognized as such by the industry and regulatory experts.

A foodservice standard has been developed by the Safe Quality Food Institute (SQFI) in collaboration with the National Restaurant Association.[1] It provides a detailed description of the elements of an FSMP that should be developed and executed by a foodservice business. This standard was developed to assist foodservice businesses to become certified by this Global Food Safety Initiative (GFSI) certification body. Foodservice industry companies can use it as a resource for assessment of their FSMPs. It is also a useful standard if foodservice business stakeholders decide to pursue SQFI certification of a program after a gap assessment is performed.

The SQFI standard (Table 1) includes program elements specific to both corporate management (e.g., Specifications, Supplier Approval and Recipe Development or Verification and Validation) and foodservice operations (e.g., Site Requirements and Approval or Equipment and Utensil Design and Maintenance, etc.). However, one important part that is missing from the standards is the corporate governance of the business functional areas that is responsible to coordinate, manage, monitor, and ensure execution of the program element standards in the business. Thus, it is important to include the governance (via Business Function Categories) of food safety management in the gap assessment.

Table 1. Global Food Safety Initiative Recognized Food Safety Standards

SQFI System Elements for Foodservice Standard*	Description
Management Commitment	Evidence for FSMP's systems development and support
Document Control and Records	Guidance for documentation of the program and systems
Specifications, Supplier Approval, and Recipe Development	All specifications
Food Safety Systems	All specifications
Product Information	Compliance and corrective actions
Allergen Management	Audits and accountability
Training	All specification and facilitation
Site Interior and Kitchen	Facility design for food safety

*For demonstration purposes only. Selected from a list of 10 system elements for a foodservice standard.

These business function categories (Table 2) often exist in different departments of the business—e.g., supply chain food safety management in the procurement or supply chain department, employee food safety training in the restaurant operations department, etc. Memos and other business functions are often led by managers who are not experienced in food safety risk management. They may not be able to define which business functional area(s) should collaborate to execute and manage product recalls, withdrawals, or perform crisis management responsibilities for the business. Thus, the gap assessment should also include the corporate governance of food safety management responsibilities and cooperations to ensure food safety.

Table 2. Business Function Categories Used for Food Safety Management Governance

Business Function	Description	Where Executed in the Business
Corporate Structure for Food Safety Management Program Development	The location of each of the business functions, the employees who manage them, and who has responsibility for implementation and execution	Quality assurance/food safety department or program
Corporate Commitment to Food Safety	The business demonstrates an understanding of employees with expertise, measuring risk across the enterprise, establishing a management program/department, implementing improvements and progress, and establishing documentation, and tracking compliance	C-Suite, board of directors, shareholders
Foodservice Location Operations: Food Safety Management	All specifications related to foodservice operations	Operations department, COO
Supplier Food Safety Management	All specifications related to ingredient products, supplier selection, and verification of compliance	Procurement or supply chain department
Technology/Data Analytics	Compliance and corrective actions tracking	IT department
Execution/Compliance	Audits and accountability	Internal audit department, risk management department, quality assurance/food safety department or program
Crisis Management	All specifications and facilitation	Risk management/legal department

To fully assess food safety management in foodservice business locations (e.g., restaurants), the gap assessment should also measure compliance to the most current U.S. Food and Drug Administration (FDA) *Food Code*[2] to ensure that foodservice operations are capable of controlling the hazards associated with food preparation (Tables 3, 4). This means that foodservice operations must have procedures in place to ensure that food is prepared according to the regulatory compliance execution. For example, the most current *Food Code*[2] now recommends allergen labeling of bulk food dispensing equipment so that customers that self-serve food ingredients or products are aware of the allergen risk of the foods.

Table 3. Biological Hazards, Their Associated Foodservice Foods, and Control Measures to Reduce Hazards Below Acceptable Levels (Other Foods Can Be Added)

Hazard	Associated Foods	Control Measures
Bacteria		
Bacillus cereus (intoxication caused by heat stable, preformed emetic toxin and infection caused by vegetative cells)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooling, cook-to-order, cooling, hot holding
Clostridium botulinum	Poultry, meat, fish	Cooking, Sanitizing, prevention of cross-contamination
Clostridium botulinum	Vacuum packed fresh, reduced oxygen packaged foods, cooked vegetables, cooked meat, garlic in oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing, cooling, cold holding, hot holding, acidification and drying, etc.
Clostridium perfringens	Cooked meat and poultry, meat and poultry products including casseroles and gravies	Cooking, cold holding, reheating, hot holding
E. coli O157:H7 other Shiga-toxin producing *E. coli*	Raw ground beef, raw meat sprouts, raw milk, unpasteurized juice, fresh contaminated by infected food workers via fecal-oral route	Cooking, raw meat/poultry kept separate from ready-to-eat (RTE) foods, employee health policy, handwashing, prevention of cross-contamination, potable water treatment or use
Listeria monocytogenes	Raw meat and poultry, fresh produce, soft cheeses, unpasteurized milk, cold smoked fish, deli meats	Cooking, date marking, cold holding, handwashing, potable water treatment
Salmonella spp.	Meat and poultry, eggs, raw sprout sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, potable water or treatment of use
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
Staphylococcus aureus (preformed heat stable toxin)	RTE potentially hazardous foods touched by bare hands after cooking and before time/temperature abuse	Cooling, cold holding, hot holding, no bare hand contact with RTE foods, handwashing
Vibrio spp.	Seafood, shellfish	Cooking, aggressive control, prevention of cross contamination, cold holding
Parasites		
Anisakis simplex	Various fish (cod, haddock, flake, pacific salmon, herring, flounder, rockfish)	Cooking, freezing
Taenia spp.	Beef and pork	Cooking
Trichinella spiralis	Pork, bear, and seal meat	Cooking
Viruses		
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, employee health policy, handwashing, potable water, employee health policy, handwashing
Norovirus (Norwalk virus)	RTE potentially hazardous foods touched by bare hands after cooking and before time/temperature abuse	Cooling, cold holding, no bare hand contact with RTE food, handwashing, prevention of cross-contamination
Other viruses (rotavirus, norovirus, rotavirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

Table 4. Chemical Hazards, Their Associated Foodservice Foods, and Control Measures to Reduce Hazards Below Acceptable Levels

Hazard	Injury Potential	Sources
Scombrotoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies, bonito, and mackerel, also found in cheese	Check temperatures at receiving, store at proper cold temperature, keep refrigerated, proper identification, obtain verification from supplier that product has not been temperature abused prior to receiving, discard
Shellfish toxins (Paralytic shellfish poisoning (PSP) Diarrheic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP)	• Molluscan shellfish from Northeast U.S. contaminated with toxins from red tide (PSP); Eastern U.S. fisheries and Scandinavia, Japan, and red tide events (DSP) • Molluscan shellfish in Japan, Western Europe, Chile, Eastern Canada, Gulf of Mexico • Molluscan shellfish from Northeast and Northwest U.S. coasts, Gulf of Mexico, Washington, Oregon, and red tide events (ASP)	Ensure all molluscan shellfish are from approved sources, tag and retain tags and shellstock for 90 days, use consumer advisories, NACMCF recommendations
Ciguatoxin	Beef fish from tuna-serrow Scombroid U.S., Hawaii, and tropical areas barracuda, King mackerel, large groupers, and snappers	Purchase fin fish from approved sources, fish should not be harvested from an area that is subject to an advisory
Tetrodotoxin	Puffer fish (fugu, blowfish)	Avoid consumer these fish
Mycotoxin, aflatoxin, patulin	Corn and corn products, peanuts and peanut products, cottonseed, tree nuts, milk products, dried figs, apples, Brazil nuts, pecans, pistachio nuts, and walnuts, other grains and nuts are susceptible but less prone to contamination	Check condition at receiving, do not use moldy or discolored products, check for mold growth, use verification from supplier or overall the use of rotate apples in juice manufacturing
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved sources
Pyrrolizidine alkaloids	Plant foods containing these alkaloids, most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families	Do not consume food or medicine contaminated with these alkaloids
Phytohemagglutinin	Raw red kidney beans (undercooked beans may be more toxic than raw beans)	Soak in water for at least five hours, pour away the water, boil rapidly for 10 minutes, with continued simmering for at least 30 minutes
Environmental contaminants: pesticides, fungicides, herbicides, insecticides, additives, growth hormones	Any food may become contaminated	Follow label instructions for use of environmental chemicals, cut or water analysis may be used to verify safety
Polychlorinated biphenyls (PCBs)	Fish	Comply with fish advisories
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in foods because of their toxicity or because they have not been shown to meet all applicable requirements of the Federal Food, Drug, and Cosmetic Act	Do not use prohibited substances
Toxic elements/compounds, mercury	Fish exposed to organic mercury: shark, skillfish, king mackerel and swordfish; grains treated with mercury (Seed fungicide)	Program training persons and persons of childbearing age and young children should not eat shark, swordfish, king mackerel, and skillfish because of their exposure to mercury; do not use mercury-containing fungicides on grains or animals
Copper	High acid foods and beverages	Do not serve acidic acid foods in copper containers, use backflow prevention devices on beverage dispensing machines
Lead	High acid food and beverages	Do not use products containing lead
Preservatives and food additives: sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Food fruits and vegetables, shrimp, lobster, wine	Sulfiting agents are prohibited when used in a preserving plant or any approved or labeling; do not use on raw products or food establishments
Histamine/histamine, mycin	Canned meat, fish, jerky food exposed to accidental contamination, spinach, meat and other foods to which sodium erythorbate is added	Cook no more than the prescribed amount of curing compound according to labeling instructions; sodium nitrite/nitrate, sodium erythorbate, and sodium ascorbate in poultry will or without nitrites or nitrates
Lichenous coast or inter-estuarineyes, lubricants, cleaners, sanitizers, pesticides, compounds, and paints	Any food cross-become contaminated	Nations through transient operating procedures for proper labeling, storage, handling, and use of chemicals, inter-material safety data sheets for all chemicals
Cleaning compounds in food establishments: Detergents, cleaners, sanitizers, cleaning/sterilizing compounds, floor cleaners, disinfectants, pesticides, and rodenticides	Sea material safety data sheets for chemical safety and toxicity to humans	Use chemicals according to manufacturer's and protective equipment recommendations as available, as required by the safety data sheets

Table 5. Physical Hazards, Their Associated Foodservice Foods, and Control Measures to Reduce Hazards Below Acceptable Levels

Material	Injury Potential	Sources
Glass fragments	Cuts, bleeding, may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, chronic may require surgery to remove	Pallets, pallets, boxes, buildings
Stones, metal fragments	Chipping, broken teeth, cuts, infection, may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Chipping, long-term if asbestos	Building materials
Bone	Chipping, choking	Fields, improper plant processing
Plastic	Chipping, cuts, infection, may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Chipping, cuts, broken teeth, may require surgery to remove	Employees

The *Food Code* also recommends the use of a Process HACCP plan and a food safety management system (Annex 2)[2] to ensure that all hazards are identified in foodservice operations, and that each is controlled by the training, monitoring, and management of corrective actions.[3] Benchmarking the FSMP elements for foodservice operations against the *Food Code* aligns the operations to best-in-class regulatory standards (contributing to health inspections) and maximizes the risk management of food safety hazards based on the specific menu.

One area in which it is difficult to perform an assessment of gaps within a foodservice business is its food safety culture. Some standards for food safety culture have been set in other GFSI standards such as the BRCGC Food Safety Culture for food manufacturers,[4] but there is currently no legitimized best-in-class standard for the foodservice business operations. Foundational to the culture is commitment by food safety management to an element of food safety culture; however, it is not the complete set of attributes within a food safety culture. A recent study performed by the Association of Food and Drug Officials (AFDO), detailed in this issue's Green Sheet, is designed to define the attributes of food safety culture within a foodservice business. In the future, it may be feasible to utilize these attributes in a gap assessment as a foodservice standard for food safety culture.

Compare and Document Program Elements against the Standard

After the program elements and the standards for business functional categories are selected, the gap assessment is ideally performed by a third party not affiliated with the business. This will ensure an unbiased transparent assessment of requirements and deficiencies within all areas of the food business. The third party should have expertise in foodservice food safety program management and business functional categories, preferably experts that have developed and/or managed an FSMP for a foodservice business that includes knowledge in supply chain and foodservice operations.

The third party should perform the assessment by first identifying where the business function categories are managed via a business organization chart or descriptions (Table 2), which program elements exist in each (either present or absent, and who is responsible for the program element(s). Then, each program element can be accessed via review of the most current business documentation related to it (e.g., the ingredient and product recall programs), as well as the appropriateness of the documented program element to the food safety standard. The documentation review should include an assessment of all food safety management operational specifications for recipes, Process HACCP plans, standard operating procedures, prerequisite program specifications[5] (including the sanitation program), training requirements, facility design, etc., for foodservice operations.

The third party should then perform site visits to representative foodservice facilities to make observations of all documented specifications, determine which of these specifications are being executed, and assess what specifications should be developed based on the food safety risk of the operations. Finally, stakeholder interviews should be performed to measure the knowledge of the existing program elements. These interviews should be based on each stakeholder's job description and include business leaders in the organization to determine how accountability is managed. Stakeholder interviews are important, as some program elements of the standard may not be documented but are instead managed by the stakeholder. In some cases, program elements could be reported as absent but exist in other forms (e.g., as part of a supplier expectations manual or in another department's program specifications).

It is important that the identified gaps are documented on a draft gap assessment report and provided to the food safety management team at each phase of the assessment to ensure that any high-risk issues (e.g., observations of incorrect food storage procedures observed during a foodservice facility walk-through) are identified and corrected immediately. Likewise, some gaps in the execution of food safety controls in existing operating procedures (e.g., improper cleaning and sanitation methods) should be addressed immediately. The business stakeholders should carefully review all data from the assessment to ensure that it is accurate and that nothing was missed during the documentation review and stakeholder interviews. They should also review the data to remove any redundancies between business functions that collaborate to manage the same program element.

> **"Once all the gaps have been identified, it is important to address those with the highest risk first and document that the program element has been added or updated, or document the plan and date as to when the gap will be resolved."**

Develop the Action Plan and Priorities Based on Risk

The food safety management team should coordinate and review all deficiencies identified by the gap assessment with the third party, and develop an action plan prioritized on the level of risk identified. An action plan is a set of strategic steps that need to be taken to resolve deficiencies identified by a gap assessment. The action plan should include recommendations by the third party on best practices to resolve the gap. In some cases, a program element may exist but is not updated and/or not managed by the appropriate business function. In other cases, a program element may exist, but it is not being executed by the foodservice operation. Thus, every gap is important to include in a prioritized action plan. Some of these gaps can be more easily addressed; for example, by moving the responsibility to a different business function or by providing training and updating documentation to training.

Once all the gaps have been identified, it is important to address those with the highest risk first and document that the program element has been added or updated, or document the plan and date as to when the gap will be resolved. Some gaps in program elements may not be such, because of the nature of the operation (e.g., availability of all food ingredients distributed to each foodservice location), and this should be noted on the action plan. A written explanation as to why a gap was not resolved should be documented.

Recommendations

A gap assessment should be performed on the foodservice FSMP on a periodic basis to ensure continuous improvement of the program effectiveness. It is sometimes advisable to perform partial gap assessments of foodservice business functions (Table 2). An example is a partial gap assessment of the food safety management of the supply chain because the business has moved into other countries or significantly changed the menu and source of ingredients and products.

A gap assessment of the program can also be most effective early in the food business growth, as a means to help build out the program; or after the FSMP has been well established, to ensure that a mature FSMP is being executed properly across the enterprise to prevent food safety hazards within the business. A gap assessment of the FSMP is, therefore, a necessary tool for ascertaining that the business is doing all it can to ensure the safety of its food for its customers, and to protect the brand reputation and associated value of the business. ■

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By Ken Margolis Dufree, Industrial Maintenance Lead, Radar Farms

Control, Monitoring, and Validation of Fruit Chemical Washing and Sanitizing Processes

Since different foods require significantly different wash methods, system design and sanitation process guidelines must be carefully considered

Critical food safety decisions are made every day by food processing employees from production workers to management. The ultimate goal is to provide safe and reliable products that meet consumer demand. In an increasingly automated world, empowering employees to make decisions based on real data is one of the most important factors in ensuring security and productivity. Continual improvement and learning should be baked into process development.

Whether establishing new processes or improving existing ones, clear and readily available frameworks help employees understand the dynamic criticality of process control points. There is limited information on establishing these systems, with much of the knowledge base existing in trade secrets. If the ultimate goal is total food safety, then it is paramount to establish industry standards that are clearly articulated and widely accessible.

Let us take the example of water use for produce cleaning. Significant evidence exists to support the washing and sanitizing of fruits, from apples to grapes to raspberries. At the same time, water is extremely effective at transmitting contaminants to fruit and vegetables, and has been linked to a number of pathogen outbreaks. Thus, wash water itself can pose a significant hazard. Since different foods require significantly different wash methods, system design and sanitation process guidelines must be carefully considered. In an effort to move toward clear, shared industry standards, this article details methodologies for wash water and sanitizer application in food processing facilities.

Preventive Controls Point

Before jumping into design and application, it is good to start by looking at the relevant standards and regulations. In the realm of agricultural and processing water use, both Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) guidelines come into play. Under the Food Safety Modernization Act (FSMA), FDA has issued regulations around produce safety. Excerpts from the two relevant sections appear below.

Referred to as "The Produce Rule," the first section is *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.*[1] This applies to raw agricultural commodities (RACs) that are intended for direct consumption.

Referred to as the "Preventive Controls Rule," the second section is *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.*[2] This section describes guidelines for otherwise processed produce. The preventive controls rule applies to facilities but not farms. *Preventive controls must be based on scientific and technical information and systematically validated for efficacy.*

To adhere to the Preventive Controls Rule, it is important to establish effective and validated systems. We have done this in my organization, and I share it here in the spirit of starting a public conversation to improve systems in food production facilities. The general steps are as follows:

1. First, do initial planning and documentation before planning and constructing a system.
2. Second, take samples of the product and analyze for contaminants, including biological, chemical, physical, and allergenic. Each type of contaminant requires an individual control methodology.
3. Next, document this methodology thoroughly for later comparison testing.
4. Finally, track results to be able to communicate the validity and effectiveness of such systems.

Many regulations address the types and concentrations of sanitizers. Different regulating agencies govern the use of sanitizers based on the process stage and which sanitizers are used. Figure 1 illustrates which agencies are responsible for regulating sanitizers at different stages. It is easier and simpler, from a regulation standpoint, to wash and apply while the product is still a RAC. As long as sanitizer concentrations are kept within a certain range, sanitizers can be assumed to not count as an ingredient when used before the product is fully processed.

FIGURE 1 Regulating sanitizers in food processing

Produce Sanitizing Methodology

The primary purpose for sanitizers in wash water is preventing cross-contamination. Water is extremely effective at spreading contamination between products. Fresh produce is typically the largest source of foodborne illness outbreaks, often through pathogens such as *Escherichia coli*, *Listeria monocytogenes*, and *Salmonella*. However, there is a growing trend of outbreaks being traced to processed fruits. Farm- and transport-level pathogenic prevention only goes so far due to the open nature of farming. Removal of hazards at the food processing site is important to consider when developing a multi-system plan of contaminant control. Although it may be counter-intuitive, washing should be viewed as a high-risk point of potential contamination. Numerous new options are available that allow sanitizing without washing; however, since many facilities still wash produce, this article will focus on the methods to best control pathogens within a wash water environment.

A limited number of scientific studies specifically address wash water sanitizing. Available related evidence is compiled here from multiple sub-sources to create general guidelines. Free chemical types are the focus of most research: chlorine in the form of calcium or sodium hypochlorite (Ca_2, percentic acid (PAA), chlorine dioxide (ClO_2), and ozone (O_3).

Chlorine is commonly used as a wash water sanitizer in the processing industry due to its low cost, wide availability, and proven effectiveness. It works by causing oxidative damage to cell walls and disrupting key enzymes needed for pathogen growth, and has no residual sterilizing effect after application. However, appropriate concerns have been raised about the harmful disinfection byproducts (DBP) produced in sub-reactions when chlorine interacts with organic matter. These sub-reactions result in significantly lowered concentrations after a relatively short exposure time. In a high-flow, low-contact system with high organic matter load, a large amount of chlorine would need to be dosed to maintain sanitizing potential and will produce a significant amount of DBPs. There is carcinogenic potential in these byproducts, which led EPA to establish limit guidelines for several DBPs, including trihalomethanes (THMs) and haloacetic acids (HAA). Given the potential hazards of chlorine with organic matter, other options should also be considered.

There is growing support for peracetic acid (PA) for multiple reasons. First and foremost, it produces significantly fewer harmful byproducts than chlorine and breaks down more slowly when exposed to organic matter. The mechanism of action for PAA is oxidation, and the sanitizing effectiveness of peracetic acid is largely pH independent. Additionally, PAA continues to sterilize for hours after application, even when frozen. These are distinct advantages in efficiency and healthfulness, compared to chlorination. Other, newer technologies have emerged that should also be considered.

Non-chemical cold plasma is a new and highly effective technology that uses energetic, reactive plasma gas at a relatively low temperature to deactivate a wide range of pathogens. Currently, however, the process is complex and expensive, and it does not remove other types of contaminants. Also, the impact on food taste and nutrients has not been studied as thoroughly to date as other methods.

Other notable approaches for disinfection include ultraviolet (UV) sterilization and ozone. The contact time each approach requires is substantial, and also be considered. For chemical-based wash water, a minimum of around 20

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Validation and Documentation

If the washing system is being considered as a control point with a need for high levels of measurable efficacy, then quantitative metrics must be established. Guidelines[3] were published by Gombas et al. in 2017 in the *Journal of Food Protection* to validate control of cross-contamination during washing of leafy and tuber vegetables. Recognizing that fruits are their own category with separate issues that are characterized by a lack of available research, fresh fruit washing makes a good starting point to explore.

Gombas et al.[3] outline three options for validation for fresh vegetables:

1. Use a test surrogate for the microbial hazard and establish clear proof that the hazard is prevented or reduced by the sanitizing wash
2. Use sensors to ensure that critical levels of sanitizer are maintained, and focus on worst-case scenarios
3. Validate the placement of sensors and ensure that a critical level of sanitizer is maintained, regardless of operating condition.

All of these are good ways of validating efficacy. In an ideal scenario, all three methods of validation would be used. Here, we will focus on methods two and three. For validation of sanitizer concentration, several solid categories of testing methods can be employed:

1. Manual chemical testing for test strips or wet-lab and manual dosing. The advantage here is low cost and instantaneous results. Samples should be taken at a minimum hourly interval.
2. Partially automated testing with sensors and manual or flowrate-controlled dosing. Advantages include ease of setup and ability to store continuous monitoring data. However, any deviation in sanitizer levels will need to be manually corrected.
3. Fully automatic testing with sensors and remote control dosing. Here, pay attention to end-to-end automation of the process to reduce the possibility of human error and ensure high levels of consistency. Deviation alarms, auto purging, and line stop can also be incorporated.

Regardless of the sanitizer testing and application method used, hazard testing should be conducted on a regular basis, such as at the beginning of every shift. The most thorough method is to test on the production line before washing, in the wash water, and post washing. This can and should be done in the initial study to determine the sanitizer levels and contact time needed with the fruit. Typically, post-wash testing on a regular basis would be sufficient to prove that microbial levels are being controlled, as long as the dosing and level control systems are functioning properly and are consistent. However, any deviation in the wash system must be thoroughly documented and retested to ensure that levels return to normal before production continues. If this happens, a failure analysis should be conducted, documented, and incorporated into the maintenance program to prevent further issues.

The distinction between validation and verification is also important. Validation focuses on determining if implemented control measures are effective. Verification is the process of ensuring that validation is carried out in accordance with the hazard control plan and is providing usable results.

While it is easy to implement, using a simple stop-or-go response method for elevated contamination levels is overly simplistic and does not aid in creating a culture of prevention. Validation should focus on driving process and control improvement, rather than just generating one-time data.

Which testing methods are selected and implemented should also be given careful consideration. The testing methods are the only conduit to proper validation. Without proper validation, there is little to suggest that a given plan is effective in reducing and controlling hazards. Testing guidelines should be not only clear, but also meaningful in their approach to providing data that is actionable and easily understood. Training of quality assurance staff is key in ensuring that hazards are recognized and understood. Common problem areas can be identified quicker and more accurately if staff know what to look for and why. With this heightened observation and knowledge, staff can communicate more concretely with supervisors, who can then develop more effective procedures for controlling identified hazards. It can also benefit processors to think outside of the scope of a HACCP program to include whole-system analysis. There is often insufficient data to truly determine the true likelihood and direct danger of a hazard. More often, there is a vague concept of "bad" or "good" results. Continuous analysis of consistent systems is the single most effective way of ensuring that the wash water itself does not become a hazard. For example, we know that maintaining the temperature of food can prevent pathogen growth, and we do not need to test every single product.

Swanson and Anderson[4] offer helpful insight into the importance of in-process testing. In their 2000 article in the *Journal of Food Protection*, they explained that in-process testing "provides more information than finished product testing," but note that "attribute-based acceptance testing is fraught with sampling issues."[5] They go on to describe some of the high stakes related to sampling:

> *Increasing the number of samples can reduce the probability of accepting a defective lot, but it cannot eliminate it entirely. For example, if 30 percent of the sample units in a lot contain the hazard, the lot will be accepted six of ten times when five samples are tested for the hazard. If 30 samples are tested, it will be accepted about five in 100 times* [illegible] *samples are tested. Having Salmonella in 1 percent of a ready-to-eat product is obviously unacceptable.*[5]

Site *te* the

System Design

Given all the potential hazards and the difficulties inherent in testing, an many parts of the system must be secured as possible. Sanitizer concentration and exposure time are critical components that can be controlled once they are identified. Dosing and maintaining acceptable sanitizer concentration and exposure time may also be the most difficult parts to get right in washing systematization. With dynamically changing organic loads and high throughput, careful chemical monitoring is needed. One historical go-to has been to make the water with high doses and do a post-rinse; this is an antiquated method with less consistency and higher potential for harmful byproducts than measured dosing and controlling sanitizer concentration.

Many commercially available sensors for monitoring sanitizer concentration exist, and they are fairly affordable. A number of methods for actual washing are also available, from flume systems to float tanks to simple spry bars. The single most effective application method is full immersion of product with wash water application. With this method, high overall exposure to sanitizing agents and long contact times improves chances of successful sanitization. This method also provides the greatest chance for cross-contamination if sanitizer concentrations have not been met, since the water can carry contamination between products.

In this article, we will focus on dosing systems and maintaining sanitizer concentration since they are critical for preventing hazards. There are three common dosing system layouts (Groups 2):

1. **Inline dosing:** The most straightforward system, this setup features a water source, inline chemical dioser, and monitoring sensor that goes directly to the point of use. This is the easiest to control and has the fastest response time to inputs; however, if concentrations are out of specification, this will show up very quickly. Integrating some sort of automated line stop or alarm is recommended.
2. **Recirculated system:** Borrowed somewhat from swimming pool chlorine dosing designs, the recirculated system can be effective if very high volumes or dynamically changing organic loads are present. A high-flow recirculated line feeds the point of use and circles back into a holding tank. An optional low-flow recirculated line can increase reliability due to the high throughput, allowing for more active monitoring. When chemical is dosed in a high-flow recirculated line, it can potentially waste a significant amount of water. This can be remedied, however, if the point of use is tied back into the low-flow recirculated line.
3. **Reuse system:** Reuse systems are common on less critical applications, such as tray, bag, and pallet washing. It typically involves multiple holding tanks that circulate the water through the point of use and back into one tank at a time while the other tank is filling. A secondary dosser can be fitted on the tanks to maintain level, but if the tanks are switched often (such as hourly), it is typically more feasible to maintain proper

FIGURE 2 Dosing system layouts

Takeaway

Given all the potential hazards in fruit washing and the intricacies of the different approaches to mediating or mitigating these hazards, it becomes clear that establishing a hazard-controlled, safe wash water system can be time-consuming and require investment on both the operations and quality side of processing. To establish such a hazard-controlled wash water system, it is critical to know the scope of the targeted hazards. The process for doing so can be summed up in four steps:

1. **Hazard analysis:** Identify presented and predicted hazards, and test for pathogenic contamination.
2. **Development of controls:** Is washing required? If it is, how can contamination be prevented from entering the wash water itself?
3. **System implementation:** Consult all involved parties on what kind of system will work best for the given application. Not only supervisors, but also line workers, will have important information for such a discussion.
4. **Post-install validation:** Test for system efficacy. Is the sanitizing process working effectively? If not, what can be changed?

A system is only as strong as its weakest link. After the entire system is designed and ready to be implemented, create a training program to educate employees on the identification and communication of hazards. Everyone who works in a processing facility should be aware of potential hazards and how to prevent them. With a whole-system, whole-process approach, we can meet regulations, minimize food contamination, and maintain business profitability.

One potential resource for designing high-flow chemical dosing systems is the American Water Works Association (AWWA). AWWA offers a manual providing detailed information on the design and operation of chemical feed systems for water and wastewater treatment, including guidance on the selection and sizing of equipment, the calculation of feed rates, and the control of chemical dosing.

Additionally, industry associations and trade organizations can be a useful source of information on the design of high-flow chemical dosing systems. For example, the National Association of Chemical Distributors (NACD) provides a range of resources and guidance on the safe handling and use of chemicals in industrial applications, including information on chemical dosing and handling. ■

***Ken Margolis Dufree** is an industrial maintenance professional with a background in food production and a deep interest in systematization, standardization, and automation.*

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By Bob Ferguson, President, Strategic Consulting Inc.

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How the Food Traceability Rule will Impact Food Processors—Part 2

Food processors are certainly aware of FDA's Final Food Traceability Rule, but many are not sure how they will be affected by it

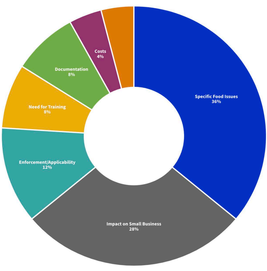
In Part 1 of this series, published in the February/March 2023 issue of *Food Safety Magazine*, we reported on the reaction we received to the U.S. Food and Drug Administration's (FDA's) Final Food Traceability Rule that was released late last year.

We learned that food processors were certainly aware of the new Rule, but many were not sure how they would be affected by it. Roughly one-third of the people we heard from said that they produced products on the Food Traceability List (FTL) and, therefore, would be directly affected by the requirements of the Rule. We also found out that as many as two-thirds of those we heard from suggested that being *directly* affected by the Rule ultimately may not matter much, as they expect that the requirements of the Rule will come to apply to other foods not on the FTL.

Many of the comments and questions we received were largely along the lines of, 'Exactly what does this mean for us, and what will we have to do to comply?' Due to the uncertainty of what exactly is required, we also heard many comments related to what help might be available for processors to better understand the requirements, as well as FDA's expectations and how we can hear those answers directly from the FDA. Processors want to know, 'What is the impact on my company and my operations?'

Anticipating these comments, we asked in our survey, 'What do you wish the FDA understood about the impact of the Food Traceability Rule?' (Figure 1)

FIGURE 1. What do You Wish FDA Better Understood about the Impact of the Final Food Traceability Rule?



In the direct answer to our question, roughly one-third of respondents mentioned that they had specific food processing issues that would arise or be impacted by the Rule (Figure 1). Twenty-eight percent said the agency needed to consider the impact of the Rule on small businesses, and the remaining one-third had questions for FDA about the agency's enforcement position, the training that may be needed, what resources and training assistance will be available from the agency, how the documentation requirements will work, and similar issues.

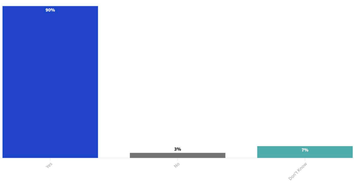
As to the first issue of specific food processing segments impacted, a food safety specialist at a fresh produce packager mentioned, 'Most fresh produce products fall under the FTL, yet FDA does not have a solid grasp on how fresh produce is traced. In the proposed Rule, they seemed to be looking for case-level traceability, which is not doable.'

Another packaging company director of quality mentioned the complexities when dealing with multiple suppliers in a production process. He said, 'Supply chain availability can sometimes require a manufacturer to pivot to a different supplier. Subtle differences, like diced tomatoes versus whole tomatoes, often prevent us from being able to do so because the ingredient deck of the finished product must specify the tomato's form. Oftentimes, whole and diced are both used, and so both must be listed accordingly. It doesn't consider that during the manufacturing process, the whole tomatoes break down and become indistinguishable from the diced, essentially making the ingredient description irrelevant, not to mention misleading. Allowing for 'tomatoes' to be listed without identifying the form would allow more flexibility and keep production lines moving. Downtime often comes when we are waiting on ingredients.'

Another quality assurance/quality control manager in a processed food facility echoed this complexity, saying, 'Mixed production facilities such as ours use the same products across multiple streams in large quantities and need to have several suppliers for some production runs.'

The impact on small businesses is another area where processors wish FDA had a better understanding. Many people indicated this concern with a concise, 'We wish they understood the impact this will have on small businesses; we are already struggling to comply with existing requirements.'

A key element of the Rule is for processors to have the ability to produce lot traceability records within 24 hours of a request for those records from FDA. Survey responses on readiness to comply with this element may be an indication of processors' confidence in their current abilities, with 90 percent of survey respondents saying they

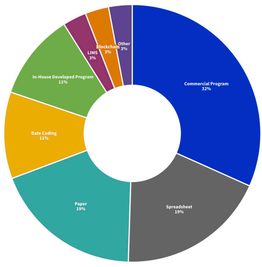


One dairy quality assurance/quality control manager added, 'I imagine, for some companies, meeting the new requirements in three years could be difficult to achieve. Some small companies might have trouble [affording the] software that would make traceability more efficient…' Another comment, also from a dairy specialist, reinforced this idea: 'It will be difficult for smaller companies to produce required documentation.'

So, what are companies using to gain this capability? We asked that too, of course!

Roughly one-third said they were using a commercial software program or an off-the-shelf module for their current enterprise resource planning (ERP) system (Figure 2). The next two responses saw 19 percent reporting that they were using spreadsheets, and 19 percent saying they had their records on paper. Together, these two categories of relatively 'manual' recordkeeping accounted for the largest subset of systems reported being used.

FIGURE 2. What Supply Chain Tracking/Traceability System Do You Use Now?



One quality assurance/quality control manager of a dietary supplement contract manufacturer said that they would have no trouble tracking their raw materials and ingredients to their origin with their existing systems and programs. 'We looked at existing systems and programs, and we found that each had gaps in what we needed. So, we worked with an independent design company, and we built our own system to meet our needs.' Once that system is ready, he indicated that tracking their products back to the source would be possible even within the 24-hour time target set by the Rule. 'We even purchase certain ingredients from domestic brokers, but we get all of the tracking data from them on the origin of the products.' The main issue to overcome in their situation arises when they sell it to their customer—the brand owner. 'The data on the distribution from our customer to the store and then to the end customer is not available to us,' the manager noted.

Another director of quality assurance at a contract manufacturer mentioned that all of their current records are still on paper. 'We have looked at a number of the commercially available options, and we think one of those—especially those that are a 'bolt-on' to our current ERP system—may work well for us.' The issue he mentioned that is holding them up from fully implementing the new module is its cost. 'Our issue is the not only the outright cost of the software and installation itself, but those costs combined with the continuing high costs we are facing in other areas—such as supply chain shortages and the high prices we are continuing to pay for logistics—makes it difficult to take on anything else. We keep waiting for our supply and logistics costs to return to normal, but it seems that once these costs went up during the supply chain crisis, there has been no incentive to reduce costs since, and that takes resources from other projects.'

Other companies that have already implemented traceability systems and new software programs commented about the lack of standardization of the software packages and the form of reports expected by FDA. Although the specific requirements of the Final Food Traceability Rule are not yet in force, several said that they have had issues with explaining what their systems collected in terms of supply chain data and how some inspectors had trouble accepting the format of the reports they produced. This lack of standardization may make communication and meeting expectations of the Rule more difficult during an inspection.

These are just a few examples of what companies are doing to prepare for compliance. This still leaves open the question of 'Am I covered by the Rule, and *do* I have to comply?' Recall in our February/March edition of Food Safety Insights that about one-third were not sure if the Rule applied to them. Furthermore, more than one-half reported that the Rule will ultimately apply to foods other than those on the FTL, expanding the applicability of the Rule. Is there anything we can do to help companies determine if they are covered?

"FDA has released a decision-tree tool on its Food Traceability Website that allows companies to go through a series of questions to determine if they are entitled to an exemption to the Rule."

As part of its outreach and education on the requirements of the Rule, FDA has released a decision-tree tool on its Food Traceability Website that allows companies to go through a series of questions to determine if they are entitled to an exemption to the Rule. Using what I learned in my interviews, I decided to try out this program. Now, certainly a caveat is in order. I took the information I was given in the interviews and applied that to the decision tool. I understand that what I learned in a 30-minute interview does not make me well versed with the particulars of any processor's or distributor's operations. In many cases, I had to estimate the correct input for the tool. These examples should be viewed as an illustration of the use of the decision tool and not as a definitive answer for anyone's particular situation. Nonetheless, this exercise was an interesting experience.

In the case of the processor mentioned earlier that works with both whole and diced tomatoes, they reported that they used a validated thermal process to treat the incoming product. Assuming that their validated process meets the Rule's requirement to comply with 21 CFR 112.2(b) to reduce the presence of microorganisms, and that process is used on all of their products, the FDA decision-tree tool seems to suggest that they should qualify for an exemption because of this kill step. This does not solve their labeling issue, but it may offer the possibility of a simpler option for compliance with the Rule.

In the February/March column, we also discussed the case of a nonprofit food bank distributor. In describing their operation, they said, 'We are a nonprofit food bank distribution center… and we do not change or process the food while in our possession.'

In running this case through the decision tool, it takes about five steps to arrive at the answer that this nonprofit distributor may not qualify for an exemption if they distribute any products on the FTL. Since they 'take physical possession' of the food and it is for distribution and not 'personal consumption,' the decision tool reports that they are *not* qualified for an exemption under 'personal consumption, holding food for specific consumers.' On the other hand, the distributor may be eligible for an exemption if all of the foods that they distribute are 'rarely consumed raw,' as defined in the Rule. This illustrates another of the complications of determining whether an entity qualifies for an exemption—there may be multiple paths to explore.

This exercise was used only as an illustration of how many questions may arise in determining which companies are subject to the Rule and much will depend on their specific situations. It does, however, illustrate that you will need to do your homework on your own, using all of the details of your specific operation to find out what you will be required to do to comply.

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It is probably a good thing that we have three years.

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By Linda J. Odenna, Outreach Specialist, National Aquaculture Association; Michael Ciaramella, Seafood Technology Specialist, New York Sea Grant; and Bob Rheault, Executive Director, East Coast Shellfish Growers Association

FOODSAFETY

Image credit: Kaminskaia/iStock | Cells, Oysters, Place via Getty Images

Guiding Principles of Shellfish Safety

The harvest, holding, transport, and sale of shellfish are tightly regulated in the U.S. to reduce the risk of foodborne illness to consumers

People have been enjoying clams, oysters, and mussels for thousands and thousands of years. In fact, the ancient Romans actually farmed oysters. Today, almost all of the molluscan shellfish (clams, oysters, and mussels) sold come from farms or aquacultre where the shellfish are raised under semi-controlled conditions.

Molluscan shellfish farms can operate in a variety of ways, using several different production methods. In general, shellfish are grown either on-bottom, where juvenile shellfish are planted directly on the sediment, or off-bottom, where shellfish are placed in racks, bags, or cages that are suspended or off-the-bottom lifted. In some situations, those structures are located in the intertidal zone, which means the shellfish are covered during high tide and are exposed during low tide. This makes it easier to perform routine maintenance. While shellfish larvae and juveniles can begin their lives in tanks, final grow-out to market size typically occurs in natural water bodies in coastal areas.

Microscopic shellfish larvae can be collected from the wild, but shellfish growers more commonly rely on hatchery-produced seed. In the hatchery, sperm and eggs from spawning adults are mixed. Larvae continue to grow in nursery systems, where they are fed high concentrations of cultured microalgae.

When the animals are large enough, they are transplanted into approved growing waters. Since they are filter feeders, they feed on the natural algae in the water column. No additional feed, fertilizers, drugs, or chemicals are used. Once transplanted, farmers often implement a variety of methods to protect them from predators like starfish, crabs, snails, and finfish.

Shellfish positively impact the environment by removing algae from the water column. This improves light penetration and incorporates the excess nitrogen and phosphorous, which promotes algae growth, into their tissues and shells. Too many algae in the water column result in lower available oxygen. Overall, the removal of excess nutrients and algae improves water quality, and the structures created by large shellfish beds provide habitat and hiding places for juvenile fish and other marine organisms. This adds to biodiversity, which is a cornerstone of a healthy ecosystem.

According to the Woods Hole Oceanographic Institute, an adult oyster can filter as many as 50 gallons of water per day, while an adult clam can filter up to 24 gallons per day, depending on environmental conditions. In many areas, such as Chesapeake Bay and New York Harbor, environmental groups are actively planting shellfish beds to restore wild populations and improve water quality. According to the Chesapeake Bay Foundation, the oysters in the Bay could once filter a volume of water equal to the entire Bay (about 19 trillion gallons) in a week. Today, it would take the remaining Bay oysters more than a year.[2]

During the 19th and early 20th centuries, oysters were extremely popular in many cities, where they were enjoyed by the rich and poor alike. They were sold by street vendors much like hot dogs are sold today. City streets were dotted with popular oyster cellars. Business was booming, but then public health officials noticed an uptick in the number of reported cases of illness associated with the consumption of raw shellfish. Shellfish are filter feeders and may concentrate microorganisms (bacteria and viruses), as well as natural toxins and chemicals, if they are present in the growing waters. This can pose serious risks to consumer health and safety, since oysters are often consumed raw and whole.

In 1925, the Surgeon General of the U.S. Public Health Service called a meeting to develop control measures to protect the public. That meeting led to the development of rules to improve sanitation in the shellfish industry. Those rules gave rise to the present National Shellfish Sanitation Program (NSSP).

The current NSSP dictates uniform requirements that every state must meet with federal oversight provided by the U.S. Food and Drug Administration (FDA). Several other agencies provide advice and consultation including the Environmental Protection Agency (EPA), the Fish and Wildlife Service, the National Oceanic and Atmospheric Administration (NOAA), the U.S. Department of Agriculture (USDA), and the Army Corp of Engineers.

> **"Dealers are required to conduct a hazard analysis to identify potential food safety hazards for each type of shellfish they handle and identify points in their process where those hazards can be controlled."**

Shellfish Safety Programs

All shellfish must be sold through a licensed dealer, and every dealer is required to have appropriate training in the principles of Hazard Analysis and Critical Control Points (HACCP), develop a HACCP plan in accordance with the Seafood HACCP Regulation (21 CFR 125), and adhere to Good Manufacturing Practices (GMPs). The HACCP regulation requires all producers to develop and implement a preventive food safety plan (HACCP plan) that identifies and controls potential hazards associated with the fish and how they are handled and processed.

GMPs ensure that dealers follow dozens of specific requirements covering issues such as facility water quality and use; employee hygiene; shellfish plant sanitation; equipment sanitation, use, and maintenance; plant construction and maintenance; appropriate storage of potential chemical contaminants; and control of pests. Shellfish harvesters must be licensed by the shellfish control authority in each state. The authority is responsible for ensuring that HACCP and GMP requirements are met under the guidance of the NSSP model ordinance. That license ensures that shellfish are harvested from approved waters and are handled in a safe manner.

The HACCP System

The harvest, holding, transport, and sale of shellfish are tightly regulated to reduce the risk of foodborne illness to consumers. All seafood processors, including those who hold and transport shellfish, are required to be in compliance with the Seafood HACCP regulation (21 CFR 125). All producers are required to develop and implement a HACCP plan, which is a preventive food safety plan meant to proactively identify potential hazards and establish controls to prevent them from occurring.

Dealers are required to conduct a hazard analysis to identify potential food safety hazards for each type of shellfish they handle and identify points in their process where those hazards can be controlled. The hazard analysis should identify hazards that can occur both inside and outside the processing facility, including before, during, and after harvest.

Every HACCP plan includes seven components:

1. **Hazard analysis:** Production, harvest, and processing methods are analyzed to identify all potential food safety hazards that could occur in a facility, species, and the products produced
2. **Critical control points:** Producers must identify specific points in their process where the potential hazards can and will be controlled
3. **Establishment of critical limits:** Minimum or maximum thresholds necessary to control a hazard must be established
4. **Monitoring procedures:** Monitoring procedures must be instituted to continually ensure that identified critical limits are met
5. **Corrective actions:** Actions are identified to address deviations from critical limits
6. **Recordkeeping systems:** Producers must keep records of all monitoring, verification, and corrective actions taken
7. **Verification procedures:** Producers must implement verification procedures to validate that the selected controls are effective (e.g., equipment accuracy checks and calibration).

Time and temperature considerations are another important component of maintaining shellfish safety and a crucial part of any HACCP plan. Small levels of bacteria are naturally present in shellfish and do not cause a health hazard. However, when shellfish are handled improperly, those small amounts could grow and result in human illness. Preventing significant bacterial growth is achieved through temperature control.

The HACCP system is not a standalone program. Dealers must also comply with prerequisite programs to ensure food safety in general. All food processors are required to abide by current Good Manufacturing Practices (GMPs). Dealers are also required to develop adequate sanitation procedures and keep records of their implementation. The Food Safety Modernization Act (FSMA) of 2011 expanded the food safety requirements specific to seafood producers. GMPs were updated to include more controls related to allergens, cross-contamination, training, and training records for staff. In addition, FSMA's Final Rule on Sanitary Transportation of Human and Animal Food was published in the *Federal Register* in 2016. This rule focuses on ensuring that all foods are transported safely and emphasizes the importance of training programs and training records.

National Shellfish Sanitation Program (NSSP)

Since shellfish are often consumed raw, extra precautions have been established to help ensure that they are safe for consumption. In addition to the mandatory FDA Seafood HACCP program, the National Shellfish Sanitation Program (NSSP) is the federal and state cooperative program overseen by FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish sold for human consumption. FDA provides formal oversight to ensure that all states meet uniform minimum standards.

The ISSC provides a formal structure for state regulatory agencies. Participants in the ISSC include state agencies, FDA, EPA, NOAA, and the shellfish industry.The ISSC publishes and regularly updates the NSSP Model Ordinance, which provides minimum standards to help ensure that shellfish have not been adulterated during cultivation, harvest, processing, shipping, or handling.[3]

The model ordinance helps ensure uniform regulation of shellfish production and harvesting across the nation. Each state designates a shellfish control authority that is responsible for monitoring and enforcing the model ordinance. State agencies, in cooperation with FDA, administer a certification program requiring wholesale shellfish dealers to harvest, handle, process, and ship shellfish under sanitary conditions and maintain records verifying that the shellfish were harvested from approved waters. Strict temperature control regimes, maintaining shellfish below 45 °F (7.2 °C), are outlined in the NSSP model ordinance and required of all shellfish dealers.

> **"Shellfish harvested from restricted waters must undergo either a relay or a depuration program to help ensure that pathogens and toxins are removed before they can be marketed."**

Shellfish Harvesters

Shellfish harvesters must be licensed by the designated state shellfish authority. Harvesters are required to complete a training program that covers safe practices for the harvest, handling, and transport of shellfish to prevent contamination, deterioration, and decomposition. Harvesters who pack shellfish for sale and distribution are also considered dealers. Dealers are required to acquire a separate certification, which can be obtained only after an onsite inspection is completed and the inspector confirms that the dealer has an effective HACCP plan and sanitation procedures in place. Dealer certifications must be renewed annually. They are also responsible for appropriate tagging of shellfish and must sell only to a certified shellfish dealer. They must provide that dealer with trip records that include time and temperature information.

Interstate Shellfish Shippers List

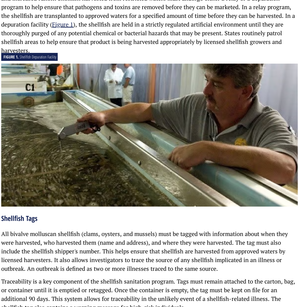
To ensure that shellfish on the market in the U.S. are harvested and handled in accordance with NSSP guidance, FDA manages and publishes a list of certified dealers monthly. The Interstate Shellfish Shippers List[5] indicates those companies certified by recognized regulatory authorities to ship shellfish in accordance with the uniform sanitation requirements outlined in the NSSP model ordinance.

Shellfish Growing Waters

Approved growing waters are designated by the state shellfish authority—the agency responsible for regulating shellfish harvest and aquaculture. Approved waters are monitored regularly to ensure adequate water quality with low concentrations of pathogens and other toxins. This is crucial to ensure that shellfish are safe for consumption, as they are filter feeders and can pick up toxins and pathogens from the water.

Growing waters are routinely inspected by state agencies and can be classified as approved, conditionally approved, or restricted. Shellfish from approved waters can be marketed directly. Conditionally approved waters are open when water quality conditions permit. For example, waters may be closed during periods of heavy rain and increased runoff. Shellfish harvested from restricted waters must undergo either a relay or a depuration program to help ensure that pathogens and toxins are removed before they can be marketed. In a relay program, the shellfish are transplanted to approved waters for a specified amount of time before they can be harvested. In a depuration facility (Image 1), the shellfish are held in a strictly regulated artificial environment until they are thoroughly purged of any potential chemical or bacterial hazards that may be present. States routinely patrol shellfish areas to help ensure that product is being harvested appropriately by licensed shellfish growers and harvesters.

Image 1. Shellfish depuration tanks



Shellfish Tags

All bivalve molluscan shellfish (clams, oysters, and mussels) must be tagged with information about when they were harvested, who harvested them (name and address), and where they were harvested. The tag must also include the shellfish shipper's number. This helps ensure that shellfish are harvested from approved waters by licensed harvesters. It also allows investigators to trace the source of any shellfish implicated in an illness or outbreak. An outbreak is defined as two or more illnesses traced to the same source.

Traceability is a key component of the shellfish sanitation program. Tags must remain attached to the carton, bag, or container until it is emptied or retagged. Once the container is empty, the tag must be kept on file for an additional 90 days. This system allows for traceability in the unlikely event of a shellfish-related illness. The shellfish tag also contains a warning message for high-risk individuals.

If someone becomes ill from consuming shellfish, then the tagging requirements outlined in the model ordinance allow states to quickly identify the waters from which those shellfish were harvested. The potentially contaminated harvest area can be closed immediately for testing, and other potentially affected shellfish can be traced, recalled, and removed from the market or destroyed. All buyers must ensure that their shellfish are properly tagged and come from a certified dealer.

High-Risk Groups and Raw Molluscan Shellfish

Molluscan shellfish, including clams, oysters, and mussels, are filter feeders and can accumulate marine bacteria and viruses. *Vibrio parahaemolyticus* and *Vibrio vulnificus* are two of the most common marine bacteria that can cause gastroenteritis. Both are naturally occurring in the marine environment and are not associated with pollution. They are often found in warmer southern waters and during the summer. Vibrios can also be carried by finfish, shrimp, and crabs, but they are easily killed by cooking. These organisms can cause fever, chills, vomiting, abdominal pain, nausea, and other gastrointestinal symptoms. In a few high-risk individuals, the symptoms may be more severe or even life-threatening.

Although these pathogens occur naturally in the marine environment, they are often in low concentrations. However, once shellfish are harvested, improper handling—specifically exposure to temperatures above 45 °F (7.2 °C)—can result in rapid growth of harmful bacterial pathogens. The strict regulatory oversight governing the harvest and sale of shellfish in the U.S. helps ensure that this does not occur, but it is also important for buyers to understand and properly handle shellfish.

High-risk individuals include those who may have compromised or weakened immune systems due to a variety of health conditions, as well as people over 65 years of age, pregnant people, and young children. Those individuals should not eat raw or partially cooked finfish or shellfish. Since thoroughly cooking oysters, clams, mussels, and preparations of raw molluscan shellfish *vulnerable* populations can continue to enjoy these seafoods in fully cooked preparations.

Harmful Algal Blooms (HABs)

Algal blooms occur when colonies of specific, naturally occurring microalgae grow rapidly. Algae make up the bottom of the food web and are an important source of food for marine animals. While most algal blooms are harmful, some algae produce harmful toxins. When these toxin-producing algae grow to high concentrations, the toxins produced rise to high levels. At these levels, they can harm marine life and cause illness in humans.

Since the population of algae is so large during a bloom, the water can change color. The color varies depending on the species growing, with red, green, and brown being the most common. Cooking does not destroy the harmful toxins produced by some algae, so this can even be a concern in cooked shellfish. When HABs are identified, growing areas are immediately shut down.

In summary, clams, oysters, and mussels have an impressive nutrient content and can play an important role in a healthy diet. They are naturally low in calories, high in good-quality protein, and an important source of vitamins and minerals. In the U.S., extensive shellfish safety regulations help ensure that shellfish is safe for human consumption.

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Regulatory Partners Expand Recall Integration Efforts Nationwide

The 2022 Recall Integration Partnership Project expanded upon critical state and federal partnerships to improve response capabilities during recall events

Food recalls are a public health challenge shared by the U.S. Food and Drug Administration (FDA), regulatory partners, and industry. Federal and state partners work together with industry to ensure prompt, effective responses to recalls. When regulatory stakeholders understand one another's roles, resources, and authorities, they can collaborate effectively at the local, state, territorial, tribal, and federal levels, and recalls can be processed faster and more efficiently—helping keep potentially dangerous products away from consumers.

With that in mind, a collaborative recall project took shape in Georgia amid the pandemic in 2020. Utilizing virtual meeting platforms, the FDA Office of Regulatory Affairs (ORA), along with state recall coordinators and their leadership teams, took a closer look at the existing regulatory recall response efforts in the state of Georgia and where collaboration was present among state and federal agencies. They confirmed that, while certain regulatory roles may overlap, more effective coordination and collaboration can prevent duplicative efforts. Better coordination and collaboration helps save time, improves information sharing, and decreases the burden on the recalling firm(s) to provide the same records to multiple agencies.

After creating a pilot template project in 2021, the recall collaboration expanded to a larger network in 2022. The feedback from the original participants, as well as the seven additional partner pairings in 2022, strengthened the project to enhance future partner integration efforts with the goal to better protect consumers during a recall (Figure 1).

Katie Blackshear, Consumer Safety Officer with ORA's Office of Partnerships, is also the Co-Chair of the Partnership for Food Protection (PFP) Surveillance, Response, and Post Response Workgroup (PFP/SRPR) and headed up the project. Formally named the Recall Integration Partnership Project (RIPP), Blackshear led the project team throughout the pilot project in 2022. Project participants included five FDA human and animal food operating divisions and seven state food protection programs (12 entities in total). The participating agencies [illegible] recalls and provided feedback to measure the impact of the project.

FIGURE 1 Successes Achieved by the Recall Integration Partnership Project (RIPP)

Background: Tracing it Back

The Georgia Department of Agriculture (GDA) and FDA/ORA already had a strong and well-established relationship prior to this shadowing project. However, increasing communication between the two agencies' recall coordinators in Georgia from 2020 into 2021 immediately enhanced the way recalls are handled.

Together, areas for improvement were identified while highlighting enhanced domestic mutual reliance (DMR) and integrated food safety efforts between the two regulatory agencies, including:

- More rapid sharing of information
- Unified state/federal calls with industry during a product recall
- Clearer expectations of roles and responsibilities
- Collaborative regulatory activities through more frequent discussions
- Identifying opportunities to shorten the timeframe between notifying regulatory entities or consumers of a potential recall, investigating the root cause, and taking regulatory action by having all partners at the table from the beginning.

The project expands upon important relationships that preexist among state and federal recall coordinators nationwide. This ensures awareness of how different state/federal partner agencies operate, their individual resources, unique authorities and expertise, and how they can maximize information sharing while protecting commercial and confidential information.

Expanding Recall Enhancements: Tracing it Forward

In 2021, the concept of integrating recall coordination among federal and state regulators became a strategic goal of the Partnership for Food Protection (PFP), an organization comprising dedicated professionals with roles in food protection and public health working toward the goal of an integrated food safety system. As the PFP's 2021–2026 strategic plan was finalized, the organization's leadership added recall shadowing as an objective to develop a model for broader implementation and to continue sharing lessons learned. This was the genesis of the Recall Integration Partnership Project (RIPP).

"The Recall Integration Partnership Project resulted in improved understanding and increased collaboration among FDA and our partner agencies. Building upon the success of this pilot project, our plan is to proceed with several strategic initiatives to socialize the project's model and framework and encourage duplication by other agencies," said Michael Dutcher, D.V.M., Deputy Director of the Office of Human and Animal Food Operations at FDA's ORA. "Doing so will strengthen and enhance the cohesiveness and effectiveness of the integrated food safety system during food recalls. This enhanced partnership benefits industry by supporting a more agile and coordinated joint recall response by leveraging each other's respective regulatory enforcement capabilities to further protect the health of the public, which is our top priority."

In the first half of 2022, the PFP/SRPR coordinated with several FDA ORA recall staff, along with seven state food regulatory programs to develop a framework for implementation to enhance recall communication and collaboration in other regions.

"The lessons we've learned from the recall regulatory partner activities have helped us to better communicate, integrate, and leverage our authorities and resources with our state, local, tribal, and territorial partners in a complex and integrated food safety system, which is consistent with our domestic mutual reliance efforts," said Tim Mueller, Director of the Division of Integration at FDA's ORA. "Leveraging best practices in our domestic partnership agreements enables us to strengthen our programs to support industry's compliance with recall requirements, while also strengthening recall effectiveness. We'll continue to use our authorities and these strategies to rapidly remove adulterated and misbranded food from the marketplace to best protect consumers."

The division/state pairs were provided best practices, tools, and templates designed by the PFP to utilize throughout the pilot. The project aimed to increase collaboration, share lessons learned, and glean feedback to drive improvements for the idea of a model template. Pre-assessments completed by individual participants were designed to capture existing relationships and knowledge of the partner agency's capabilities and opportunities to collaborate. The RIPP team administered and evaluated a post-project assessment to summarize key outcomes.

"We felt we already had a great relationship with our partners at FDA, but this project only served to improve it even more," participant Kimberly Stryker with the Alaska Food Safety and Sanitation Program Manager said. "The time we dedicated with our colleagues at FDA on the recall shadowing project helped deepen our relationship to be [illegible] the project also served to broaden and share knowledge among our staff."

> **"The Recall Integration Partnership Project is intended to strengthen critical partnerships to protect public health and improve response**

Recall Integration Partnerships: A Call to Action

The RIPP framework provided the 12 participants the opportunity to enhance partnerships and gain a better understanding of how the agencies operate during recalls. Participants who completed the program strengthened the concepts of an integrated food safety system by gaining a greater understanding of partner responsibilities and preferred methods of communication and collaboration during recall events.

"Many of the participating agencies reported implementing activities and initiatives due to their involvement in the project," Blackshear noted. "A large majority [82 percent] indicated they gained a greater awareness of their partner agency's responsibilities during recalls. The successful implementation of these activities will have an immediate effect on the collaboration and coordination among agencies during recall events."

The RIPP is intended to strengthen critical partnerships to protect public health and improve response capabilities during recall events. This collaboration is particularly beneficial considering resource constraints and competing priorities. With step-by-step instructions, tools, and templates to help guide the process, the project is designed to be a long-term, continuous improvement initiative that can easily be incorporated into existing partnerships. The best part is that it can be revised to meet different agencies' needs, address different areas of improvement, and encourage ongoing collaboration.

Call to Action

Any agency interested in participating in the Recall Integration Partnership Project can do so now! A downloadable toolkit, developed by the project team, offers agencies all the resources needed to get started with the project on their own. From setting initial goals to generating discussion topics with partner agency recall staff, the toolkit provides an easy implementation structure to fit individual state and FDA division needs. Learn more and download resources today: www.cfp-ifss.org/RIPP

Special thanks to the five FDA divisions and seven state agencies who participated in the RIPP pilot and for providing their invaluable feedback to the project team:

- HAFE1 and the Connecticut Department of Consumer Protection and the New York State Department of Agriculture and Markets
- HAFE6 and the Michigan Department of Agriculture and Rural Development
- HAFW1 and the Minnesota Department of Agriculture, as well as the Wisconsin Department of Agriculture, Trade, and Consumer Protection
- HAFW4 and the Colorado Department of Public Health and Environment
- HAFW6 and the Alaska Department of Environmental Conservation. ■

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Establishing an ISAC for the Food and Agriculture Sector

With security threats on the rise, an Information Sharing and Analysis Center (ISAC) is needed for the food and agriculture sector

In our first Cybersecurity and Food Defense column, we discussed how security threats against the food and agriculture sector are increasing, and how cyber threats against the global supply system are also on the rise. We also suggested that an Information Sharing and Analysis Center (ISAC) be formed for the sector. It does not need to be fully capable at the start; just a few large companies that agree to pool and analyze threat information can plant the initial seeds. If successful awareness and deterrence can be demonstrated, then other companies will join. At full capability, the ISAC can serve as a watch and warning center for the sector, providing timely threat analysis for members at all levels.

ISACs bring together experts from different industries to share information and collaborate on cybersecurity, physical security, and other issues. In this article, we look at the history of ISACs, explore the need for an ISAC in the food and agriculture sector, and discuss the steps that should be taken to establish one.

The History of ISACs

The first ISACs were established in the U.S. following the publication of Presidential Decision Directive 63 (PDD-63),[1] which mandated the creation of public-private partnerships to reduce the nation's vulnerability to cyber and physical attacks. The directive aimed to improve the nation's cybersecurity capabilities by promoting information sharing and collaboration between government agencies and private organizations. PDD-63 called for a single ISAC to be established by the private sector with appropriate federal assistance. It set forth a vision of a coordination center similar to the Centers for Disease Control and Prevention (CDC) in Atlanta:

As ultimately designed by private sector representatives, the ISAC may emulate particular aspects of such institutions as the Centers for Disease Control and Prevention that have proved highly effective, particularly its extensive interchanges with the private and non-federal sectors. Under such a model, the ISAC would possess a large degree of technical focus and expertise and non-regulatory and non-law enforcement missions. it would establish baseline statistics and patterns on the various infrastructures, become a clearinghouse for information within and among the various sectors, and provide a library for historical data to be used by the private sector and, as deemed appropriate by the ISAC, by the government. Critical to the success of such an institution would be its timeliness, accessibility, coordination, flexibility, utility, and acceptability.[1]

Ultimately, a single ISAC was not created, but instead separate ISACs were established by each of the critical infrastructure sectors. The first was the Financial Services ISAC (FS-ISAC), established in 1999. The financial sector recognized the importance of sharing information and collaborating on cybersecurity issues, and the FS-ISAC quickly became a model for other sectors to follow. Following the September 11 terrorist attacks in 2001, it expanded its role to include physical threats to the financial sector.

Today, there are more than 20 ISACs in operation, covering critical infrastructure sectors ranging from healthcare and transportation to energy and defense. These organizations have played a crucial role in preventing cyber and physical attacks and in responding to them when they occur.

Missing from the list of sector ISACs is the food and agriculture sector. One was created in 2002, but it was disbanded six years later. Since then, a smaller special interest group (SIG) hosted by the IT-ISAC[2] remains as the only information sharing group with a focus on food and agriculture security. It meets virtually and has no physical location for a real-time, around-the-clock analysis and warning staff. It also does not conduct training, exercises, and other functions performed by the larger-sector ISACs.

> **"By bringing together experts from across the food and agriculture sector, an ISAC can facilitate information sharing, analysis, and collaboration, allowing organizations to better protect themselves against cyber and physical attacks."**

Why an ISAC is Needed for the Food and Agriculture Sector

The food and agriculture sector is a vital component of the global economy, and it is increasingly reliant on computer technology. From farm equipment and crop management systems to food processing and distribution networks, computer technology plays a critical role in every aspect of the industry. Those computer systems are connected by networks and, in many cases, those networks are accessible to the public internet.

A successful attack on these networked systems could compromise food safety, damage crops, and disrupt the entire food supply chain. Unfortunately, many organizations in the sector are ill-equipped to deal with these threats, and there is a lack of technical threat information sharing and collaboration across the industry.

This is where an ISAC can play a critical role. By bringing together experts from across the food and agriculture sector, an ISAC can facilitate information sharing, analysis, and collaboration, allowing organizations to better protect themselves against cyber and physical attacks.

Does Information Sharing Violate FTC Regulations?

Price fixing entails development of an agreement (written, verbal, or inferred) among competitors to raise, lower, maintain, or stabilize prices or price levels. A food and agricultural sector ISAC would *not* collect, discuss, or disseminate any information related to prices. The ISAC charter could expressly include this prohibition as a requirement for entry into the organization and a cause for dismissal. Inclusion of such requirements would be up to the member companies. Other sectors' ISACs are also subject to price fixing regulations and have successfully navigated these concerns. Since ISACs frequently communicate with each other, their charters could serve as models for the development of a new food and agriculture charter, or perhaps even serve to provide advice on best practices.

ISACs focus solely on threat-related information, enabling the development of industry best practices that better assure protection and thereby decrease liability, but also assist in containment, mitigation, and remediation should a threat event occur. ISACs belong to the sector members and are designed to help those member companies better protect themselves. ISACs do not belong (and are not dictated by) the government.

If desired by member companies, a food and agriculture ISAC could work in collaboration with the Cybersecurity and Infrastructure Security Agency (CISA) by aiding the identification and subsequent protection of "Protected Critical Infrastructure Information" or "PCII." The Critical Infrastructure Information (CII) Act of 2002 and 6 CFR Part 29 ensures that information voluntarily shared with the government that is confirmed as PCII is protected from:

- Disclosure from Freedom of Information Act (FOIA) requests
- Disclosure under state and local disclosure laws
- Use in regulatory proceedings
- Use in civil actions.[3]

CISA's PCII Program also enables CISA and other federal, state, and local government security analysts to assist companies in the following activities:

- Analyzing and securing critical infrastructure and protected systems
- Identifying vulnerabilities and development of risk assessments
- Enhancing preparedness, resilience, and recovery measures.

In other words, CISA's PCII Program protects your company's critical infrastructure-related information and enables you to better identify vulnerabilities and find problem solutions. The PCII Program does *not* compel companies to share their business-related and sensitive information. Instead, it asks that companies voluntarily share what they are willing to share, including that which is identified as PCII. The business decides what is and is not shared with CISA.

PCII access requirements are strictly defined. CISA regulates access and stipulates that, "Only authorized federal, state, and local government employees or government contracted personnel who are trained and certified in the strict safeguarding and handling requirements, have a need-to-know, have homeland security responsibilities, and sign a non-disclosure agreement (non-federal employees only) may access PCII."[3] Regulatory agencies (e.g., the Department of Agriculture and/or the Food and Drug Administration) and personnel (inspectors, auditors, etc.) will not have access to PCII unless they have a need-to-know for a specific purpose and "sign a non-disclosure agreement" prior to receiving the information.

> **"Establishing an ISAC for the food and agriculture sector is a critical step in improving the cybersecurity posture of the industry."**

Steps to Establish an ISAC for the Food and Agriculture Sector

Establishing an ISAC for the food and agriculture sector will not happen quickly. To be successful, a limited pilot capability might be a useful first step. The pilot Food and Agriculture ISAC (FA-ISAC) can then be expanded into a larger and broader organization. To ensure success, the food and agriculture sector will need to:

1. **Identify key players:** Stakeholders will include representatives from across the industry, including growers, processors, distributors, retailers, and others.
2. **Determine goals and objectives:** This should include identifying the types of threats the ISAC will focus on, the types of information that will be shared, how the information will be analyzed, and the expected products to be created by the organization.
3. **Establish a governance structure:** This includes identifying a chairperson or executive director, establishing a board of directors, creating subcommittees as needed, and outlining the roles and responsibilities of each member.
4. **Develop operational procedures:** The FA-ISAC must have well-defined operational procedures that outline how information will be shared, how incidents will be reported, and how response efforts will be coordinated. This includes creating an incident response plan and establishing a system for tracking incidents and responses.
5. **Secure funding:** Funding can come from a variety of sources, including government grants, private donations, and membership fees.
6. **Develop information sharing policies:** Information sharing is a core component of any ISAC, and policies must be established to ensure that sensitive information is protected while still being shared with relevant parties.
7. **Establish a technology platform:** An ISAC requires a technology platform to facilitate information sharing and collaboration. The platform should be secure, scalable, and easy to use, and should allow members to share information in real time. These platforms are in use at other ISACs and are commercially available.
8. **Build relationships:** An ISAC is only as strong as the relationships it builds with its members and other organizations. The FA-ISAC should work to build relationships with industry associations, government agencies, and other relevant organizations to ensure that it has the support and resources it needs to be effective.
9. **Conduct regular training and exercises:** Regular training and exercises are essential to ensure that members are prepared to respond to cyber threats. The FA-ISAC should conduct regular training sessions and tabletop exercises to test response plans and ensure that members are up to date on the latest threats and best practices.

Establishing an ISAC for the food and agriculture sector is a critical step in improving the cybersecurity posture of the industry. By bringing together experts from across the sector, an ISAC can facilitate information sharing and collaboration, allowing organizations to better protect themselves against cyber and physical attacks. ■

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In our next articles, we will look at how threat information currently flows within the sector and discuss how those flows can be improved via the proposed FA-ISAC. We will also explore options for where a food and agriculture ISAC should be hosted and if it should be virtual, like the current SIG, or if it should have a physical facility with around-the-clock staffing, similar to other large-sector ISACs.

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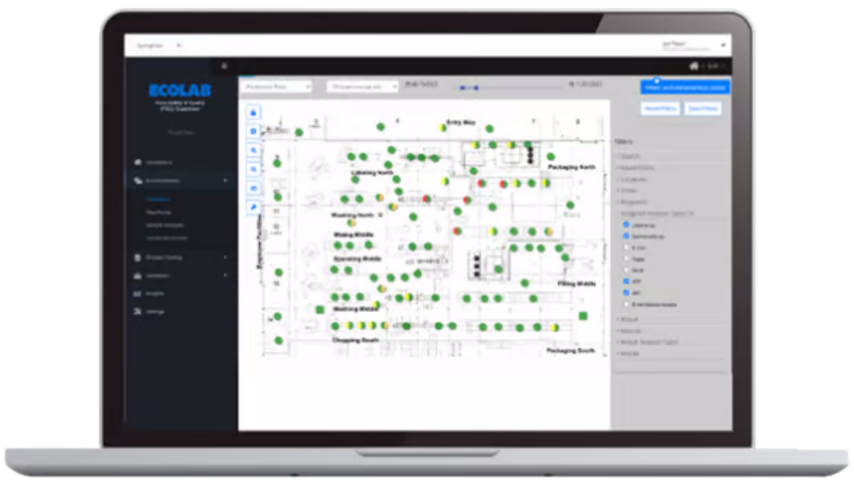
TraceGains has announced Regulatory Global, a new module for its Networked Ingredient Marketplace that enables food, beverage, and dietary supplement companies to mitigate risks inherent to international markets. Regulatory Global makes sourcing materials and developing products for international distribution safer and faster, with coverage of more than 200,000 regulations across 237 countries, regions, and territories. Features include customizable filters, consolidated country guides, and ESG guidance.

tracegains.com

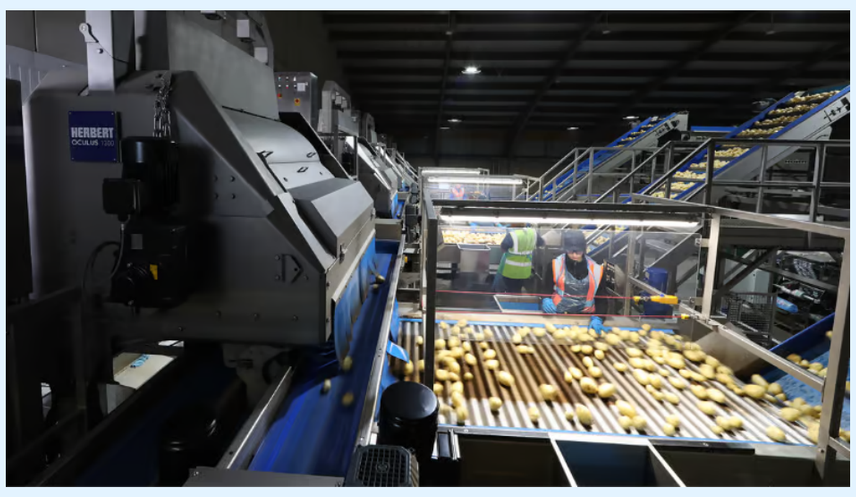


FSQ Supervisor Platform for Manufacturers

Ecolab, +1 800-352-5326

Ecolab has launched the new Food Safety and Quality (FSQ) Supervisor, a web-based platform designed exclusively for food and beverage manufacturing, to fill a growing need for a comprehensive solution to gathering and reporting FSQ data. The modular platform allows users to selectively deploy a phased approach to simplify digital transformation and align with existing workflows. FSQ Supervisor arms food and beverage producers with actionable insights to empower data-driven decision-making across the entire food and beverage process, all in one web-based system, featuring:

- Environmental Monitoring: Records sampling and testing
- Test Point Management: Automated alerts for compliance with testing standards
- Interactive Dashboards: Relevant analytics with authorized users
- Standard Operating Procedures Management: Instructions for critical control points
- Cleaning Verification: Ensures observance of methods, procedures, and tests
- Reporting: Automation of internal and audit and quality reporting
- Floorplan Visibility: An interactive, birds-eye-view of sample points
- Strong Security: Only authorized users have access to necessary data and insights.



Optical Sorter for Whole Potatoes

Key Technology: +1 509-540-7415

Key Technology has introduced the enhanced Herbert OCULUS optical sorter for whole potatoes. Ideal for fresh market potatoes or whole potatoes prior to processing, the enhanced, higher-resolution, 64-bit operating system improves performance to better find and remove potatoes with defects. Its superior sorting capabilities help ensure product quality while reducing labor requirements and achieving consistent line capacity despite fluctuations in incoming raw product quality. Its advanced detection capabilities enable the sorter to remove a wide range of color defects, diseases, and surface abnormalities including skin discoloration, green and dark colors, bruising, mechanical damage, blackleg, and silver scurf.

key.net

Tanker Port with Security Lid for Sampling

QualiTru: +1 651-501-2337

QualiTru Sampling Systems has introduced the new TruStream7 Adjustable Tanker Port with Security Lid, specifically designed for dairy and other liquid food tanker trucks. The new adjustable tanker port welds onto the inner tank wall and accommodates trailers with varying insulation thickness that ranges from 4.3 to 6 inches, minimizing the need for additional retrofitting and fabrication. Sampling can be achieved off the side or back of a tanker truck for accurate and safe antibiotic, component, or microbiological sampling, thereby increasing receiving bay efficiency and sampling safety.

qualitru.com

Weatherproof Device Box Covers

Atkore Calbrite: +1 800-536-2248

Atkore's Calbrite weatherproof device box covers and in-use covers are designed to protect electrical circuits positioned in wet locations, such as washdown in food production, and harsh environments. Calbrite's UL Listed, NEMA 4X approved weatherproof single-gang blank covers protect device boxes or boxes not in use. Offering protection for all indoor and outdoor blanks, GFCIs, switches, and receptacles, the 316 stainless steel covers accommodate multiple wiring devices. UL Listed for wet, damp, and dry locations (UL514D, UL 50E), Calbrite's box covers are labeled with hygienic laser etch markings to eliminate microbial harboring points.

calbrite.com

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