February | March 2020
foodsafetymagazine.com

FoodSafety™ magazine

Science-[illegible]olution [illegible]afety and Q[illegible]lity Professionals Worldwide

Challenges to the World's Food Supply

The Regulatory Environment for Cell-Culture-Based Food

Allergens: What You Need to Know

Training for an Integrated Food Safety System

The Podcast for Food Safety Professionals

Produced by the *Food Safety Magazine* editorial team — the leading media brand in food safety for over 20 years. Each episode features news and trends, or another surprise segment, followed by a conversation with a food safety professional who shares their experiences and insights about the important job of safeguarding the world's food supply.

Featured Guests

Dave Theno | Larry Keener | Lone Jespersen | Steve Taylor
John Spink | Joe Corby | Scott Brooks | Ben Chapman
Bill Sperber | Mike Taylor | Patricia Wester | David Acheson
Darin Detwiler | Hal King | Will Daniels | Lee-Ann Jaykus
Mike Cramer | Jorge Hernandez | Melanie Newman | Bill Marler
Kathy Gombas | Mike Robach | Bob Brackett | Sean Leighton
Dane Bernard | Frank Yiannas | Maple Leaf Foods
Shawn Stevens | John Butts | Keith Warriner | Maria Lapinski
Chris Elliott | Sara Mortimer | Joe Stout | Samuel Godfroy
Jeremy Zenlea | Craig Wilson | Jeff Farber | Bob Powitz
Joan Menke-Schaenzer | Cindy Jiang | Oscar Garrison | EFSA
Sanjay Gummalla | Lan Lam | Jennifer McEntire | Bob Whitaker

FoodSafety MATTERS

Access our library of over 75 regular and bonus episodes

New episodes posted twice a month

Listen and subscribe on your favorite podcast player or visit our website: www.foodsafetymagazine.com/podcast

FoodSafety magazine

Solutions *for* TODAY, Planning *for* TOMORROW

MAY 4–7 | 2020

Rosemont, IL | Donald E. Stephens Convention Center

WE WANT YOU *to* PARTICIPATE IN THE FOOD SAFETY COMMUNITY!

It's Your Summit — Get Engaged!

There are many ways to interact with the Food Safety Summit for an immersive, engaging experience. Our hands-on approach gets attendees excited about food safety solutions!

- ***DOWNLOAD*** *the mobile app to have a virtual summit in the palm of your hands!*
- ***PARTICIPATE*** *in the Community Discussion Groups and troubleshoot solutions with your peers.*
- ***ATTEND*** *the networking receptions to make lasting connections.*

Join the conversation at the Learning Lounge on the show floor for small-group discussions on the most pressing issues.

DEVOTED *to* COMMUNITY

The Food Safety Summit is devoted to working together as a community to achieve the common goal of keeping our worldwide food supply safe, and ensuring that the highest level of safety standards and solutions are implemented.

Visit www.FoodSafetySummit.com for more details on our exciting 2020 program!

Register by March 31 *to* SAVE $100 off Registration Fees!

2020 GOLD SPONSOR

Purell

2020 SILVER SPONSORS

intertek alchemy

InstantRecall

MEDIA PARTNER

FoodSafety magazine

OWNED AND PRODUCED BY:

FOOD SAFETY STRATEGIES

bnp media

A Supplement of BNP Media

February/March 2020
Vol. 26, No. 1

Food Safety magazine

FEATURES

COLUMNS

DEPARTMENTS

Revolutionizing Food Safety

EnSURE™ Touch

The smartest AOAC Validated Sanitation Monitoring System available.

PERFORMANCE TESTED
AOAC
RESEARCH INSTITUTE

Join the Revolution
www.hygiena.com/revolution-ET

hygiena™

Editor's Letter

2020: What to Expect?

Although my generation grew up with the Magic 8 Ball, where if you didn't like the answer, you could turn it upside down and read your fortune again, there is no crystal (or plastic) ball to predict what the new year will bring to the food industry.

(Besides, the Magic 8 Ball required yes/no questions, limiting its utility, even for the children it was designed to entertain.) So, let's speculate on what we can expect in the year ahead:

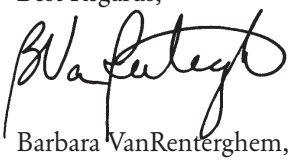
CBD in food products: Cannabidiol (CBD) products, including edibles, are undeniably widespread, but federal law prohibits the addition of CBD to food. Huh? And in the state where I live, Massachusetts, recreational marijuana is legal, so before we have an outbreak related to CBD (or THC), can we *please* have some guidance from the U.S. Food and Drug Administration?

Meal/food delivery and e-commerce: What began years ago as pizza delivery has expanded to delivery of your entire grocery shopping list (e.g., Peapod from Stop & Shop), ingredients to make your evening meal (e.g., Blue Apron), or a Big Mac (e.g., McDelivery® with Uber Eats). Or what about people who buy up all those white fudge-covered Oreos (you know who you are) and then sell them for a million times the price on Amazon? These third-party retailers often don't consider themselves part of the food industry, so who polices them? How do they find out about recalls?

The "greening" of retail: While I applaud efforts to use less plastic, what happens when a consumer buys that split chicken breast and the package leaks all over the inside of their cloth bag? What does the chicken juice touch in that bag? Maybe something ready-to-eat? Do they know to at least put that chicken in a small plastic bag conveniently located near the meat section? Are we educating consumers enough? (Probably not.)

These are just a few things to keep your eyes on in 2020… among many others. Hang on, it's going to be a bumpy ride.

Best Regards,



Barbara VanRenterghem, Ph.D.
Editorial Director

FoodSafety magazine

CEO, The Target Group Inc. Don Meeker
Publisher Stacy Atchison
Disappointed Seahawks Fan Bobby Meeker
Editorial Director Barbara VanRenterghem, Ph.D.
Director of Sales Adam Haas
Art Director/Production Craig Van Wechel
Digital Editor Tiffany Maberry
Circulation Manager Andrea Karges
Administrative Manager Allison Demmert-Poland
Publishing Office 1945 W. Mountain St.
Glendale, CA 91201
Main 818.842.4777
Fax 818.955.9504
customerservice@foodsafetymagazine.com
Production Office 5392 Lighthouse Pt. Ct.
Loveland, CO 80537
Phone 970.484.4488
craig@foodsafetymagazine.com

Editorial

Barbara VanRenterghem, Ph.D. • 508.210.3149
barbara@foodsafetymagazine.com
Tiffany Maberry • 678.853.1062
tiffany@foodsafetymagazine.com

Advertising Sales

Bobby Meeker • 818.842.2829
bobby@foodsafetymagazine.com
Adam Haas • 321.804.4319
adam@foodsafetymagazine.com

ASBPE American Society of Business Publication Editors

FOOD SAFETY MAGAZINE (ISSN 1084-5984) is published bimonthly by The Target Group Inc., 1945 W. Mountain St., Glendale, CA 91201; (818) 842-4777; Fax (818) 955-9504; E-mail info@foodsafetymagazine.com. Periodicals Postage Rate paid at Glendale, CA, and additional mailing offices. Subscriptions: Free to qualified subscribers as defined on the subscription card; $85.00 per year for nonqualified subscribers. Back Issues: $10.00 per copy, prepaid. Change of Address: Notices should be sent promptly; provide old mailing label as well as new address. Allow two months for change. Editorial Contributions: Unsolicited manuscripts should be submitted to: Barbara VanRenterghem, Ph.D., Editorial Director at: barbara@foodsafetymagazine.com. Notice—Every precaution is taken to ensure accuracy of content; however, the publishers cannot accept responsibility for the correctness of the information supplied or advertised or for any opinion expressed herein. Postmaster: Send address changes to Food Safety Magazine, 1945 W. Mountain St., Glendale, CA 91201.

Remembering Daniel Fung, Ph.D., Pre-eminent KSU Microbiologist

Daniel Y. C. Fung, Ph.D., retired professor in the Department of Animal Sciences and Industry at Kansas State University (KSU), died on December 1, 2019.

He received his Ph.D. from Iowa State University in 1969 with a groundbreaking dissertation entitled "Rapid Methods for Determining Staphylococcal Toxins and *Salmonella* Associated with Poultry Products," which inaugurated the field of rapid methods and automation in microbiology. He began a 36-year tenure at KSU, where he supervised 36 Ph.D. and 85 M.Sc. students, authored over 800 scientific publications, and chaired the KSU Food Science graduate program (1979–1987). He was founder and director of the International Workshop on Rapid Methods and Automation in Microbiology, which ran from 1981 to 2010 at KSU, and founder and editor of the *Journal of Rapid Methods and Automation in Microbiology* (1992–2009). Memorial donations may be made to the Sunflower Lions Club of Manhattan, KS, and the Blue Valley Memorial United Methodist Church, marked "in memory of Daniel Y. C. Fung." Online condolences may be left at www.ymlfuneralhome.com.

FDA Releases Supplement to the 2017 Food Code

The U.S. Food and Drug Administration (FDA) has made a supplement to the 2017 Food Code available. The update addresses recommendations made by regulatory officials, industry, academia, and consumers at the 2018 Biennial Meeting of the Conference for Food Protection.

The supplement modifies the 2017 Food Code to, among other things, allow food establishments that pose minimal risk of causing, or contributing to, foodborne illness to operate without a person in charge, as approved by the regulatory authority; remove the allowance for use of chemically treated towelettes for handwashing because the means to wash hands in limited situations is readily available and handwashing has been determined to be effective; and expand and clarify the type of information that should be included when a Hazard Analysis and Critical Control Points plan is required by a regulatory authority.

The Food Code is the model for retail food regulations in all 50 states, the District of Columbia, and other territories. FDA encourages its state, local, tribal, and territorial partners to adopt the current version of the FDA Food Code, including the supplement. FDA's National Retail Food Team is available to assist regulatory officials, educators, and industry in their efforts to understand, adopt, and implement the FDA Food Code. Inquiries may be sent to: retailfoodprotectionteam@fda.hhs.gov or directly to an FDA Retail Food Specialist.

The 2017 FDA Food Code and its supplement are available on www.fda.gov/food/fda-food-code/food-code-2017. The next complete revision of the Food Code will be published in 2021.

EFSA Releases EU One Health Report

The European Food Safety Authority (EFSA) and the European Center for Disease Prevention and Control released their joint annual report—*The European Union One Health 2018 Zoonoses Report*—on trends and sources of zoonoses. Their research found that, in 2018, nearly a third of foodborne outbreaks in the EU were caused by *Salmonella*. Out of 1,581 *Salmonella* outbreaks reported, roughly two-thirds of them occurred in Poland, Slovakia, and Spain. These outbreaks were mainly linked to eggs. The most commonly reported gastrointestinal infections in humans in the EU were campylobacteriosis (246,571 cases reported), followed by salmonellosis (91,857 cases reported), Shiga toxin-producing *Escherichia coli* (STEC) (8,161 cases reported), and listeriosis (2,549 cases reported). The number of STEC cases represents a 37 percent increase compared with 2017, but researchers believe this may be partly due to new laboratory testing technologies that make detection of sporadic cases easier. You can read the full 276-page report at efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5926.

BizTracks

Kestrel Merges with Tellevate

Kestrel Management LLC and Tellevate LLC have merged to provide enhanced compliance and management consulting services to industry and government agencies, creating more efficiencies in the business and helping elevate client operations and business processes. Major service areas include process, program, and project improvement; compliance assurance; management systems; and food safety certification.

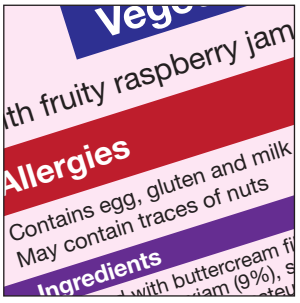
ONLINE & OF NOTE

https://www.fmi.org/food-safety/food-safety-resources

The Food Marketing Institute (FMI) has assembled food safety resources, including food safety programs, training, and guidance, as well as a Food Safety Modernization Act resource center, offering a one-stop shop for food retailers.

By John M. Packman

Allergens: Where Food Safety and Labeling Intersect



Regulatory challenge presented by allergens

Allergens present a unique regulatory challenge. For the small percentage of the population who suffer from an allergy to a particular type of food, a product containing that allergen can potentially cause anaphylactic shock, which can be deadly. Yet such a product poses no threat to the rest of the population.

How do U.S. laws and regulations protect the allergic consumer without unduly restricting the dietary choices of the rest of the population? The simple answer is that they mandate that food labels clearly disclose the presence of allergens, so that allergic consumers can avoid the foods that can kill them.

The viability of this solution depends on strict compliance by the food industry with the requirement of label disclosure.

It also depends on the unrelenting vigilance of allergic consumers, who must constantly check food labels for the presence of the ingredients to which they are allergic. A consumer with a peanut allergy can easily avoid peanut butter. But he/she must search the ingredient declaration of a frozen stir-fry meal to determine whether peanuts are among the numerous ingredients.

Given the potentially fatal consequences of an undeclared allergen, relying on food labels to ensure the safety of allergic consumers may not seem sufficiently protective. But, for example, prohibiting the use of peanuts in all foods to protect peanut-allergic consumers would be excessive. So, in the U.S., Congress struck the compromise of mandating clear disclosure of allergens on food labels. This article reviews the requirements that Congress imposed to ensure that this compromise is sufficient to do the job.

To be sure, the food safety requirements enforced by the U.S. Food and Drug Administration (FDA) address allergens as well. Pursuant to the Food Safety Modernization Act (FSMA), FDA implemented regulations mandating that food manufacturers protect against allergen cross-contact through both Good Manufacturing Practices (GMPs) and preventive controls. This article also reviews these requirements.

Bear in mind, however, that FDA imposed its allergen-related FSMA regulations to prevent the *unintended* presence of allergens in food. With respect to allergenic ingredients that manufacturers add intentionally to foods, label disclosure is the only protection.

The Allergen Hazard

According to the Mayo Clinic website,[1] food allergy affects an estimated 6 to 8 percent of children under age 3 and up to 3 percent of adults. Some children outgrow their food allergies. In many people, exposure to the relevant food can cause symptoms such as tingling, itching, or hives. In some people, however, exposure can cause life-threatening anaphylaxis, which can include constriction of the airways, a severe drop in blood pressure, shock, and loss of consciousness. Without emergency treatment, anaphylaxis can result in a coma or death.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004

An FDA guidance document (*FDA Allergen Guidance*)[2] explains the history behind the need for legislation requiring explicit label disclosure of allergens:

Powering Your Workforce

Your frontline workers are the first line of defense against costly food recalls and incidents. Intertek Alchemy's comprehensive food safety training and compliance solutions give your employees the knowledge and confidence needed to positively impact safety, quality, and productivity.

- Access hundreds of multilingual & customizable courses
- Provide coaching tools for supervisors
- Ensure compliance with automated recordkeeping

Visit us in **Booth #107** at the Food Safety Summit, or learn more at **IntertekAlchemy.com**.

intertek alchemy

As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §343(i)] required that the label of a food that is fabricated from two or more ingredients declare each ingredient by its common or usual name (except that spices, flavorings, and colors could be declared as a class).

Although ingredient declarations complying with section 403(i) provide some information to food allergic consumers, in some cases, the common or usual name of an ingredient may be unfamiliar to consumers and many consumers do not recognize that certain ingredients contain or are derived from a food allergen.

This situation led, at least in part, to the enactment of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282).

> "...U.S. laws and regulations...mandate that food labels clearly disclose the presence of allergens, so that allergic consumers can avoid the foods that can kill them."

In passing FALCPA, Congress noted that eight major foods or food groups–milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans–account for 90 percent of food allergies. These findings also cited a 1999 FDA review of randomly selected baked goods, ice cream, and candy showing that 25 percent of the sampled foods failed to list peanuts or eggs as ingredients on their labels, plus a study showing that many parents of children with food allergies were unable, when looking at food labels, to identify correctly the ingredients derived from major food allergens.

Congress observed that, although ingredients must be listed on food labels by their "common or usual name," "in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen."

FALCPA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to address these problems: 21 U.S.C. §§ 321(qq) and 343(w). As amended, the FD&C Act requires that the label disclose the presence of an ingredient derived from one of the eight listed allergenic foods/food groups by stating its name as it appears in the statute.

This disclosure can be made in either of two ways. The statutory language describing these alternatives is confusing. As a practical matter, however, they are as follows:

1) Disclosure by Means of a "Contains" Statement – Immediately after or adjacent to the ingredient list, the label must state "Contains," followed by the name of each of the eight listed allergenic foods/food groups from which an ingredient in the product is derived. The FD&C Act and the *FDA Allergen Guidance* impose certain requirements as to how the "Contains" statement must be presented.

The *FDA Allergen Guidance* provides this example: "Contains milk, egg, peanuts."

2) Disclosure in the Ingredient List – If an ingredient is derived from one of the eight allergenic foods/food groups listed in the statute, but the common or usual name of that ingredient does not state its name, the declaration of the ingredient in the ingredient list must be followed by the name of the allergenic food/food group in parentheses.

The following examples illustrate this alternative:

- Semolina (wheat)
- Whey (milk)
- Lecithin (soy)

The FD&C Act requires that, in the case of tree nuts, fish, and crustacean shellfish, the label must state the particular type of nut or the particular species of fish or shellfish. The definitions section of the FD&C Act provides the following examples of the various species encompassed by the listed food groups:

- Tree nuts (e.g., almonds, pecans, or walnuts)
- Fish (e.g., bass, flounder, or cod)
- Crustacean shellfish (e.g., crab, lobster, or shrimp)

The *FDA Allergen Guidance* lists additional examples.

Special Cases

FDA's label regulation for spices, flavorings, and colorings provides that such ingredients need not be listed by their specific names, but rather may be listed by category name.

This was an additional problem noted in the findings of FALCPA: "in other cases, the ingredients may be declared as a class, including spices, flavorings, and certain colorings."

In a "Notice to Manufacturers" issued in 1996,[3] FDA stated:

[T]he agency is…considering whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403(i) [21 U.S.C. §343(i)] notwithstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No. 5. The agency is open to suggestions on how to best address this problem.

Through FALCPA, Congress amended the FD&C Act to mandate disclosure of the allergenic food/food group present in "a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen."

Another FDA label regulation completely exempts incidental additives from declaration in the ingredients if they meet certain conditions. This was also noted as a problem in the legislative findings of FALCPA: "in other cases, the ingredients…are exempt from the ingredient labeling requirements, such as incidental additives."

Because of the risk this exemption

could pose for consumers with food allergies, FALCPA amended the FD&C Act to require label disclosure by specific name of incidental additives containing one of the eight listed foods/food groups. FDA explained the reasoning behind this change in its 1996 "Notice to Manufacturers":

FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food.

The recent adverse reaction reports indicate that some manufacturers have… incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant.

With respect to flavorings, colorings, and incidental additives containing food allergens *other than* the eight major food allergens listed in the FD&C Act, FALCPA amended the Act to provide authority for the issuance of regulations requiring label disclosure by name rather than by category.

Pursuant to this authority, FDA in 2008 issued a regulation requiring the colors cochineal extract and carmine to be declared by their specific names in the list of ingredients.

Exception for Highly Refined Oils

An allergic reaction does not result from every food ingredient derived from one of the eight foods/food groups listed in FALCPA. FALCPA therefore exempts highly refined oils derived from the listed foods/food groups, plus ingredients derived from such oils. The rationale is that highly refined oils contain extremely small levels of allergenic proteins, and studies have shown that allergic people can consume them safely.

The *FDA Allergen Guidance* makes a subtle distinction with respect to packaged foods provided by foodservice locations, such as cafeterias and restaurants, and retailers of freshly prepared food:

- FALCPA applies if the food is placed in a package for future consumption, independent of an order from a consumer.
- But FALCPA *does not apply* to food that is boxed or wrapped for near-term consumption in response to an order from a consumer.

Recent Developments

Rye and Barley

In 2018, FDA denied a Citizen Petition that urged the agency to issue regulations requiring the specific label disclosure of rye and barley.[4]

Sesame

The Center for Science in the Public Interest submitted a Citizen Petition in 2014 asking FDA to add sesame to the FD&C Act's list of eight major food allergens. FDA issued a request for comments in October 2018. Over 4,800 comments were submitted. So far, FDA has not taken further action.[5]

Coconut

In September 2019, the Coconut Coalition of the Americas undertook an effort to persuade FDA to remove coconuts from the list. The coalition asserts that:

The FDA misclassified coconut, which is causing confusion for a lot of people because it shouldn't be classified with tree nuts. Consumers with a tree nut allergy, but not a coconut allergy, are being deprived of this fruit. And, industry is being greatly impacted as contract manufacturers wanting to use coconut have to unnecessarily classify their facility as a tree nut facility when they're not.[6]

Allergens under FSMA

FDA's regulations implementing FSMA include 21 C.F.R. Part 117, which governs Current GMPs and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

Section 117.3 defines "Allergen cross-contact" to mean "the unintentional incorporation of a food allergen into a food."

GMPs

Subpart B of Part 117 establishes Current GMPs. Each of the following sections within that subpart imposes GMP requirements with respect to the prevention of allergen cross-contact:

- § 117.10 – Personnel
- § 117.20 – Plant and grounds
- § 117.35 – Sanitary operations
- § 117.40 – Equipment and utensils
- § 117.80 – Processes and controls
- § 117.93 – Warehousing and distribution

> "…FDA imposed its allergen-related FSMA regulations to prevent the *unintended* presence of allergens in food."

FDA's 1996 "Notice to Manufacturers" explains that label statements such as "may contain peanuts" are not an acceptable substitute for GMPs:

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP.

Hazard Analysis

Subpart C of Part 117 establishes requirements as to Hazard Analysis and Risk-Based Preventive Controls. Section 117.130(a)(1) requires the operator of a food facility to conduct an analysis to identify known or reasonably foreseeable hazards. This regulation explicitly lists food allergens as hazards to be considered.

(continued on page 49)

By Will Daniels

Is That Tomato Raw or Ready-to-Eat?

Food safety challenges grow as raw produce is viewed as RTE

As a food safety professional, we often find ourselves in situations where we see clear food safety issues, but the circumstances make calling it out somewhat difficult. My family and I were invited to our friend's house for a barbecue. Normally, this story would lead to cross-contamination due to the meat, but my story is in the kitchen with my friend. She was preparing a salad as we caught up since our last visit. She was meticulously washing the lettuce and other vegetables for the bountiful salad, then cutting and placing them in a bowl. As she was finishing, she grabbed a clamshell of cherry tomatoes that was on the counter, opened it, and dumped them into the salad without any preparation, including the wash step. This was my uncomfortable moment as I pointed out that those tomatoes should be washed prior to eating, and they were not ready-to-eat (RTE). Her response was what I would expect most consumers to say. "They look clean, and what is a little rinse going to do?"

Over the years, the push for convenience has edged many of those raw agricultural commodities to the side for fresh-cut, RTE products. These items were first introduced to the foodservice industry in the 1980s, helping chefs cut down on labor to shred carrots or dice onions. Growers and shippers caught on with the invention of value-added items like chopped romaine and iceberg salads. This was looked at as a win-win scenario: The producers would get better yields by using more of the products from their fields, the shippers created a whole new business by manufacturing these products, and the consumers had fresh RTE salads. What could go wrong?

RTE Products and Risk

The challenge with all of these fresh-cut, RTE products is that they were not getting any processing step required to eliminate the hazards that may exist on the raw materials, like enterohemorrhagic *Escherichia coli*, *Salmonella*, and *Listeria monocytogenes*. Consumers–perhaps unaware that RTE doesn't mean risk-free–pull the product out of their fridge, pour it in a bowl, and eat it. As the demand for these items grew and manufacturers became more savvy on how to get better shelf life, the distribution of these items moved from local to regional to national to international. Items with a shelf life of 4 or 5 days early on were being pushed to 15 or 16 days. These increased days were typically added to meet distribution demands in the supply chain. The shipper would hold the product a couple of days, the ride across the country took 5 days, the distributor required 10 days, and pretty soon you're up to a 17-day shelf life. The industry grew so fast for the next decade that no one really seemed to pay attention to this evolution. Salads looked good in the stores, consumer demand was soaring, and manufacturers created a niche industry that, by 2010, was making millions of servings a day.

Another interesting addition to the produce section that came with all this fresh-cut product was branded and coded items. Consumers had brand choices and shelf life dates to follow. The competition was fierce for store shelves, and consumers grew fond of brands that frequented their store shelves. What this also allowed for was something to trace back to when illness occurred. Before, there was just a head of lettuce, an apple, or a mango; now, we had major brands showing up and taking a stance. Consumers could then recall these brands in interviews and the regulators had something to look at. As more fresh-cut products were implicated

in outbreaks and recalls, the regulatory and science communities began to realize that produce, specifically fresh produce, may be contributing in a large part to foodborne illness in the U.S.

What Industry Has Learned about Pathogen Control

The fresh-cut industry is now decades old and starting to mature. Gone are the days of washing in bathtubs and drying using the spin cycle of a washing machine. The industry today talks about sanitary design and preventive controls. Much of the learning has been focused around pathogens and how they get onto the produce. What most have realized is that produce is most susceptible to contamination in its raw form. More consumers are eating fruits and vegetables this way, including whole commodities. This has further shed a light on the entire industry, and the U.S. Food and Drug Administration (FDA) has been paying attention. There has clearly been a push to emphasize the risk of fresh fruits and vegetables with the Food Safety Modernization Act (FSMA) Produce Safety rule. Officials have said to industry in meetings that if your raw agricultural commodity can be eaten raw, it should be treated like an RTE product. I don't think they are trying to threaten industry with this statement but rather are getting them to pay attention to what our science and society are telling us. If people can eat your product right out of the clamshell, then you should do everything reasonably possible to prevent contamination.

Officially, the Federal Food, Drug, and Cosmetic Act of 1938 defines a raw agricultural commodity as any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. An "RTE food" means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. Going back to my friend's comment (and where FDA is going), if those tomatoes are contaminated, will rinsing them for a few seconds under running water "significantly minimize biological hazards"?

Traditionally, FDA treated a raw agricultural commodity and an RTE product as completely different foods. Raw agricultural commodities were regulated by the U.S. Department of Agriculture, as they were traditionally packed in the field, and RTE products were regulated by FDA, which payed little attention to raw agricultural commodities. Raw agricultural commodities are traditionally managed with Good Agricultural Practices (GAPs). RTE products are managed with Good Manufacturing Practices (GMPs) and supported by a robust food safety plan that includes Hazard Analysis and Critical Control Points/Hazard Analysis and Risk-Based Preventive Controls plans, specification, Standard Operating Procedures (SOPs), Sanitation SOPs, etc. Growers of raw agricultural commodities rely on GAPs. One would argue that the time has come for us to realize that we cannot rely on GAPs/GMPs to control the risks that exist in the supply chain.

FSMA has brought new awareness to food risk, especially in produce. Produce is the only food group that is associated with every regulation of FSMA. Growers are now required to have a documented food safety plan that includes a Hazard Analysis. What does this mean for companies dealing with raw agricultural commodities that can be consumed raw? Do they have to provide a kill step? Do they have to package the product? Should they do anything different in their process? The answers to these questions may be less complex than one perceives.

A Path to Making Safe Products

The answer to the challenge is to be vigilant. Understand the risks associated with the product and do everything you can to prevent those hazards from occurring. Most of these steps are already required by the FSMA Produce Safety rule and should not be revolutionary to the growing community:

Develop a Food Safety Plan – The grower should put together a process flow diagram to describe the entire process from field selection through harvest and holding. The process flow then informs the hazard analysis and risk assessment. During this process, the grower must determine those areas that bring risk and develop adequate controls. Be truthful about the intended or unintended use of the product. If it can be eaten right from the field, assume people are doing so.

In the field, the grower must understand the risks from their surroundings, inputs, agricultural practices, the equipment, and the workers.

In the packing shed, they need to focus on the environment, the equipment, and the workers.

In distribution, they need to focus on handling practices and cold chain management.

Manage the Plan – The grower should act upon the hazard analysis and control points. Understand that documentation is critical to the process; document all control points at the frequency that is determined to be appropriate. When a control point limit is exceeded, take all appropriate steps to control the product implicated and gain control again.

The simple fact that one should do everything one can to prevent foodborne illness should be enough to drive food safety awareness. If that doesn't motivate you, FSMA should. As we brand more and more commodities, the ability for the consumer to identify whose raw agricultural commodity they ate will only increase. That, coupled with our ability to detect microorganisms with higher sensitivity, our ability to communicate illness between states, and whole-genome sequencing, only means that the investigation will come back to the fields more often than not. Don't let the regulators tell you that you have a problem: Act now and control the risks that exist with your product in the supply chain. ■

Will Daniels *is president, Produce Division, of IEH Laboratories & Consulting Group.*

What's In Your Ingredient Sea Salt?

If it's more than just salt, should you be concerned?

Quality isn't just an issue of aesthetics. Dirty sea salts are a serious concern for food manufacturers and processors facing increasing scrutiny from third-party auditors who monitor food safety, as well as consumers who expect high-quality ingredients in their food.

If you are a manufacturer or a processor in the food industry, ask yourself this: What is in my sea salt, and how can I make sure it is of the highest quality?

One way to answer those questions is by performing a simple and inexpensive test — the results of which might surprise you.

Grab a sample of your current ingredient sea salt and pour the contents onto a flat surface.

What do you see?

You might be startled to find a lot of things other than the pristine, all-natural, snowy-white salt listed on the ingredient statement.

Look closely, and things such as rocks, rubber, sand, seaweed, shells, sticks, plastic, and even hair may be revealed. What's more, the color of your sea salt — stained, bruised, rheumy, and sepia-toned — might appear odd and unappealing.

With this in mind, here are three simple things you should know about your ingredient salt.

Anti-Caking Agents

By its very nature, salt is a thirsty compound. Its hygroscopic profile means that, if not packaged or stored properly, salt will absorb and retain moisture from the air, causing it to stubbornly clump, harden, or turn sticky.

As a workaround, most salt companies add "anti-caking agents" — a tame euphemism for sodium ferrocyanide, sodium silicoaluminate, tricalcium phosphate, and other chemical additives that aim to keep their packaged salt dry, yet still seem to work against the clean-label pedigree and spirit that many natural food manufactures try to achieve and convey.

Take a few seconds to review the contents of your ingredient salt. Do they include any chemicals? If so, it might be time to switch to a more clean-label, all-natural sea salt.

CHECK THE LABEL *— Undesirable anti-caking agents are often used to combat clumping.*

Water Sourcing

Sea salts can contain traces of sand, shells, rocks, and other insolubles that require some processing to remove. Still, where your sea salts are sourced makes a huge difference.

If you want to use the highest quality and safest ingredient salt possible, it makes sense to choose a sea salt that is crystallized from the world's cleanest oceans.

Proper Packaging

If a salt supplier wants to show off the clean, safe, and pure qualities of their ingredient salts, why would they pack their products in opaque polyethylene bags, cardboard containers, or fibrous paper sacks?

Such packaging makes visual inspection nearly impossible. Additionally some of the materials used to create the packaging, including paper, glue, or string can end contaminating the salt.

When packaged in clear containers

and bags, salt has nothing to hide. It's an invitation for you to visually inspect what you are purchasing, and a simple thing to consider when choosing who will supply your ingredient salts.

OFF-THE-SHELF COMPARISON *– All ingredient salts are not created equal.*

The Answer Is SaltWorks

Meeting — and exceeding — all of these expectations, SaltWorks' all-natural, unrefined, and clean label ingredient sea salts offer delicious and balanced flavors.

SaltWorks selects the world's cleanest oceans from which to source all of its salts. For example, two of the company's most popular ingredient brands are Pure Ocean® Sea Salt and Polar® Cold Water Sea Salt®, which is sustainably harvested from the pristine waters of the Antarctic Ocean — revered for its icy-cold, highly ventilated, and hypersaline qualities. Moreover, the sparkling white color and clean-tasting flavor of these ingredient sea salts reveal their uniquely pristine source.

All of SaltWorks' bulk products are packaged in airtight, multi-layered, vapor-proof bags with large inspection windows. The company's consumer packaging is clear as well, and features moisture barrier seals that foster a longer shelf life.

When sourcing your ingredient sea salts, it makes sense to consider all of these factors so you can offer your customers the cleanest, safest, and highest quality product available. ■

Learn how SaltWorks produces the best Ingredient Sea Salt available

A CLOSER LOOK *– SaltWorks certified QA Technicians identify contaminants with careful examination.*

Questions to Ask Your Salt Supplier

Food processors and manufacturers should ask the following questions when making the most informed purchasing decisions:

Q: Is my salt supplier registered with the FDA and in compliance with current FSMA regulations?

A: SaltWorks' facilities in Woodinville, Wash., are registered with the FDA and in compliance with the requirements of the Food Safety Modernization Act (FSMA). The company holds certifications with the Global Food Safety Initiative (GFSI), Safe Quality Food (SQF) Institute, Good Manufacturing Practices (GMP), and Hazard Analysis Critical Control Point (HACCP).

Q: Is my ingredient salt from a trusted and reputable salt supplier?

A: SaltWorks has relationships with trusted and reputable production partners who are required to register with the FDA. Also, as a member of the Supplier Ethical Data Exchange (Sedex), SaltWorks holds its suppliers to a strict standard of ethical practices.

Q: Is my ingredient salt organic compliant?

A: All of SaltWorks' sea salts are all natural, additive free and organic compliant for the ultimate in quality.

SALTWORKS®
America's Sea Salt Company®

SQF CERTIFIED

HACCP

Call SaltWorks® Today for a FREE Technical Sample Kit!
SaltWorks Inc • seasalt.com • (800) 353-7258

By Bob Ferguson

Food Safety Priorities and Plans for 2020 – Part 2

The year 2020 promises to be a busy one for food processors

Food Safety Insights is a collaboration between Food Safety Magazine *and the food safety market experts at Strategic Consulting Inc. to bring you the latest market research, insights, and trends in food safety, analytical testing, diagnostics, laboratory services, sanitation, and related topics in quality and safety testing, and assurance in the food and beverage industry.*

In our last Food Safety Insights column, we discussed what processors told us about their project plans for 2020. We received responses from more than 200 processors from around the world across all types of food products.

From the responses that we received, and as we reported in the December 2019/January 2020 issue of *Food Safety Magazine*, it was clear that food safety professionals will have a lot on their plate this year. But even with the numerous issues they identified that need to be addressed, processors made it clear that issues related to microbiology, environmental monitoring and pathogen control, and employee training will be the leading issues of concern.

We wanted to find out more by talking directly to those who responded to the survey. We spoke with individuals from many different companies, including dairy, packaged foods, and retail, but heard most often from produce processors, especially of leafy greens.

What's in Store for Leafy Greens?

Last year was undoubtedly a tough year for leafy greens, especially with the attention on romaine lettuce. We heard that finding out what is happening in the affected growing regions and solving the issue that is causing the contamination and high-profile recalls are certainly on everyone's to-do list to solve as soon as possible.

Many, of course, believe that the root of the contamination in leafy greens is irrigation water. For this reason, many processors told us that they believe that the implementation of the Produce Safety rule and its water testing and control requirements will be a key measure in improving on-farm water control. In our interviews, many agreed that better control of irrigation and on-farm water will be an important area where we'll see significant progress in the coming year. The people we spoke with, however, did add that the farms that they work with are already in compliance with the testing requirements, even though compliance has been delayed until 2022.

One interviewee mentioned that perhaps a more impactful change will be the requirement for a Preventive Controls-Qualified Individual (PCQI) at many of the packinghouses. According to this individual, many of the multi-farm packinghouses have not had this type of individual with formal training in the past. Having someone available with better knowledge and training will help tighten operational controls and contribute to improvements in the food safety culture at farms and packers. The requirement for a responsible person to oversee and implement the Produce Safety rule at single-grower sites and a PCQI downstream at multi-site packinghouses will help greatly in advancing the needed farm site improvements.

Certainly, not all the farms are complying; some, it seems, are even impeding the ongoing investigations needed to solve the underlying contamination issue. In our interviews, we heard reports that officials from the U.S. Centers for Disease Control and Prevention and the U.S. Food and Drug Administration (FDA) who are working on investigations of romaine contamination are getting resistance from some farmers who are reluctant to give them access. The resistance has been evident for the on-farm visits that are part of outbreak investigations and for the re-

search needed to better understand the problem. While regulators should have more authority to gain access in cases of regulatory investigations, we were told it is easier to impede or delay an investigation for research purposes. In the News Bites (page 7) section of the December 2019/January 2020 issue of *Food Safety Magazine*, we reported that FDA is conducting a 1-year project to collect and analyze samples of raw agricultural products for foodborne pathogens. If this delaying tactic is as acute or as widespread as we have heard, one can imagine that this will become an issue that we will be hearing quite a bit about throughout 2020.

We also heard comments that once the root cause has been identified and a solution has been found, better processes for supply chain control from farm to fork will need to be implemented. One practice that was mentioned as an issue that may need to be revised is the "one-time buy" of agricultural products—that is, buying products lot by lot in what was described to us as an auction process. These lots of product are much more difficult to track and leave the buyer with little insight into controls at the farm level versus a more integrated, long-term relationship between a buyer and the farms supplying product.

One of the fruit and vegetable processors that we talked with also said that supply chain issues were impeding improvements of their environmental monitoring program. While they emphasized that they were confident that their program was effective at controlling pathogens, there were details of their program that nonetheless need improvement but were being delayed by the lack of progress by some of their suppliers. They reported that they worked with many small farmers who were struggling with elements of their own programs, especially wildlife control. Uncontrolled wildlife on farms can not only negatively impact the product itself, but the pallets, containers, packaging, and equipment used on the products can have impacts as well, and many of the smaller farmers lack the resources to effectively solve these types of problems. Again, while they reported that they have good control of their processing at the plant level, and their in-plant processing can compensate for shortcomings at the farm level, these issues with their suppliers are holding up their Safe Quality Food certification. This is a key issue that they would like to solve early in 2020 to achieve that certification.

"One of the fruit and vegetable processors that we talked with also said that supply chain issues were impeding improvements of their environmental monitoring program."

Supply Chain Challenge: Environmental Monitoring

A supplier of spices also said that issues of environmental monitoring in their supply chain were a top priority. As their supply chain is global, they deal with not only many small farms and suppliers, but also farms from around the world and in countries and regions that may have a limited understanding of Food Safety Modernization Act requirements and, in some cases, of pathogen controls. Spices are a difficult matrix to work with and, as we were told, *"You need to really look for microbiological contamination and not just run a few tests or wait to respond to something that happens…this is a reality that is not well-understood around the world."* Again, we heard that larger companies were better at managing this than smaller ones, but *"in the world of spices, you will inevitably find yourself dealing with many smaller companies—especially in a worldwide market."*

Keeping Up with Employee Training

The other prominent issue we heard about was training, especially finding better means to make training more effective. As we discussed in the last issue, respondents indicated that training was not only one of their key priorities in 2020 but also a foundational part of everything else they wanted to achieve.

One of the individuals we spoke with had a unique perspective. This person works in a high-volume foodservice operation serving more than 16,000 meals to more than 8,000 individuals every day. In this operation, similar to what we heard from processors, it was not the specifics of the training that will be their focus but finding better ways to ensure compliance with the training or, as we were told, to *"get the training to stick."* In our interview, we heard, *"We have all of the required and needed food safety training that one would expect in a well-run operation, but we need to use whatever better means we can to continue to reinforce the training. We use regular handouts, posters, and constant reminders to bolster the most important points of food safety in a foodservice application such as ours. We are planning on adding a special section in each employee meeting to address food safety issues, and this is an improvement we hope to add in 2020."*

A person with a large retail operation echoed these same thoughts about the importance of training. *"We make sure that every person with food contact responsibility has a 'food contact permit' and is well-prepared for their job. We don't assume that every 18-year-old foodservice employee automatically knows the right thing to do. We make sure that they do know and continually reinforce all of the practices they need to follow."* When asked for more detail, the respondent added, *"Each of our regions is responsible for regular retraining programs, and they follow those up with unannounced spot audits to assure compliance."* This person also added that they reinforce food safety and compliance on a regular basis by making it a key part of all of their employee communications. *"In our regular employee newsletter, we have a section for 'Hot Topics'* *(continued on page 49)*

By Christopher Weiss, Ph.D., and Gerald Wojtala

IFPTI Fellowship in Food Protection:

Developing an Integrated Food Safety System

Training the next generation of food safety regulators

The Fellowship in Food Protection is offered by the International Food Protection Training Institute (IFPTI) and funded by the U.S. Food and Drug Administration (FDA). It is a truly unique program that is open to individuals who perform food protection regulatory functions at the federal, state, local, tribal, or territorial level, with at least 4 years of experience in the food regulatory field, and who want to make a positive impact through association membership, advocacy, and leadership. The program focuses on helping the Fellows gain leadership competencies and requires each Fellow to design, conduct, report, write an article, and present primary research on a food safety issue of their choosing. Unlike more traditional training programs that largely involve instructor presentations, the Fellowship emphasizes participatory activities that allow the Fellows to practice specific skills and concepts. The Fellowship Lead Instructors are recognized leaders in the food regulatory arena.

Seven cohorts (75 alumni) have successfully completed the Fellowship Program, and Cohort VIII commenced in September 2019. Fellowship alumni have reported increased career advancement, increased professional involvement through associations, and greater leadership roles within their agencies since completing the Fellowship Program.

As part of IFPTI's partnership with FDA through Cooperative Agreements (IFPTI is currently in year 4 of a second 5-year Cooperative Agreement), the institute created the Fellowship Program in 2010 to help create future food regulatory leaders who can continue to promote an Integrated Food Safety System (IFSS) through agency collaboration. The program received American National Standards Institute accreditation in 2012 and International Association for Continuing Education and Training accreditation in 2015.

The Fellowship Program Curriculum

The Fellowship is a yearlong program incorporating three on-location weeklong sessions (typically at IFPTI's Portage, MI, location), periodic webinars, and a mentor-guided research project. Week 1 focuses on Professional

Week 1 Professional Communication	Analytical Skills	Written Communication	Interpersonal Skills	Professional Behavior	Public Speaking	
Week 2 Program Management	IFSS	Management	Applied Science	Policies and Administration	Negotiation	Legal Proceedings
Week 3 Applied Leadership	Leadership	Facilitation Skills	Advocacy	Stakeholder Engagement	Political Awareness	Public Relations

Figure 1. Fellowship Program Curriculum Framework

Communication, Week 2 focuses on Program Management, and Week 3 focuses on Applied Leadership. The program layout is shown in Figure 1.

Competencies (knowledge, skills, and abilities) for each of the content or topic areas were built out utilizing IFPTI's competency-based curriculum framework development process. The IFPTI process has served as the foundation for FDA's National Curriculum Standard (NCS), the goal of which is a true IFSS in the U.S., comprising a competent food regulatory workforce doing comparable work across all jurisdictions. A comprehensive article on the creation of the NCS was featured in the August-September 2016 issue of *Food Safety Magazine*.[1]

To identify the competencies within the Fellowship content or topic areas, IFPTI facilitated a subject matter expert workshop comprising experienced food protection professionals who held various leadership positions in food regulatory agencies and associations such as the Association of Food and Drug Officials (AFDO). A total of 369 distinct competencies covering the topic areas were identified. The competencies served as the foundation for learning objectives, and the Fellowship Program content was subsequently developed. Examples of these competencies and learning objectives include:

- *Discuss the importance of emotional intelligence. (Interpersonal Skills, Week 1)*
- *Define ethical behavior. (Professional Behavior, Week 1)*
- *Define the process of policy making. (Policies and Administration, Week 2)*
- *Identify how science is used by food safety regulatory agencies. (Applied Science, Week 2)*
- *Demonstrate negotiation techniques. (Negotiation, Week 2)*
- *Identify the attributes of a facilitator. (Facilitation Skills, Week 3)*
- *Explain political influencers. (Political Awareness, Week 3)*

During Week 1 (Professional Communication), Fellows discuss the role of leadership within the food regulatory arena and are presented with examples of various leadership approaches. Fellows then look at the history of the effort in the U.S. to establish an IFSS and the benefits of integration. Analytical skills are then examined, with the Fellows being given the opportunity to assess various agency policies against community, political, and food safety backdrops. Writing skills, interpersonal skills, and public speaking skills round out Week 1, with the Fellows creating written briefing reports, delivering presentations to their peers, and discussing the role of ethics.

During Week 2 (Program Management), Fellows continue to examine the benefits of an IFSS, with an emphasis on the need for effective collaboration across all food regulatory jurisdictions. Fellows then look at foundational functions of management, including planning, organizing, employee development, staffing, directing, team building, and controlling. The topic of applied science is covered next, with the Fellows discussing how science is used in the food regulatory environment. Week 2 then shifts to the process of policy making, public and administrative policies, negotiation skills and tactics, and legal proceedings, which include public hearings, agency legal authority, and due process.

During the final week of the Fellowship, Fellows focus on leadership skills, including effective facilitation techniques, advocating on behalf of their regulatory agency, engaging with stakeholders, and political awareness. Fellows also examine the topic of public relations and are given the opportunity to create and deliver their own food safety messages.

Figure 2. Map of Solaris

The Solaris IFSS

Throughout the program, the Fellows apply the concepts discussed to collaboratively design an IFSS for Solaris, a fictitious island nation located off the eastern coast of Florida, near the Bermuda Triangle (Figure 2). Each of the Fellows assumes a regulatory position within the country and is required to represent local and regional stakeholder needs, while helping to craft a food safety system unique for the country that fosters economic growth through international trade.

While creating the Solaris IFSS, Fellows:

- Identify stakeholders
- Negotiate with stakeholders
- Develop an organizational chart
- Conduct policy planning
- Craft messages to stakeholders
- Develop an implementation plan
- Interact with parliamentary committees

Aim of the Research Project

The Fellowship Program also requires each Fellow to design, conduct, report, write an article, and present primary research on a food safety issue of their choosing. Each Fellow is assigned a mentor, who helps guide the Fellows through all aspects of their research project, including conducting background research on their selected topic, designing a data collection instrument (e.g., electronic surveys, phone interviews, focus groups), analyzing collected data, presenting the data, drawing conclusions, and making recommendations (e.g., changes in food regulatory policies and/or procedures). Additionally, each Fellow's research article is published in a special edition of the *AFDO Journal*, and each Fellow presents his or her research findings at the AFDO Annual Educational Conference. (The current cohort will present their research findings at the AFDO conference in Glendale, AZ, June 27–July 1, 2020.)

While the current Fellowship Program has the Fellows present their research during the AFDO Annual Educational Conference, due to the number

of proposed Fellows, IFPTI encourages and supports Fellows to attend other food protection-related conferences, such as the Association of American Feed Control Officials, AFDO affiliates, the National Environmental Health Association conference, and the Food Safety Summit.

The Fellows' research projects have covered a variety of food regulatory issues, and a handful of projects have resulted in AFDO resolutions. To illustrate, Table 1 displays a list of Cohort VII research articles.

A full list and text of all Fellow research articles can be found on the IFPTI website at ifpti.org/fellowship-program/published-works/.

Success of the Fellowship

Results of the Fellowship alumni survey, which is sent out annually, clearly demonstrate the program's effectiveness. Since completing the Fellowship:

- 97% have recommended the Fellowship Program to their coworkers and colleagues
- Almost 66% have been promoted
- 86% have become more active in professional associations or work committees
- 80% have been given a greater leadership role within their agency
- 91% have kept in touch with their cohort classmates
- More than 50% have taken on leadership role(s) in professional associations or work-related committees
- 83% have used the designation "IFPTI Fellow" when describing themselves
- Two of the Fellows forwarded their leadership career into FDA positions
- One Fellow advanced to the U.S. Centers for Disease Control and Prevention

Additionally, IFPTI Fellows have assumed various leadership positions within AFDO and regional AFDO affiliates. Currently, four Fellowship alumni serve on the AFDO Board of Directors; five alumni serve on the AFDO Southern States Board; two alumni serve as advisers to the Mid-Continental AFDO Board; two alumni have served as presidents of regional AFDO affilitates; and a handful of Fellowship alumni currently serve on committees for the Central Atlantic States Association.

"The Knowledge, Practices, and Perceptions of Produce Safety by Commercial Aquaponic Growers of Fresh Fruits and Vegetables in Hawaii" (Luisa Castro, Ph.D., Hawaii Produce Safety Program Manager, Hawaii Department of Agriculture)
"Taproom Regulation Challenges in the Midwestern United States" (Hannah Davis, MPH, RS, Food Standards Compliance Officer, Minnesota Department of Agriculture)
"Refrigerated and Frozen Pet Food: Estimating Risk Factors and Analyzing Regulatory Authority" (Ashlee-Rose Ferguson, AFRPS Coordinator, Washington State Department of Agriculture)
"Foodborne Illness Risks in Iowa Agritourism 2014–2018" (Brianna Gabel, CP-FS, Environmental Health Specialist, Linn County Public Health [Iowa])
"Survey of Retail Food Transportation Inspection Activity in the U.S." (Jill Lozmack Mollberg, Food Safety Specialist, Michigan Department of Agriculture and Rural Development)
"Oklahoma Weather Effects on *E. coli* in Surface Water and Produce Safety" (Justin McConaghy, Produce Safety Program Coordinator, Oklahoma Department of Agriculture, Food, and Forestry)
"Food Truck Risk Factors and Public Health Intervention Violations in Suffolk County, NY" (Amanda McDonnell, Senior Public Health Sanitarian, Suffolk County Department of Health Services)
"Cooling Protocol Compliance of Restaurants in Carson City and Douglas County, NV" (Mike Oravetz, REHS, Registered Environmental Health Specialist Public Health Regional Partnership)
"An Exploratory Study of Finished Product Testing in Georgia" (Andrea Riley, Food Processing Specialist, Georgia Department of Agriculture)
"Factors Contributing to Incidences of Foodborne Illness from Manufactured Foods: 2015–2018" (Richard Stephens, Biological Administrator I, Florida Department of Agriculture and Consumer Services)
"Survey of Food Handler Training and Knowledge" (Felissa-Marie Vazquez, Environmental Health Supervisor, Buncombe County [NC] Health and Human Services)
"Direct-Reading and Rapid-Test Methods Used to Evaluate Food Safety Controls in Maryland High-Priority Firms" (D'Ann Williams, DrPH, MS, LEHS, Chief, Center for Food Emergency Response and Defense, Maryland Department of Health)

Table 1. IFPTI Cohort VII Research Projects

Fellowship's Potential for Expansion

Due to the success of the IFPTI Fellowship, the program has the potential to expand beyond the U.S. food regulatory arena. The Fellowship could easily be modified for food industry representatives, and the program could also be tailored to attract international food protection professionals, especially with IFPTI's recent and ongoing efforts with the Canadian Food Inspection Agency and Egypt's National Food Safety Authority.

IFPTI is accepting applications for Cohort IX. Anyone interested in the program is encouraged to submit their application through the IFPTI website at www.ifpti.org. The selection process for the next cohort begins May 1, 2020.

About IFPTI

IFPTI is a 501(c)(3) organization based in Portage, MI, whose mission is to protect public health and the global food supply by building workforce capacity. IFPTI was founded in 2009, largely to help in the creation of the IFSS in the U.S., comprising competent regulators doing comparable work across federal, state, local, tribal, and territorial jurisdictions. The idea of the IFSS was first identified by AFDO, which realized the need to create a training organization to assist regulatory agencies in training regulatory food protection professionals. The Food Safety

Modernization Act further required the integration of our food safety system. With assistance from FDA, the Partnership for Food Protection, the Kellogg Company, AFDO, and Battle Creek Unlimited, IFPTI was established in Battle Creek, MI, and later relocated to Portage.

Since its founding, IFPTI has collaborated extensively with industry, academia, federal, state, local, and international governments to build competency-based solutions for training food protection professionals. The organization has been the architect of the FDA, which sets forth the competencies needed by food safety regulators, across all jurisdictions, to successfully perform their job functions. IFPTI has led the development of the NCS through 5-year Cooperative Agreements with FDA's Office of Training Education and Development, the most recent of which was awarded in 2016.

IFPTI focuses on five core competencies (capabilities): needs analysis, competency-based learning systems, capacity building (at the system, organizational, and workforce levels), regulatory food protection expertise, and project management. In addition to staff members with years of experience in regulatory food protection, IFPTI has a unique mix of talent on staff to design, deliver, and evaluate learning experiences. Additionally, IFPTI maintains a strong network of food protection professionals who provide services such as content development and instruction. IFPTI's strong network of individuals from various professions allows the institute to nimbly respond to staffing needs of various projects. ■

***Christopher Weiss, Ph.D.**, is director of curriculum framework development for IFPTI. For the last 5 years, Chris has been facilitating the development of competency-based curriculum frameworks for multiple regulatory food protection professionals in conjunction with FDA, including regulators of retail food establishments, manufactured food facilities, and animal feed. Chris has also been facilitating curriculum framework development for various audiences within the Canadian Food Inspection Agency.*

***Gerald Wojtala** is the executive director of IFPTI. Jerry has an extensive background in food safety inspection, state and federal regulation, and food regulatory program management. He served as deputy director of the Michigan Department of Agriculture (MDA) Food and Dairy Division from 2001 through 2010, after serving as an inspector, regional supervisor, and state food scientist for MDA for close to 15 years. Jerry also served as president of the AFDO from 2008 to 2009.*

Reference

1. www.foodsafetymagazine.com/magazine-archive1/augustseptember-2016/building-a-national-competency-based-learning-system-for-food-officials/.

By Donna F. Schaffner

Removing Allergens Means Rethinking What "Clean" Means

What equipment designers and sanitation staff should know

Controlling the labeling of allergens in a finished product is a fairly straightforward process for products that you intentionally add an allergenic ingredient into. The problem comes from other products made in the facility that were not labeled for allergens. They were not supposed to contain an allergen but were tainted through cross-contact in the processing environment or from shared equipment that was not adequately cleaned between the processing of products with different allergen profiles.

Controlling a shared environment by segregating products using physical separation and separating dedicated equipment and utensils sounds easy, but the cost to do that effectively may be prohibitive for companies in older buildings that were not purposely built for this task.

For companies that have decided to segregate products by time using either the same environment or equipment for products with different allergen profiles on different days, there exists a real risk that some parts of the environment or equipment will not be cleaned sufficiently to remove all traces of the allergen.

Designing a Sanitation Program for Allergens

Sanitation is a key component of the allergen program for companies that make products with different allergen profiles in the same facility. A robust cleaning program for the entire production environment is an absolute requirement for keeping allergenic components out of products not labeled to contain those allergens.

The U.S. Food and Drug Administration (FDA) mandates that food contact surfaces of shared equipment be "visually clean" after running an allergen-containing product and before a non-allergen-containing product (or product with a different allergen profile) is run on that same equipment. Yet, misbranded products (products found to contain allergens that are not declared on the label) continue to be the subject of food product recalls and FDA Import Alerts.

The simple fact is that companies need to go beyond "visually clean" during their verification activities after cleaning shared equipment. I've seen it happen over and over in many food processing facilities: Equipment that was monitored and documented to have been "visually clean" by the sanitation crew at night is found to be *not clean* upon pre-operational inspection by the quality department the next morning.

And just one instance of the quality department being less diligent during that pre-op inspection could mean a serious allergic reaction or even death to a consumer of your food product.

It is vitally important, then, that your sanitation crew understands that "Sanitation to remove *allergens*" is different from "Sanitation to remove *pathogens*." The methods of cleaning and the chemicals used might be the same, but the verification (and validation) activities are different.

When cleaning to remove pathogens, swabs taken for micro testing could be a verification activity. When

Kikkoman LuciPac A3 Sanitation System

The Kikkoman LuciPac A3 Sanitation System is an innovative, new test for hygiene monitoring that offers better detection and higher sensitivity. Just as easy and fast to use as conventional ATP tests, but its patented A3 technology has been proven to find food residue that other products miss.

Find what you have been missing. **www.KikkomanA3.com**

LuciPac™ A3

Official Distributor

kikkoman®

WEBER SCIENTIFIC

cleaning to remove allergens, a different type of swab is needed: one that is reactive to the specific allergenic protein you are looking for.

Many of the personnel working in sanitation understand that the equipment needs to be "clean" with no visible food residue, but they may have never known the consequences of doing less than a good job of cleaning. For pathogenic bacteria, a tiny amount left in a hard-to-reach corner or underneath an impeller inside a hard-to-reach area of a piece of equipment might not be enough to cause an outbreak of illness (or food poisoning) in consumers after being mixed into a large volume of product made the next day. Those few cells of bacteria probably need "time" in a favorable temperature and in a favorable growth medium to grow to the larger numbers of cells that might be needed to cause illness.

> "Sanitation is a key component of the allergen program for companies that make products with different allergen profiles in the same facility."

Allergens, however, do not necessarily need to "grow" to large amounts or need to go through various life stages to produce a toxin that would make consumers ill.

That small amount of allergenic material left between the close-fitting parts of the equipment or underneath the scraper blades in that kettle could be pushed out with the next batch of product and be sufficient to cause a severely allergic consumer to have a reaction or even die.

Putting the Right Tools in Place

At the end of a sanitation shift, the equipment and floors of a wet-cleaned environment are wet and most likely are shiny and look clean to an observer. The "film" or "residue" that the quality assurance (QA) person will find tomorrow morning on the dry equipment is not visible tonight while it's still wet. To do a better job of monitoring for the presence of allergenic material on the "cleaned" equipment, and verifying that "visually clean" is really clean enough, sanitation supervisors need to be given better tools and better training.

Swabs

The use of new, super-sensitive swabs for ATP detection where even trace amounts of protein are detected might alert a sanitation supervisor that the piece of equipment is not really "clean" before releasing the room to production. Or, that same supervisor might use enzyme-linked immunosorbent assay-specific swabs to see if there is a color change–looking for the specific allergenic protein that had been run on that equipment before the cleaning took place–before determining that sanitation is finished for the night.

Proper training

Another issue that I've often seen in the past is the failure of the person doing the post-cleaning inspection to actually get a look at the hard-to-reach areas of a piece of equipment. Training by a longtime inspector, auditor, or QA person could help this problem if those types of people would share some of their "tricks of the trade," such as using a mirror with an extendable handle for inspection. Another "tool" that I've seen used very effectively is a long, thin blade-type instrument (such as a shiny metal icing spreader) used in conjunction with a narrow-focus flashlight to help get a look under and between tight spaces inside equipment or between conveyor linkages, and to provide a reflected image of that area that is not possible from the view you have from standing in front of it.

Equipment

A very stubborn piece of equipment might have a hidden area where product hangs up, which is only discovered when particles of material distinctly belonging to yesterday's product just "appear" in today's batch of product, even though the piece of equipment was rinsed out several times before the start of today's production. For this type of situation, the only way to be sure that all the hung-up product from yesterday is no longer there might be to fill the piece of equipment with water and then test the water for the presence of the allergen. It might even be that water won't remove all the hung-up product, but that you will have to push some amount of today's product through the line, stop the line, do a thorough inspection of that product, and then test the product with allergen-specific swabs. Once you've done that a few times, you'll know with much more accuracy what amount of product needs to be run through your system (and then discarded because of cross-contact with the allergen from yesterday's production) before a test will confirm that it is really "clean" of allergen carryover.

My prediction is that after more people really start to inspect the insides and undersides of food processing equipment for cleanliness, they will start demanding that those pieces of equipment be better designed. "Purposely built" for the function of the equipment in the design engineer's mind sadly seldom includes the question "How will this thing be cleaned once it is in use?"

Too often, the people who make the decisions about purchases of large-price-tag equipment are not knowledgeable about sanitation and food safety. They need dedicated food safety professionals to look for all those details that the design engineers never took into consideration!

Learning from Experience: Educating the Designers

My own experiences with custom-manufactured pieces of food processing equipment were extremely bad experi-

ences for the people I was buying from. When contracting for the equipment to be built, I required that I would be allowed to inspect the piece of equipment while it was still at the manufacturer's (machine shop) location and before it could be transported to my location. In each case, I refused to take delivery of the equipment until after a number of changes were made. And only after several such inspections (and refusals to take delivery) did the manufacturers get the piece of equipment to meet with my approval regarding cleanability.

Some other examples: A spacer that the engineers put into parts of my equipment was simply a long bolt with a stack of stainless steel washers put between some parts to make it "fit." That was completely unacceptable to me because spillage of (liquid) product onto that spacer would allow a tiny bit of nutrient-rich liquid to run down between each of those surfaces and create an excellent growing environment for bacteria in a place that was not accessible for cleaning. When I pointed out that I would not accept this, the design engineer demanded to know, "Well, what do you want me to do about that? I needed to create that amount of space in that location." I replied, "You told me that you could make any shape out of moldable plastic. Now that you know the exact length of the space needed there, make me one piece of molded plastic to replace the bolt with the stack of washers. This one piece will not have all those tiny spaces that would collect food and grow bacteria." My solution was simpler and actually cheaper to build than a whole long stack of stainless steel washers.

Another example: After putting together a custom piece of equipment with a conveyor running along the top length of it to carry bottles of liquid product, the engineers had left various openings in the sides of the housing under the conveyor. Each of those openings would have let spilled product run inside, where it was not accessible for easy cleaning. The engineers claimed that they had needed those openings to get things inside the housing and be able to see what they were doing when assembling the thing. I requested that now that they were done, all of the openings in the sides needed to be closed with sanitary welds. I also needed a drop-down door system to be installed on the underside of the housing to make the inside area (with all those electrical components) water resistant for the sanitation crew but accessible for maintenance and the eventual replacement of parts.

We all know that to remove all food debris from a non-solid belt conveyor, the belt needs to be removed for the proper cleaning of both the top and bottom surfaces. An engineer built one for me and then was very happy to show me how "easy" it was to remove. He said, "Anyone *(continued on page 50)*

When Even the Cleanest Areas Aren't Clean

Detecting pathogens and spoilage organisms is of utmost importance in food production facilities. Even with robust cleaning and sanitation programs, microorganisms are often left behind, presenting food safety and shelf-life risks. With both human health and product quality on the line, manufacturers often turn to sanitation verification tools to ensure their cleaning process is effective. But the industry standard tool for monitoring cleanliness—testing for adenosine triphosphate (ATP)—has evolved, and new tools more capable of identifying bacterial threats have been introduced.

Limitations of ATP Testing

When testing for microorganisms, time is often a major factor in choosing a method for analysis. Traditional microbiological methods that require colony cultivation can take days, if not weeks, to see results. As an alternative, a quick and simple test for the presence of ATP was developed to obtain rapid results.

ATP is an energy molecule found in all living organisms, including bacteria, mold, plants, and animals. When ATP reacts with a light-emitting enzyme, the relative light units (RLUs) can be measured, correlating to a quantifiable amount of ATP. By measuring the amount of ATP present in a sample, the total amount of biological material present can then be estimated. Instead of waiting days for bacterial cultures to appear, now overall contamination levels can be determined in seconds. In high-risk areas that need to be free from pathogenic or spoilage organisms, ATP testing has been the most effective way to find what risks are present.

The use of ATP testing as a measure of sanitation effectiveness has been prevalent since its emergence. However, production facilities, particularly aseptic environments, may require higher sensitivity than what ATP testing alone can provide, since biofilms and spore-forming bacteria may persist, even on surfaces free of detectable ATP. So how can manufacturers be sure that their operation is truly clean?

A3 Technology

To overcome these limitations, the Kikkoman Biochemifa Company developed a way to measure more than just ATP. Kikkoman A3 technology measures adenosine mono- and diphosphate (AMP and ADP) in conjunction with ATP, capturing three different biological molecules instead of relying on the presence of one alone. ATP, ADP, and AMP are found in all living organisms as part of cellular metabolic pathways. A3 technology captures more than ATP testing alone, allowing manufacturers to find what they may have been missing.

Improved Sanitation with A3

A production brewery in the Midwest began using the Kikkoman A3 system in the spring of 2018. Prior to this time, the brewery had been using traditional microbiological media techniques and had not encountered excessive contamination on production surfaces after clean-in-place (CIP) had been completed. As reported by the brewery, the product contact surfaces were thought to be fully cleaned prior to implementation of the A3 system.

The brewery chose three primary Critical Control Points, all product contact surfaces on the canning line. These included the can filler nozzle, which dispenses liquid beer into empty cans; the liquid degassing "bubble breaker," which removes large bubbles from filled cans; and the can purge gasser, which uses ionized air and CO_2 to purge empty cans of contaminants. All of these points were regularly cleaned as part of the canning line CIP process. There had been no reported contamination by bacteria or indicator organisms prior to using the A3 system.

However, when the A3 system was implemented, all three test points exhibited significant, persistent contamination. In particular, the bubble breaker and can purge gasser exceeded the maximum RLU value recommended for stainless steel food contact surfaces. The high RLU count showed that these control points were at risk for contamination, even when no contamination had been found previously.

With these data, the brewery was able to streamline their cleaning and sanitizing protocol to limit contamination in these problem areas. Within 2 months, all test points showed a significant decrease in measured RLU values, indicating that potential points of contamination were reduced. In fact, there was a 35-fold decrease in measured RLU values on the bubble breaker over the 3-month test period.

Overall, the A3 system was not only an effective sanitation verification tool for this user, but it also identified unknown risk points before they could cause contamination. The brewery stated that the recorded A3 measurements proved their operation was cleaner: "This substantial decrease demonstrates that the implementation of the RLU measurements has contributed strongly to [the brewery's] ability to maintain a cleaner facility."

Summary

When ATP testing alone isn't enough, using the A3 system can find the hidden threats in your operation. Testing with A3 provides a more sensitive method of detection for dangerous pathogens and spoilage organisms, leading to a more effective sanitation program.

Kikkoman Biochemifa Company's A3 technology is AOAC certified and available in convenient, single-use swabs for both surface and liquid applications. The A3 system is offered and distributed by Weber Scientific.

Specialists in Food Sampling and Test Supplies

NEW! Weber Scientific MegaSampler™ Sampling Device

Biofilm scraping blade incorporated into the handle

A pre-moistened sponge, with 10 ml of DE Neutralizing Broth, individually wrapped in a reusable sample bag, is secured to the sampling handle using a unique design that enhances sampling efficacy.

- Twice the sampling surface
- Sampling tip for hard to reach places
- Sponge is held in place without glue or chemicals
- Sponge is easy to separate from handle

Peel Plate® Microbial Tests

Modern Technology – Many Advantages over Older Methods

- Quantify colony development by color
- For Aerobic Count, Coliform, *E. coli*, Enterobacteriaceae and Yeast and Molds
- AOAC-RI and PMO Approved (AC and EC)
- Colony counter and High Volume Format
- *FREE Samples Available!*

Put together a Peel Plate® Testing Package with Weber Scientific and you may **save 25¢ or more per test!**

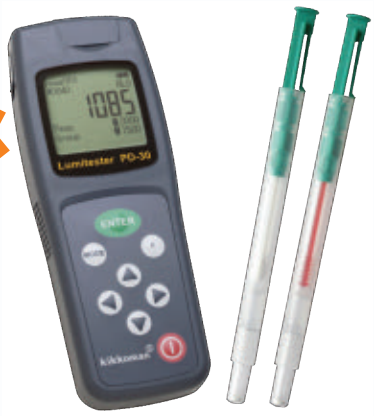
The LuciPac™ A3 Sanitation System

Superior sensitivity leaves food residue with no place to hide

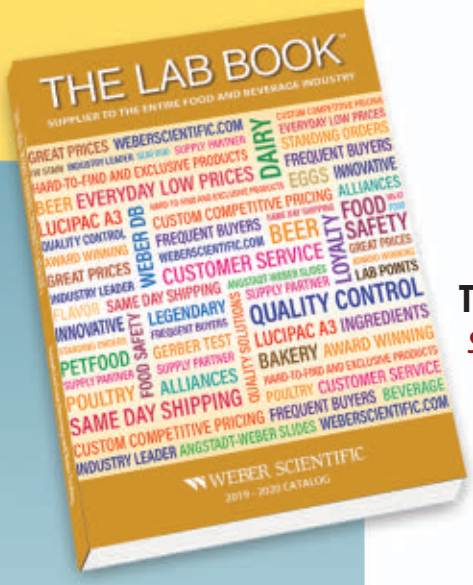
The most advanced sensitivity and detection sanitation hygiene system available.

- Only Kikkoman's new patented System detects ATP+ADP+AMP
  - ATP can be unstable and decompose into ADP and AMP
  - Conventional systems that test for ATP alone may fail to find the true presence of contamination and may produce false negatives
- Results are an order of magnitude or higher than other tests on the market

Be sure to ask about our FREE Luminometer Program!



We Carry Many Hard-to-Find & Exclusive Products



Request your FREE copy today of our 265-page buyer's guide!

Call 800-328-8378 or visit weberscientific.com

WEBER SCIENTIFIC

Legendary for quality products and great prices since 1959

800-328-8378 • weberscientific.com

AWARD WINNING LABORATORY SUPPLIER

By George G. Misko, Esq.

Biobased Plastics and the Sustainability Puzzle

Advancing sustainability with biobased food packaging

As consumer interest in sustainable alternatives to fossil fuel-based plastics continues to grow and food and beverage companies set goals to reduce their environmental footprint, the use of biobased plastics in food packaging is expanding. Revenue for the U.S. biobased plastics manufacturing sector was $177.9 million annually, according to a 2018 report prepared for the U.S. Department of Agriculture (USDA) titled, *An Economic Impact Analysis of the U.S. Biobased Products Industry*.[1] The report also estimates a 4.5 percent growth rate for the sector from 2018 through 2023.

The total production volume of biobased building blocks and polymers (worldwide) was 7.5 million tons in 2018, or about 2 percent of the production volume of petrochemical polymers, with a growth rate of 4 percent expected through 2023, according to a report by Nova-Institute GmbH.[2] The potential for significant growth is much higher, but low oil prices and a lack of political support are hampering growth, notes the report.

Examples of the use of biobased plastics in food packaging include Snickers candy bars with a biobased film wrapper made from potato starch by-products that were introduced by Mars in 2016 and the soon-to-be-available 20-ounce Dasani water bottles made with up to 50 percent renewable plant-based and recycled polyethylene terephthalate (PET) material beginning in mid-2020. The Coca-Cola Company first launched recyclable bottles made partially from plants (PlantBottle) in 2009 and expanded access to the PlantBottle IP in early 2019 to encourage industry-wide adoption. The new bottle, referred to as HybridBottle, includes recycled PET material in addition to the plant-based material.[3]

Other uses of biobased plastics in food contact articles include bags; containers for fruit, vegetables, eggs, and meat; bottles for soft drinks and dairy products; flexible packaging; and coffee pods. Biobased plastics also have been used in foodservice ware, such as bowls, cups, and straws.

Like most materials that are intended to be used to package or otherwise come in contact with food, biobased materials are also subject to the regulatory requirements imposed by several jurisdictions throughout the world. This article will focus on the requirements related to obtaining regulatory approval of biobased food contact materials (FCMs) in the U.S. and the European Union (EU), safety considerations, and future considerations.

We'll begin with some definitions. "Biobased" means related to or based on natural, renewable, or living sources. "Biodegradable" means capable of being broken down naturally into basic elemental components (water, biomass, and gas) with the aid of microorganisms. Compostable plastics are a subset of biodegradable plastics that biodegrade under specified conditions and time frames.

Several international standards are available to determine compostability of plastic packaging. The European Committee for Standardization standard EN 13432, "Requirements for packaging recoverable through composting and biodegradation," is a harmonized European standard and is linked to the EU Directive on Packaging and Packaging Waste (94/62/EC). In the U.S., American Society for Testing and Materials standard ASTM D6400, "Standard Specification

for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities," is cited in various regulations. For example, California requires that food and beverage containers labeled as "compostable" must meet the ASTM D6400 standard.

Biobased Plastics versus Bioplastics

An important distinction exists between biobased plastics and bioplastics. European Bioplastics defines "bioplastics" as a plastic material that is either biobased or biodegradable or both. On the other hand, "biobased plastics" are plastics manufactured from renewable biomass, such as vegetable oil, cornstarch, pea starch, and microbiota. Accordingly, a product can be both biobased and biodegradable, but it can also be biobased and not biodegradable, or biodegradable and not biobased.

"'Bio-based food contact materials' (BBFCMs) are derived from biological renewable resources (animal or plant biomass) that consist of polymers directly extracted or removed from biomass, produced by chemical synthesis using renewable bio-based monomers, or produced by microorganisms or genetically modified bacteria," according to the 2019 report *Bio-Based Materials for Use in Food Contact Applications*.[4]

The first bioplastics were developed from traditional agricultural resources, such as sugarcane, soy protein, starch, and cellulose. Within this group are polymers directly extracted from biomass and polymers produced by chemical synthesis using renewable biobased monomers. For example, polylactic acid (PLA), which is commonly used as a base material or coating in food packaging, is produced through the polymerization of lactic acid, which can be derived from the fermentation of agri-food wastes such as sugar beets or sugarcane.

PLA exhibits barrier properties comparable to fossil fuel-based plastics, such as low-density polyethylene and polyethylene, and has been used as a replacement for them, although it has the disadvantage of being more expensive to produce. The first generation of bioplastics also includes polymers produced by microorganisms or microbial fermentation, such as polyhydroxyalkanoate (PHA) and poly-3-hydroxybutyrate.

The second generation of bioplastics that are beginning to be introduced are made from raw materials such as food by-products, wood, and sawdust, explained Patrick Krieger, Plastics Industry Association, in an interview for the 2018 USDA report mentioned above. He added that the next or third generation of bioplastics, many of which currently are in the laboratory stage, will come from algae and other organisms that are not associated with the production of food. Another area of research is the production of strains of microbes through genetic engineering that can improve yields of biobased polymers.

> "…biobased materials are also subject to the regulatory requirements imposed by several jurisdictions throughout the world."

While biobased plastics offer myriad benefits related to sustainability, there are some concerns related to end-of-life issues. A potential disadvantage arising from the use of BBFCMs is the need to ensure effective segregation from fossil fuel-based materials to enable their effective recycling, suggests Fera Science in the UK report. For example, the presence of small quantities of PLA can prevent recycling of PET into a transparent product suitable for reuse in food and drink applications. Also, bioplastics produced from polymer blends that include biobased fillers may be difficult to recycle or may adversely affect the existing recycling stream.

Legislation for Plastic FCMs

Generally speaking, biobased plastics are required to comply with the same regulations with respect to food safety as fossil fuel-based plastics.

In the U.S., the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. Section 301, et seq., provides that any substance, the intended use of which is reasonably expected to become a component of food (e.g., migrates from packaging into food), must be authorized for such use by the U.S. Food and Drug Administration (FDA) through a food additive regulation or in the case of packaging and other FCMs, a Food Contact Notification (FCN), or the substance must be generally recognized as safe (GRAS) or used in accordance with a sanction or approval issued prior to 1958 by either FDA or USDA, among other potentially available exemptions and exclusions.

Polymers cleared for food-contact use through food additive petitions are listed in Title 21 of the *Code of Federal Regulations* (C.F.R.), Part 177, "Indirect Food Additives: Polymers." This part is further divided by types of polymers. Polymers and other food contact substances can also be cleared through an FCN. FCNs are proprietary and may be relied on only by the notifier/manufacturer and its customers.

For plastic packaging materials, FDA regulations generally clear the final polymer, not unreacted starting materials. There are, however, some exceptions where FDA permits certain starting reactants to be used to make a finished polymer. For example, in Part 175.300, "Resinous and polymeric coatings," FDA lists cleared precursor materials since these substances are typically complex and often cross-linked compounds.

In addition, any food packaging material intended to come in contact with food must comply with FDA's Good Manufacturing Practices (GMP) regulation, found in Title 21 C.F.R. Section 174.5. GMP requirements apply to both the use level of an additive and its purity. This means that additives may only be used in an amount necessary to achieve their function or purpose and

may not contain impurities at levels sufficiently high as to result in the adulteration of food.

In the EU, the Plastics Regulation, (EU) No. 10/2011, governs the use of plastic materials and articles intended to contact food. It applies to the plastic layers in all multi-layer food contact articles. This regulation includes a positive list of permissible monomers and other starting substances, additives (other than colorants), and some polymer production aids. In contrast to U.S. regulations, the EU Plastics Regulation does not include limits on co-reactants or use levels for starting materials, temperature restrictions, specification of single versus repeated use, and food types for specific substances.

> "'Biobased' means related to or based on natural, renewable, or living sources."

Anyone can petition to add a new monomer or additive to the Plastics Regulation's positive list. These petitions are first reviewed by the European Food Safety Authority (EFSA), which will issue a formal opinion on the safety of the substance when intended for use with food and any limitations that should be observed. Once EFSA has issued an opinion, finding a proposed use of a substance to be safe, the European Commission (EC), provided it concurs with the opinion, will add the substance to the list through an amendment to the regulation.

Finally, all FCMs in the EU must comply with the safety criteria set forth in Framework Regulation (EC) No. 1935/2004, which specifies that FCMs and articles may not transfer their constituents to food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristic of the food. All FCMs must also comply with the GMP Regulation, (EC) No. 2023/2006.

While certain biobased polymers have been cleared in the U.S. and the EU, such as PHA, a number of regulatory issues need to be considered for new materials or new applications for existing materials. For example, when preparing a submission to obtain clearance of the material, what are the appropriate food simulants to be used to estimate the potential for migration? Likewise, how do you prove to authorities (and to customers) that the substance is stable for an intended application that involves a specific type of food or temperature range?

Also, in some instances, it may be necessary to demonstrate the suitable purity of a product with respect to the potential presence of organic matter, such as cellular debris. Possible contamination with naturally produced contaminants (e.g., mycotoxins and algal biotoxins) may also need to be considered. In addition, possible contamination with organic compounds (e.g., dioxins and polychlorinated biphenyls) or inorganic compounds (e.g., lead and arsenic), nitrates, pesticide and veterinary medicine residues, and plant toxins may need to be evaluated. In addition, depending on the feedstock and processing conditions, process contaminants such as acrylamide could be formed due to Maillard reactions occurring when complex biomaterials such as food are heated.

Additional questions could result from the inclusion of nanoscale materials—to improve barrier function and to achieve similar or better shelf life—in biobased packaging. There could also be questions about the genetically modified microbial strains, if they are used, to produce the biobased plastic. The UK Food Standards Agency (FSA) report points out that, to date, there have not been any studies that address the presence of genetically modified materials present in the biomass used for the production of BBFCMs.

Another regulatory consideration concerns the use of alternative fiber sources in biobased food packaging—an area that is being investigated in both the U.S. and the EU. A potential application for fiber is the addition of bamboo to a polymer backbone for products such as reusable cups. Regulators in the EU are considering the use of bamboo in contact with food. With respect to other fiber sources, in the U.S., pulp is listed as GRAS under 21 C.F.R. Section 186.1673 for food packaging uses, including paper production. It is defined as "soft, spongy pith inside the stem of a plant such as wood, straw, sugarcane, or other natural plant sources" and therefore gives wide latitude in the potential candidates that could be available for use as alternative pulp sources. In the EU, untreated wood flour and fibers are cleared as additives in the Plastics Regulation. However, in all these cases, the suitable purity/safety demand of the regulations is still applicable.

Conclusion

The report *Bio-Based Materials for Use in Food Contact Applications* was the result of a review commissioned by FSA on potential risks and other unintended consequences of replacing fossil fuel-based plastic FCMs with BBFCMs. The key findings from the study are summarized below.

1. Limited research has been conducted on BBFCMs derived from agri-food by-products.
2. BBFCMs can exhibit barrier properties similar to traditional fossil fuel-based plastics, enabling comparable shelf life performance and consumer protection.
3. Information on the presence of inorganic contaminants such as heavy metals, persistent organic contaminants, and natural toxins in BBFCMs, and their capacity to transfer from biomass-derived BBFCMs into food, is required.
4. Polypeptide-based materials used for packaging may include substances that are known or suspected allergens or are extracted from matrices that contain allergens. More information is needed on the allergenicity of BBFCMs, as well as on the potential for transfer of allergens to food.

5. Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil fuel-based plastics to food are expected to be appropriate for or adaptable to BBFCMs.

While the current use of BBFCMs is low, the UK report predicts that their use will grow significantly in response to consumer pressures, manufacturer demand, and increased levels of industrial production. Also contributing to the growth of biobased plastics are new regulations that encourage movement toward sustainable products, especially in the EU, and the development of biobased polymers with increased performance benefits, such as ones that can be used in lighter-weight bottles that can hold carbonated pressure longer. Finally, increased demand for biobased products is likely to drive down production costs. ■

> "While biobased plastics offer myriad benefits related to sustainability, there are some concerns related to end-of-life issues."

***George G. Misko, Esq.**, is a partner in the Washington, DC, office of Keller and Heckman LLP.*

References

1. www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf.
2. news.bio-based.eu/2018-was-a-very-good-year-for-bio-based-polymers-several-additional-capacities-were-put-into-operation/.
3. www.coca-colacompany.com/press-center/press-releases/dasani-takes-steps-to-reduce-plastic-waste.
4. www.food.gov.uk/sites/default/files/media/document/bio-based-materials-for-use-in-food-contact-applications.pdf.

By Lone Jespersen, Ph.D., Matt Henderson, M.Sc., and Wade Fluckey, Ph.D.

Five Unusual Ways to Use Your Corporate Culture to Eliminate Foreign Material

Lessons from companies that "get" food safety

Culture-enabled food safety performance was a much-discussed and acted-upon topic in 2019. As outlined in the Global Food Safety Initiative position paper,[1] fostering a culture of food safety is essential across the entire food supply chain. Building an integrated plan that takes all five of the dimensions outlined in the position paper into consideration is paramount to creating lasting improvements. Clearly, the focus on building food safety management systems has created improvements in consumer safety; it is equally clear that only through the combined efforts of systems and culture can we continue the positive trajectory toward better protecting our food. This requires lasting improvements in the control and mitigation of all hazards (physical, chemical, and biological) that may pose a risk to consumers.

This article focuses on minimizing physical hazards through the elimination of foreign material (FM). Physical hazards have been defined as any potentially harmful extraneous matter not normally found in food. They are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify.[2] "Severity" by this definition ranges from an unpleasant taste or gastrointestinal discomfort to life-threatening choking or cutting. It is the less-researched hazard of the three Codex hazards, specifically biological, chemical, and physical. In a search of the relevant literature, we identified a short list of papers and articles focused on physical hazards, FM, or extraneous matter associated with food or drink products (see Resources at the end of the article). The research concentrates largely on detection methods. However, none of the papers address the impact of organizational culture.

Facts, like most organizations, are highly fragmented, and food safety expectations are often lost between silo walls and hierarchies. Fortunately, we found two leading meat companies that have learned how to eliminate FM from their consumers' plates. Based on these learnings, we were able to identify five unusual ways to use your corporate culture to minimize the existence of FM in your products.

Cultural Characteristics That Impact FM Elimination

Any culture of food safety consists of several characteristics. We will focus on five qualities that we believe specifically impact how well your company controls food safety hazards, including FM:

1. Promoting trust and courage, not blame
2. Integrating food safety into management principles, reliability, and operations
3. Setting and revising internal expectations and consequences
4. Focusing on competent employees at all levels/functions in risk analysis
5. Adhering to the belief that winning organizations are built on cross-functional teams

Details for each follow.

Promoting trust and courage, not blame: Placing an emphasis on finding someone to blame when something goes wrong fosters paranoia and distrust. It may also drive employees into isolation rather than communication and cooperation. It is far more effec-

tive to champion a culture of trust that promotes the courage to identify hazardous issues and, when necessary, take appropriate actions to correct them. Look for ways to express appreciation for courageous acts, including showcasing them through work team discussions, physical displays such as videos and bulletin boards, and other public acknowledgements. Consider setting up friendly competitions between different departments to promote acts of trust and courage.

Integrating food safety into management principles, reliability, and operations: Integrating quality food safety practices into everyday business tasks should be considered a principle of management, not merely a compliance tool. Track the costs of maintaining food safety internally in relation to FM findings. Include this information in leadership reports and post it on plant performance bulletin boards. Such actions will help your organization avoid inconsistencies in processes and behaviors during times of high staff turnover.

Setting and revising internal expectations and consequences: Each organization is a living, evolving entity. Ever-new technologies continue to drive change, as do an aging workforce and countless other business issues. Management must be prepared to change with the times through a constant review of its internal processes, expectations, and consequences related to both.

Focusing on competent employees at all levels/functions in risk analysis: It is important to recognize what and where competencies exist throughout an organization. Employee aptitude can be measured using a number of methodologies. Effective root-cause analysis can be used to identify such qualities as visual literacy, an analytical mindset, and an understanding of the "big picture" across the enterprise.

Winning organizations are built on cross-functional teams: Problem-solving coalitions such as so-called seek-and-destroy teams should include not only internal groups but suppliers as well. By creating a forum to share experiences and best practices with suppliers, it is possible to learn from each other and forge relationships between those responsible for FM prevention at both ends of the supply chain. This will improve communication and problem solving should an FM incident occur that involves more than one company.

What Can Be Done to Eradicate Foreign Contaminants in Products?

Eliminating FM in finished products requires prevention strategies focused on both internal and external sources of contamination. External strategies demand engagement with ingredient vendors to ensure that FM control programs are deployed and consistently monitored. The timely sharing of FM findings with suppliers is critical, along with documentation of corrective and preventive actions. Strategies to prevent FM originating from internal sources require identification and interventions at appropriate points in the process that include metal detection, X-rays, magnets, screens, and/or visual inspection where appropriate. When using product contact materials with the potential for shedding into the product stream, these materials should be capable of identification by the FM intervention. If the material is plastic and incapable of exposure by metal detector or X-ray, the material should be brightly colored to assist with visual detection.

"Eliminating FM in finished products requires prevention strategies focused on both internal and external sources of contamination."

Additionally, look for commonalities in root cause and determine why preventive measures either were unsuccessful or successful if no repetitive findings are evident in the time period chosen. Use continuous improvement (CI) tools to dig deeper into the root causes identified. Then, as a cross-functional team, develop a strategy to eliminate the foreign contaminants. And of course, measure and evaluate when and where possible.

Tactically speaking, we recommend tracking the cost of internal failures to FM on the plant metric dashboard, as well as the rate of in-process FM findings. FM found during processing has a cost both in terms of product that must be disposed of and the labor required to manage the issue and ensure no affected product reaches consumers. Giving all teams a clear view of the overall impact of FM on their business helps drive action and maintains a sense of urgency.

Another method we have found successful is organizing an annual meeting with our suppliers' food safety and quality representatives and their counterparts at our plants to share best practices in FM prevention. Hosting such a forum promotes shared learning and nurtures relationships among everyone responsible for FM prevention across the supply chain. The goal is to improve communication and problem solving during FM events.

Another tactic, reliability engineering, deals with the longevity and dependability of parts, products, and systems. More importantly, it is about controlling risk. Reliability engineering incorporates a wide variety of analytical techniques designed to help engineers understand the failure modes and patterns of these parts, products, and systems. Traditionally, the reliability engineering field has focused upon product reliability and dependability assurance.

In recent years, numerous organizations have begun to deploy various reliability engineering principles in production settings for the purpose of production reliability and dependability assurance. *(continued on page 51)*

Breaking Boundaries to Avoid a Food System Crisis

By Jennifer van de Ligt, Ph.D.

"Food is the moral right of all who are born into this world." – Norman Borlaug

Humanity is facing a daunting challenge that, if not addressed now, will rise to epic proportions. The challenge: Ensure food security while volatile, uncertain, complex, and ambiguous (VUCA) challenges arise at a faster rate than ever expected. If we continue down the same path that we're operating on today, a food system crisis will cripple our ability to feed Earth's estimated 10 billion people by 2050. How do we effectively avert this looming crisis while also ensuring a robust, healthy planet for our children and grandchildren?

We must be willing to break boundaries—boundaries that currently exist in our food system that inhibit us from more effectively collaborating, innovating, and discovering better paths to address today's and tomorrow's challenges. We must shift from compartmentalized, specialist, and siloed thinking and approaches to embrace a broader food systems mindset. A mindset centered on navigating our roles and choosing our actions within the food system through a holistic lens that promotes better outcomes at the personal and organizational level as well as locally, regionally, and globally for the food system.

VUCA and the World's Food Supply

To better understand the impact that shifting to a food systems-thinking approach can have on addressing our challenges, it's important to explore key pressures facing our food system and how VUCA relates to that system. "VUCA" is a term coined at the U.S. Army War College to describe the more volatile, uncertain, complex, and ambiguous world after the Cold War. The collapse of the Soviet Union triggered a new world order that required new ways of seeing and reacting. At the simplest level, the concepts of VUCA address rapidly changing conditions that can be positive or negative. When you look at the dynamics of the food system today, they meet the very definition of VUCA.

Volatility, or the nature and speed of change, is increasing in the food system. Many factors affect the volatility of the food system, including consumer preferences and technological innovation. For example, the exponential growth of plant-based meat alternatives and cell-cultured animal proteins in the past year is changing the food landscape. It has also contributed to the pressure on animal agriculture, which when combined with environmental concerns such as extreme weather, global warming, disease, and water stress, creates further volatility (see "Climate Change – A Key Pressure and Challenge Facing Our Food System," right). From a different aspect, labor shortages are also driving volatility. With unemployment at historic lows in the U.S., many food producers from farm to retail cannot hire enough labor or may be relying on temporary labor, forcing rapid change in diverse areas from mechanization to training. Overall, volatility and the rapid change in the food system create uncertainty that must be addressed.

Uncertainty, or lack of predictability, in the food system has multi-factorial causes. For example, nutrition has often been highlighted as an aspect of uncertainty within the food system. As nutrition science advances, conflicting messages have been presented to consumers. The headline messages of "eat this, not that" have overwhelmed the basic nutrition guidance of balance promoted by our scientific and governmental authorities. However, when the "eat this, not that" headlines reverse to "eat that, not this," consumers grow confused and frustrated. The uncertainty of consumer preferences, along with vacillating guidelines and opinions, leaves the industry struggling with ambiguity and the potential for misreads.

Complexity, or the confusion that surrounds issues, within the food system has many interconnected parts and variables. Many of these inter-relationships are potentially predictable, but the volume of information is often difficult to process. One of the simplest examples in the food system to illustrate complexity is the multi-national producer. With business units worldwide, there is a need to hire and develop appropriate resources to address the various regulations and cultural values in its widespread markets. Or one may consider complexity from a product-launch point of view, where the inter-relationships between consumer desire, product formulation, manufacturing parameters, supply chain and procurement of ingredients, and distribution and sales are often well-understood, complex relationships. However, when the volatility, uncertainty, and ambiguity of each of those factors are considered, the complexity of a successful product launch grows exponentially.

Climate Change – A Key Pressure and Challenge Facing Our Food System

The recent Climate Change and Land report[1] from the Intergovernmental Panel on Climate Change (IPCC) explores the impact of climate on our food system. Although the current food system feeds most of the world's population and the per capita global food supply has increased more than 30 percent since 1961, an estimated 821 million people in the world are currently malnourished and more than 2 billion adults are overweight or obese. In addition, the food system supports the livelihoods of almost 1 billion people worldwide. However, climate change is already putting pressures on food security.

Increasing temperatures are affecting crop yields, changing precipitation patterns are affecting growing conditions, and the greater frequency of extreme events only amplifies effects. For example, this year in the Upper Midwest, a very wet spring with late planting followed by early freezes meant that many root crops like potatoes and sugar beets were lost. The U.S. Department of Agriculture estimates the 2019 potato harvest will be 6 percent lower, one of the lowest crops on record,[2] and many farmers in Minnesota lost almost half of their sugar beets.[3] Conversely, higher, and fluctuating, temperatures and drought decreased the 2019 olive harvest by over 30 percent in many regions of Europe, and this follows low production in 2018 affected by a cold snap, heat wave, and severe flooding.[4]

As David Wallace-Wells reports in *The Uninhabitable Earth*,[5] scientists estimate that for every degree we heat the planet, the yields of staple cereal crops will decline by an average of 10 percent, approximately. If we carry on with business as usual, key staples are likely to collapse by some 40 percent as the century progresses. These changes in production capacity are expected to lead to global food price increases, which will put more people at risk of undernutrition, especially low-income consumers.

Under normal circumstances, regional food shortages can be covered by surpluses from elsewhere on the planet. But environmental models suggest there's a real danger that climate breakdown could trigger shortages on multiple continents at once. According to the IPCC report,[1] warming more than 2 °C is likely to cause "sustained food supply disruptions globally." As one of the lead authors of the report put it: "The potential risk of multi-breadbasket failure is increasing."

NEOGEN

Reveal 3-D *for Food Allergens*

Protect your product and your brand with NEOGEN's Reveal® 3-D for Food Allergens, providing a 5-minute, best-in-industry time to result. **Learn more at NEOGEN.com**

Ambiguity, or the mixed meanings of conditions, in the food system results when there is no precedent or when cause-and-effect relationships are unclear. Within the food system, policy frequently is an area that struggles with ambiguity. In many policy areas, it's expected that national governments and local communities can single-handedly ensure food security. However, this expectation does not address the causal relationships that result in food insecurity or identify solutions to address root causes. In some cases, local and state power to influence food supply production and distribution is limited; local efforts to capture food loss and waste may not align with state policy and regulations. Development of solutions to such issues will require a better understanding of not only the causal relationships but also the complexity of the food system and how it affects those relationships.

To solve the big VUCA challenges in the food system, we need to better educate our workforce into thinking beyond their current roles. We must expand and broaden viewpoints of emerging organizational leaders or those being groomed for succession. We must ensure these future leaders understand the food system from interdependent and collaborative perspectives, including primary production, processing, procurement, sales and marketing, food safety and quality, construction, and more. We need to ensure they have skills to problem-solve, communicate, negotiate, think critically, ask the hard questions, and be willing to propose bold solutions to break down boundaries. And most importantly, we need current leaders who will commit to fostering, supporting, and encouraging the development of these future leaders.

Food Systems Thinking to Achieve Better Outcomes

By embracing and understanding the VUCA nature of the food system, future leaders will be able to leverage capacity and build deeper understandings of all components of the food system. A VUCA mindset combined with a food systems-thinking approach promotes a more holistic path to solve problems and provides future leaders with:

- tools to think more broadly and become more effective problem solvers within their organization or across disciplines;
- the opportunity to break boundaries to positively influence how decisions, policies, and unforeseen circumstances ripple across the system to create success to avert the looming food crisis; and

What to Do with 700 Pounds of Turnips?

As we face the daunting task of feeding almost 10 billion people by 2050, let's break it down to a simple user-case scenario of how breaking boundaries via a food systems-thinking approach can have an impact that could have a ripple effect. In this case, it's a question of turnips, to ensure all edible food reaches consumers' plates.

Turnips are an easy-to-grow root vegetable related to broccoli, Brussels sprouts, arugula, and kale. Like other vegetables, turnips provide plenty of nutrients and are low in calories. In addition, both the root and the leafy greens of the plant may be eaten.

However, turnips are perishable and need to travel from farm to fork relatively quickly, especially the greens. In the U.S., turnips are not considered a staple food, and many people simply do not know how to cook them. The turnips will most likely remain untouched, rot, and end up in the dumpster.

This was the case for a food bank that recently received a shipment of 700 pounds of turnips.

Due to the volatility and uncertainty of shipments arriving at food banks, it is possible that the ambiguity in identifying customers and the complexity of finding creative ways to promote consumption of the unexpected foods present boundaries in need of breaking. In addition, the turnip case highlights the perishable nature of food and the time constraints to identify other, more creative solutions such as providing turnips to an industrial-scale composting system to transform the pre-consumer food waste into finished compost for farms.

The turnip scenario begs an important question for food systems leaders to consider: If turnips end up in the dumpster, how many aspects, inter-relationships, and collaborative approaches of the food system must be improved to avoid disposing of good, healthy food that could provide nourishment to people or the land?

For example, in this scenario, the food bank's supplier donated produce they had too much of and couldn't sell. The donation provided financial compensation through tax breaks. The consumer demand was not as high as anticipated, and once the donation happened, its perishable nature meant that identifying alternate uses was limited.

What often gets overlooked when finding customers for perishable food is education. That is, how can foods—especially unfamiliar foods—become part of one's diet? In the case of the turnip and the food bank community, for turnips, or other uncommon vegetables, to be considered an option for the consumers in the underserved community, product information and recipes must be provided. The food bank could offer recipes and how-to sheets to send out to food pantries. For example, did you know that turnips can be:

- boiled and mashed for a tasty alternative to mashed potatoes;
- chopped and used as a salad topper;
- added to soup or stew at the same time as adding potatoes;

- broader knowledge and understanding of interdependencies across the food system—from the private to public sectors, from farm to fork.

Combining VUCA with systems thinking will better equip the food industry to both meet immediate challenges and create solutions that will avert a food system crisis and achieve a sustainable food-secure future. This change in perspective will require future leaders in the food system to think broadly, keep an open mind, connect and explore new ideas, and challenge existing paradigms. It will allow food security to be achieved while continuing to offer food that is grown locally or overseas, regenerative or conventional, animal or plant based. The combination of approaches means future food system leaders must learn and leverage skills to encourage cooperative and proactive dialogue and collaboration across the food system from farmers and scientists to manufacturing experts and logisticians to sales and marketing executives.

In addition, future food system leaders must also be able to critically evaluate potential solutions to identify unexpected consequences (see "What to Do with 700 Pounds of Turnips?" on page 38). To make the challenge even harder, future leaders will need to communicate in a way that builds confidence within a cultural environment where food innovation is feared. In "Why We Fear the Food We Eat,"[9] Jack Bobo explains that food in the U.S. has never been safer, yet consumers are more afraid of their food than ever. The food industry must identify and develop leaders who have potential and desire to communicate with experts outside their field, understand inter-relationships driving important decisions, and create shared values across groups that may not agree with one another. Moreover, food system leaders must understand and navigate the combination of innovation, communication, media presence, and filter bubbles that are present in the food system. On-the-job learning is possible and essential, but it will not occur fast enough to avert the looming food crisis. The VUCA nature and speed of change in today's food system means that traditional approaches to learning will not be enough.

Building the Path to a Better Future

True impact will be achieved when a food systems mindset is embodied throughout the organizations and stakeholders within the food system. The hurdle to true

- cubed in a slow-cooked roast; or
- shredded into a favorite coleslaw recipe, baked, or steamed?

With the wide variety of perishable items arriving at food banks with minimal days left of appropriate food-safe quality, lack of advance notice and time to prepare appropriate education materials for the uncommon donations results in 45 percent root and tubers food loss and waste globally.[6]

Although 700 pounds of turnips are a tiny amount in the total quantity of root and tubers food loss and waste—equal to about 1 billion bags of potatoes each year—every little bit counts. Overall, more than one-third of the food produced in the world annually is lost or wasted. This amount alone could feed the expected population increase by 2050. In addition, tackling food loss and waste addresses what the UN Food and Agriculture Organization deems "a major squandering of resources, including water, land, energy, labor, and capital and needlessly produce[s] greenhouse gas emissions, contributing to global warming and climate change."[7] This is essential because climate change is also projected to decrease current food production levels due to shifting plant hardiness zones and precipitation patterns, and extreme weather events. As a result, it seems that a more robust, holistic approach to global food distribution, including contingency planning for unexpected surpluses, would help alleviate food loss and waste, like the turnip example, or the thousands of others that happen daily worldwide, and help ensure a more food-secure future.

The example of the humble, nutritious, tasty turnip highlights the boundaries that must be broken to solve everyday challenges happening across the globe.

This line of thinking leads us back to the local level and how we as individuals can help address food loss and waste. What is the role of the food pantry in the food system? Ideally, it is an arm reaching out to address hunger within the community. Geoff Tansey, author of *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, suggests "we look where the power lies to see what pushes food through our food system."[8] Given that lens, we can see that those in need, the underserved, are not the ones asking for large pallets of turnips. But what would it look like to move power in that direction? How would it change the function of the system and the relationships between the food pantries and the retailers?

When we consider that people in need aren't the ones asking for big deliveries of turnips, might there be other points of redistribution earlier in the food supply chain that convert the turnips into a different form that would be more suitable to the consumer? For example, if the turnips had value to another kind of producer who'd be happy to receive more of them, how might the turnips be redirected, and how might value be captured that becomes funding to support other types of food-based programs or policies for communities in need that gives them the power or autonomy to build what they need? How might we think beyond the examples of what we've seen? In other words, how can future food system leaders think holistically to break boundaries, one at a time, to help avert a food system crisis?

impact lies with providing opportunities to foster and grow the shift to a food systems approach. To begin that journey, the first action is for current leaders to recognize the need and identify future leaders with desire to lead in the VUCA food systems paradigm. Opportunities for development of the food systems skills will be required for leaders, and many programs already exist to assist in this development.

Many organizations provide training for their next level of managers that are specific to their context. However, to achieve the food-secure future envisioned, an expanded leadership mindset with food systems thinking across roles and departments will also be needed. Organizations should encourage and support expanded food systems leadership training and development opportunities not only to help their next-level managers gain a broader leadership approach but also develop emerging leaders who have demonstrated interest, growth, and desire to promote change.

Continuing education provides one option to access expanded food systems leadership development. There are several programs, courses, and workshops focused on leadership and critical thinking as well as food systems. However, many of these are either too narrow or too general in focus to tackle the complexities of the entire food system. A newer approach is to embed leadership development within a program focused on expanding food systems understanding and thinking.

In addition to the formal training programs within an organization or offered by academic institutions, informal development opportunities are available and play an important role in creating a broader food systems approach. These include industry and professional associations, conferences, and mentors. To promote the broader food systems view, joining and participating in association committees that are outside of role or disciplines will be needed. When attending conferences, intentional selection of sessions outside of an individual's domain expertise, networking, and asking questions of those in different specialty areas should be encouraged. On a more personal level, discussion with peers and identification of mentors outside of specialty areas will help build and leverage relationships and conversations that can lead to expanded knowledge and sharing across disciplines. Really, it's about identifying opportunities to think beyond one's boundaries, becoming involved, and being willing to raise a hand to explore new ways to approach the broader and rapidly changing food system.

Through a multi-pronged approach including both formal and informal food systems leadership development, our future leaders will be able to grow their skills and add near immediate value to their home organizations.

Averting a Crisis and Moving Our Food System Forward

In addition to growing leaders who are fluent in a food systems approach

and comfortable with the VUCA nature of the food system, it will take engagement from all stakeholders in the food system to avert a crisis. When thinking about stakeholders, disciplines and sectors are both important, and we must break boundaries and build bridges between them. For example, public-private partnerships, multi-cultural cooperation, and cross-disciplinary innovation will grow in importance. We must be willing to think more holistically and outside of the norm. We must foster a culture of enhanced collaboration that drives discovery and innovation across the continuum of the food system.

Most importantly, we need to work with and instill in our emerging leaders a food system mindset. This will allow us to develop and implement more effective food system solutions, and achieve a more sustainable global future. By fostering and embracing a food systems-thinking approach, which focuses on the inter-relationships and complex interactions found in our multi-faceted food system, we will be able to mitigate negative aspects and promote positive factors that will allow us to avert a crisis.

Let's break boundaries. Join my quest to shift our orientation to a more holistic, food systems-thinking approach—an approach that will allow us to effectively collaborate, innovate, and discover better paths to address today's and tomorrow's challenges. Together, we can ensure a food system crisis is averted so that our children and their children have both a food-secure future and a robust, healthy planet. ■

***Jennifer van de Ligt, Ph.D.**, is the director of the Integrated Food Systems Leadership program, director of the Food Protection and Defense Institute, and associate professor at the University of Minnesota.*

References

1. www.ipcc.ch/srccl/.
2. Katz, B. 2019. "Poor Potato Crops Could Lead to a North American French Fry Shortage." *Smithsonian Magazine*.
3. Nickel, R. 2019. "Frozen Harvest Leaves Bitter Taste for U.S. Sugar Beet Farmers." Reuters.
4. Cortina, M. 2019. "How Climate Change Has Impacted the 2019 Harvest." *Olive Oil Times*.
5. Wallace-Wells, D, *The Uninhabitable Earth: Life After Warming* (New York: Penguin Random House, 2019).
6. www.fao.org/3/a-i3901e.pdf.
7. www.fao.org/save-food/resources/keyfindings/en/.
8. https://idl-bnc-idrc.dspacedirect.org/bitstream/handle/10625/35059/IDL-35059.pdf?sequence=1&isAllowed=y.
9. www.ted.com/talks/jack_bobo_why_we_fear_the_food_we_eat.

Learning from "Near Misses" in Sanitation

Experience is often the best teacher, and learning from mishaps that have almost happened is just as important as leaning from those that do. In the occupational health and safety sector, incidents that could create larger problems—such as repositioning a box on a shelf before it has a chance to fall or cleaning up a spill before an employee can slip and fall—are recorded as "near misses." These incidents are valued not only for their immediate impact on safety but also for their ability to point out flaws in existing processes.

In the food industry, sanitation near-misses can be:

- Finding a clean drain brush stored with other clean brushes that are used on food contact surfaces
- Storing food-grade sanitation chemicals in the same room as office cleaning supplies
- Storing allergen ingredients in unlabeled containers
- Forgetting to verify the cleanliness of a processing line after a sanitation activity has been completed

Preventive controls can work together with learning from these near-misses to improve sanitation safety standards.

Recommendations on Preventive Strategies

Creating proper sanitation controls is about much more than just fixing a problem when it has occurred; it is about planning ahead to addressing the root cause(s) of issues to avoid not only actual but also potential food safety problems from happening in the near future.

The following are some proactive approaches that could help avoid near-misses during an operational sanitation regime:

Conduct a comprehensive food safety hazards risk assessment: Having a robust food safety plan that has a detailed Hazard Analysis in place can act as a good blueprint in avoiding any sanitation-related (or other) mishaps within a facility.

Manage the process flow to control contamination: To avoid potential violations in hygienic zoning between, say, the raw and ready-to-eat zones, the site must control the process flow. Also, the flow and movement of air, water, waste, people, and items must be monitored, as uncontrolled flow may compromise food safety and sanitation.

Make use of color-coding as a preventive control: Color-coding is effective and relatively inexpensive. As a preventive control, it can communicate the process status, act as visual cues for identifying items, separate hygienic or sanitary zones, and help promote food safety culture among employees.

Implement a well-integrated cleaning and sanitation approach: Having good Sanitation Standard Operating Procedures is important but equally so is the education, training, and competency of the employees who are carrying out sanitation tasks.

Invest in hygienically designed facilities, equipment, and materials: Hygienically designed facilities, equipment, and materials of construction are easily cleanable, more durable, and are less like to carry contaminants of a food safety concern (e.g., allergens, foreign materials, and pathogens).

Monitor and maintain the quality of the sanitary environment continuously: A good monitoring program not only verifies the effectiveness of sanitation tasks but also tracks the key hazards (pathogens, allergens, and foreign material contaminants) that help develop, implement, and maintain risk-based food safety prevention programs.

Aiming for Zero on Sanitation Near-Misses

Although processors can and should learn from any near-misses, it's vital to also continue to improve the processes, conduct regular employee training, and explore relevant tools to eliminate or reduce these almost-mishaps. Here are some tips for the industry:

- Allocate resources to issues that are most critical to food safety and sanitation, and monitor or trend them regularly to ensure continuous compliance. Educating and training staff members conducting these tasks is most important.
- Do not take a "near-miss" on a sanitation issue too lightly. Conduct a thorough analysis of its root cause and consider all significant factors.
- Test your food safety system to ensure it is resilient and able to stand up to the "worse-case situations" that may compromise food safety and sanitation. Avoid falling into the "comfort zone" of assuming that everything will always be fine.
- Encourage employees to report any near-misses in sanitation even when food safety, integrity, quality, and legality has not actually been compromised. Management can then deal with these cases on a risk-by-risk basis and take steps to ensure they don't happen again.
- Invest in tools and technologies that can make a beneficial difference to food safety and especially to the sanitary conditions in the plant. Proper selection, storage, care, and maintenance of cleaning and material handling tools, for instance, can make a positive impact.

Preventing sanitation mishaps can assure auditors, inspectors, customers, and other stakeholders that the facility is processing safe and wholesome food. The goal for the food industry is to work toward significantly reducing or eliminating the near-misses encountered during sanitation that might compromise the product safety or sanitary conditions within a food processing environment.

More products in more colors than any other color-coding system

Remco

a Vikan company

Visit remcoproducts.com to learn more.

By Matthew Michael and Jeremiah Fasano, Ph.D.

Animal Cell-Culture Food Technology: A New Regulatory Frontier

FDA, USDA will share oversight with safety in mind

The Food and Drug Administration (FDA) and U.S. Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) are working together to pave the way for regulation of food produced using animal cell-culture food technology. During 2018, public discussion and press coverage of animal cell-culture food technology were increasing, and questions arose concerning which government agency would be responsible for ensuring that products coming to market were safe and accurately labeled. FDA and USDA-FSIS hosted a joint public meeting in October 2018 to explore safety and labeling issues related to this new technology. The meeting was followed by the signing of a formal agreement outlining a joint regulatory framework for overseeing the production of human food products derived from the cells of poultry and livestock using cell-culture food technology. The agreement leverages FDA's expertise in technology used to grow cells, gained through decades overseeing biologics and various food production technologies, and USDA-FSIS's expertise in the oversight of meat and poultry processing and labeling. In this article, we explore how the two agencies are coordinating regulatory oversight of the process and how this oversight fits with the agencies' regulation of more traditionally produced food.

New Food on the Block

Animal cell-culture food technology is an emerging food production technique involving the controlled growth of animal cells from livestock, poultry, fish, or other animals, their subsequent differentiation into various cell types, and their collection and processing into food. This new technology has sparked substantial discussion related to regulatory oversight. In the United States, legal authority over food is primarily shared by the FDA and USDA-FSIS. In the face of a new food technology–animal cell-culture food technology–FDA

BE A FOOD SAFETY ROCK STAR!

Let the good times roll by attending the world's leading food safety conference, where more than 3,600 food safety professionals will rock Cleveland throughout hundreds of informative symposia, roundtables, and technical presentations. Our Professional Development Group meetings provide additional opportunities to tune in and hit the classic high notes in food safety!

IAFP2020

AUGUST 2–5 ▲ CLEVELAND, OHIO

HIT THE HIGH NOTES IN FOOD SAFETY!

Rock the food safety world with hundreds of opportunities to share, learn and grow to keep the global food supply safe.

International Association for Food Protection®

6200 Aurora Avenue, Suite 200W | Des Moines, Iowa 50322-2864, USA
+1 800.369.6337 | +1 515.276.3344 | Fax +1 515.276.8655
www.foodprotection.org

and USDA-FSIS are using their distinct statutory authorities and unique areas of expertise to ensure that these new products are safe and truthfully labeled.

There has been much discussion on food safety oversight as well as debate over what to call these products. You may have heard them referred to by other names. To avoid confusion, we are going to refer to them as animal cell-culture food products. These food products begin with cells obtained from livestock, poultry, fish, or other animals. Selected cells are prepared and stored for later use in a cell bank. The food production process then starts in a controlled environment, where small amounts of cells from the cell bank first multiply many times over and then, where they differentiate into various cell types, including the muscle, fat, and connective tissue cells that make up muscle tissue. Finally, the cells are collected and processed into food products.

"Animal cell-culture food technology is an emerging food production technique involving the controlled growth of animal cells…, their subsequent differentiation into various cell types, and their collection and processing into food."

A Call to Action

With advances in technology and increased interest from many parties, the prospect of producing food products that incorporate cultured animal cells became a hot topic of conversation in 2018. Many companies, both foreign and domestic, are actively working on developing products using this technology. Some of these products are being designed to have the same or similar smell, texture, taste, composition, and nutritional characteristics as traditional meat and poultry products. As public discussion and press coverage of animal cell-culture technology increased, questions about regulatory authority came to the forefront of conversations.

In February of 2018, the United States Cattlemen's Association filed a petition with USDA-FSIS regarding the labeling of cell-based products. Specifically, the petition requested that the definition of "beef" be limited to products from cattle born, raised, and harvested in the traditional manner, and that the definition of "meat" be limited to the tissue or flesh of animals that have been harvested in the traditional manner. This petition was posted publicly and directed significant attention to cellular agriculture, including over 6,000 comments from industry trade associations, consumer advocacy groups, businesses operating in the meat, poultry, and cell culture-based food product markets, and consumers.

FDA and USDA-FSIS hosted a joint public meeting in Washington, DC, on October 23 and 24, 2018, to explore safety and labeling issues related to this new technology. The meeting allowed interested stakeholders to share their thoughts on potential hazards, oversight considerations, and labeling of cell-culture food products derived from livestock and poultry. Meeting attendees included meat and poultry packers, processors, and producers; firms intending to produce food cultured from the cells of livestock, poultry, and seafood; consumer advocacy groups and consumers; and academia. FDA's Science Board also met publicly to discuss potential hazards and nutritional considerations in the production of food derived from animal cell-culture technologies on October 22, 2018.

So, Who Makes Sure It's Safe?

The species of the animal from which the cells originate is the starting point for determining which agency regulates these products. Under the Federal Meat Inspection Act of 1906 (FMIA), USDA-FSIS is responsible for the inspection of any meat or meat food product intended for human consumption and derived from cattle, sheep, swine, goats, or fish of the order Siluriformes (i.e., catfish). USDA-FSIS also inspects poultry and poultry products under the Poultry Products Inspection Act of 1957 (PPIA). Food products from animals not subject to inspection under the FMIA or PPIA (non-amenable species) are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA). It follows then that food products derived from cells of species not subject to USDA jurisdiction fit solely under the regulatory authority of FDA. However, food products made from the cells of species regulated by USDA under the FMIA and PPIA will be regulated by FDA during production (cell collection, selection, and growth) and by USDA-FSIS during processing and labeling. This arrangement resembles, in some ways, the division of jurisdiction over traditionally produced meat and poultry products. Traditionally, FDA has food safety authority over amenable livestock and poultry during on-farm production, and USDA-FSIS assumes food safety authority when they are presented for slaughter and processing. The agencies subsequently share authority over amenable livestock and poultry, with USDA-FSIS assuming primary responsibility for their regulation.

FDA has extensive experience regulating various forms of cellular technology, including substances produced by cultured cells for both food and therapeutic uses, cultured cells from non-animal sources used as foods, genetic engineering used to develop new varieties of plants, and cultured cells

and tissues for therapeutic applications. This experience spans multiple centers at FDA and includes the regulation not only of food products but also of drugs and biologics under the FFDCA, some of which are produced using similar cell-culture techniques.

Similarly, USDA has experience regulating complex food processing systems, including irradiation, enzyme-based processing, and advanced meat recovery systems. USDA-FSIS conducts inspection at over 6,400 establishments, where inspectors are present during all hours of operation at livestock and poultry slaughter establishments and once per production shift at establishments that process meat and poultry products post-harvest. USDA-FSIS also has the authority to require pre-approval of labeling, including labeling claims for meat and poultry products. With this authority, USDA-FSIS can review labels for accuracy, including claims such as health claims, an "organic" claim, or a claim regarding animal raising or meat and poultry processing methods.

"The species of the animal from which the cells originate is the starting point for determining which agency regulates these products."

A Regulatory Path Forward

FDA and USDA-FSIS continued to meet following the public meeting and on March 7, 2019, signed a formal agreement outlining a joint regulatory framework for overseeing the production of human food products derived from the cells of livestock and poultry using cell-culture food technology. The agreement defines the roles and responsibilities for each agency; it leverages FDA's expertise in technology used to grow and differentiate cells and USDA-FSIS's expertise in the oversight of meat and poultry processing and labeling.

The bottom line of the agreement is that FDA will regulate the production process up until the point of cell harvest. At harvest, FDA and USDA will coordinate to transfer regulatory oversight from FDA to USDA-FSIS. USDA-FSIS will then assume primary regulatory oversight for the further processing and labeling of these products. And again, it's important to remember that this framework applies only to cells extracted from animals already under USDA-FSIS jurisdiction–livestock, poultry, and fish of the order Siluriformes. Food products derived from cells extracted from other animal species not subject to USDA jurisdiction, including all other fish and shellfish, will be under the sole jurisdiction of FDA.

As described in the March 2019 formal agreement, FDA's approach to regulating products derived from cultured animal cells will involve a thorough pre-market consultation process that includes evaluation of the production process and produced biological material, including tissue collection, cell lines and cell banks, manufacturing controls, and all components and inputs. Establishments that conduct cell banking, cell proliferation or differentiation, and cell harvest activities will be required to comply with FDA's Current Good Manufacturing Practices and preventive control requirements for food production facilities. After a successful pre-market safety consultation, FDA will conduct routine inspections and other oversight activities at cell banks and facilities where cells are cultured, differentiated, and harvested, to ensure that potential risks are being managed and that biological material exiting the culture process is safe and not adulterated within the meaning of the FFDCA. In conducting inspections and other oversight activities, FDA will be able to draw on both the results of its pre-market consultation for the cellular material being produced by each facility and its assessment of production records maintained by the facility to ensure that all food produced there meets those standards. Should FDA uncover areas of noncompliance, it will consider enforcement action. FDA also will ensure that labeling of cell-culture products derived from animal species not subject to USDA jurisdiction is truthful and not misleading, consistent with coordinated FDA and USDA-FSIS principles for product labeling and claims.

Authority for regulatory oversight will be transferred from FDA to USDA-FSIS at the harvesting stage of the cell-culturing process (the stage at which cells are removed from a sealed growth environment and prepared for traditional food processing). As part of the formal agreement, FDA and USDA-FSIS are working to develop detailed procedures to facilitate coordination of shared regulatory oversight related to the harvest of biological material.

USDA-FSIS will carry out inspections at establishments where cells derived from livestock and poultry are harvested. These establishments will be required to have USDA grants of inspection and meet USDA-FSIS regulatory requirements for Hazard Analysis and Critical Control Points systems and sanitation. USDA-FSIS inspectors will review batch records to verify the cellular products are safe, wholesome, and not adulterated, and verify compliance with applicable USDA-FSIS regulatory requirements for any product processing. If cells are shipped to other establishments for further processing, these establishments also will be subject to USDA-FSIS inspection. USDA-FSIS inspection of cell harvest and processing will occur at a frequency of at least once per shift, the inspection frequency also required for the processing of traditional meat and poultry products. This level of verification is necessary for products to receive the USDA mark of inspection. Finally, USDA-FSIS will ensure that cell-based products are labeled truthfully and consistent with coordinated FDA and USDA-FSIS principles for product labeling and claims.

Importantly, both FDA and USDA-FSIS currently have the statutory authority to regulate animal cell-culture food technology from their respective laws (FFDCA for

FDA, and FMIA and PPIA for USDA-FSIS). Both agencies have agreed to work together to identify and work through any changes needed to statutory and regulatory authorities. However, at this time, neither agency anticipates that additional legislation will be necessary for this food production technology. USDA-FSIS has publicly stated that it is interested in developing new labeling requirements for meat and poultry products produced using this process. USDA-FSIS is committed to a public process for developing these requirements, which likely will involve rulemaking.

The joint FDA and USDA-FSIS public meeting also served to identify key areas where coordination between both agencies will be necessary to inform future decision making; three FDA and USDA-FSIS work groups have been formed as a result. The first work group established, led by FDA, is a pre-market food safety assessment group tasked with developing the overall pre-market consultation process. The second work group concerns transfer of jurisdiction and will develop the procedures for transferring inspection from FDA to USDA-FSIS at the cell harvest stage; FDA and USDA-FSIS are co-leads for this work group. The final work group is the labeling group, led by USDA-FSIS, which will develop coordinated principles for product labeling and claims to ensure consistency and transparency.

Bringing the Production Process into Focus

Although animal cell-culture food technology products are in various phases of development, both FDA and USDA-FSIS are engaging with industry to learn about the specific processes and technologies that companies are using to develop products. The agencies recognize that some details of this technology might be considered proprietary, but we encourage industry to share information with regulators sooner rather than later. The more we know about the finer points of the processes and technologies now, the better we will be able to design regulatory processes that work with each technology, preventing regulatory delays down the road.

We expect that many characteristics of the products that can be produced by these processes and technologies will vary, such as the composition, nutritional content, shelf life, and functionality. We believe that many of these characteristics will need to be reflected through the labeling of these products, which may require careful evaluation and an iterative, data-driven dialogue with industry. Given these considerations, we also believe that these discussions with industry should begin soon to prevent unnecessary delays once companies are ready to bring products to market. ■

Matthew Michael *is the Director of the Issuances Staff at USDA-FSIS.* ***Jeremiah Fasano, Ph.D.****, is a senior policy advisor in the Office of Food Additive Safety's Division of Science and Technology at the Center for Food Safety and Applied Nutrition, FDA.*

(continued from page 11)

Preventive Controls

Section 117.135, which establishes requirements for preventive controls, states that such controls include, as appropriate to the facility and the food:

(a)(2)Food allergen controls. *Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:*

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) [§343(w), which requires disclosure of allergens by specific name] of the Federal Food, Drug, and Cosmetic Act.

(3)Sanitation controls. *Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:*

…[p]revention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food contact surfaces and from raw product to processed product. (Emphasis added.)

Conclusion

On October 29, 2018, in the context of FDA's request for information about sesame allergy, then-FDA Commissioner Scott Gottlieb issued a statement that included the following, which sums up FDA's view on this topic:

Thousands of Americans experience life-threatening, food-related reactions each year, and an estimated 20 people die from them annually. In some cases, such reactions occur despite a careful reading of packaged food labels by conscientious consumers. To me, that's unacceptable. The FDA is committed to advancing our efforts to help ensure that Americans have access to the information they need about common allergens in packaged foods.

In particular, the undeclared presence of allergens in foods—the leading reason for food recalls—continues to be a significant public health issue and an area of active policy consideration by the agency.[7] ■

***John M. Packman**, DLA Piper LLP, can be reached at john.packman@dlapiper.com.*

References

1. www.mayoclinic.org/diseases-conditions/food-allergy/symptoms-causes/syc-20355095.

2. *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004* (Edition 4); Final Guidance, FDA, October 2006 (*FDA Allergen Guidance*) (emphasis and paragraph breaks added); available at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4.

3. wayback.archive-it.org/7993/20170403234936/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106546.htm.

4. iegpolicy.agribusinessintelligence.informa.com/PL215400/FDA-says-rye-barley-should-not-qualify-for-major-food-allergen-list.

5. www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&D=FDA-2018-N-3809.

6. www.prnewswire.com/news-releases/the-coconut-coalition-of-the-americas-launches-initiative-to-remove-coconut-from-the-fda-major-food-allergen-list-300914453.html.

7. www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-consideration-labeling-sesame-allergies.

(continued from page 17)

that we frequently use for food safety topics. We not only emphasize best practices that they should be following to keep it top of mind, but we also show statistics on foodborne illness to emphasize the crucial nature of the work that they are doing and keep them thinking about the people that they are serving food to."

More Eyes on Food Fraud

While food fraud was not one of the higher-ranked priorities in our survey, it was mentioned by a number of respondents and is a topic we have discussed many times here in Food Safety Insights. In the same interview with this retail professional, they emphasized that they are seeing the nature of food fraud changing, and it is increasingly becoming a priority on their list. *"It is not the largest issue that we deal with, but we do see that food fraud is becoming a more difficult issue all the time,"* they said. Another respondent with a global supply chain added, *"We have found products with our brand name on the label coming in from Asia that were clearly not our regular product. We were able to show that the product (in this case, mixed nuts) in the can were counterfeit by sending them to a forensic food safety lab for DNA testing to prove the product was counterfeit."* They added that while they had seen issues of fraud as long ago as 20 years, the speed at which the counterfeiters are improving their methods and getting "very good" at reproducing labels and packaging is making fraudulent product more and more difficult to detect.

Looking Ahead

We would like to express our thanks to everyone who participated in our survey and especially those who agreed to be interviewed for this article.

And, as long as we are talking about goals for 2020, our goal here at Food Safety Insights for this year is to continue to follow these and other important issues in food safety. We will also continue to seek out what is actually happening "on the ground" in food processing companies, to listen to the viewpoints and ideas of food safety professionals from around the world, and to deliver that information to you. ■

***Bob Ferguson** is president of Strategic Consulting Inc. and can be reached at insights@foodsafetymagazine.com or on Twitter at @SCI_Ferguson.*

(continued from page 25)

can take this punch and a hammer and remove the metal rod holding the links together at any point on the belt. Very easy for your cleaning crew." Oh boy! He actually thought that would make me happy? Of course not!

I pointed out that I didn't think anyone would give members of their sanitation crew a hammer and punch for disassembling a belt because they would obviously use excessive enthusiasm for that task and quickly turn the belt and pretty shiny aluminum side rails into a mangled, damaged mess. I wanted one easily removable pin, with a handy loop pull ring installed, so that the same place could be taken apart each time without the need for a hammer and punch. Oh, and by the way, pull pins needed to be installed at the edge of the stripe. "What stripe?" asked the engineer, "the belt is one solid color." I replied that I had specified in my original order that I would be provided with two belts in two different colors. The engineer said, "That doesn't help. Each belt is a solid color for the entire length. There are no stripes on them." I replied, "Take six links from each color belt and swap them. I need an easily seen stripe on each belt." As you might have guessed by now, the engineer hated to even ask me why, but I explained that having a different-colored stripe on the belt made it easy for my sanitation people and my QA people to watch the entire belt run and do visual sanitation checks and belt inspections. That also allowed my QA people to make sure that they were swabbing different areas of the belt each time, so that they didn't create a false sense of "clean" by sampling the same area over and over, making it cleaner each time they swabbed it.

The other type of mistake that food processors often make in relation to equipment and sanitation is when installing equipment. To make the equipment fit into a space that is already tight with other things, they place the equipment too close to a wall or too close to other pieces of equipment, so that it is very difficult for people to get into the right location for proper cleaning performance. Your employees cannot be blamed for doing less than a great job of cleaning when they cannot physically reach that entire side of the equipment that is right up next to the wall. Likewise, is it the sanitation person's fault that you installed a piece of equipment too tall for him to reach but placed in a location surrounded by open drain lines where a ladder cannot safely be set up? More thought needs to go into the design, installation, and setup of equipment for it to be more cleanable and for allergen carryover from shared equipment to become a thing of the past. ■

***Donna F. Schaffner** is the associate director of food safety, quality assurance, and training at the Rutgers Food Innovation Center.*

(continued from page 33)

As suggested previously, make the discovery and elimination of FM a competition between departments, with appropriate acknowledgements and rewards for the winners. Set up regular meetings focused on FM. Just make sure you're not the only one talking!

The strategies that do *not* work include yelling at people, firing staff, and generating detailed paperwork regarding retraining staff how to detect FM.

Company Cultures That Help or Make It Challenging to Identify FM

It is a challenge when groups such as QA and CI are viewed as overhead rather than part of the value arm of the business. High turnover rates, while not necessarily cultural but perhaps a symptom of a challenging corporate culture, can lead to inconsistency of applications and processes; line of sight from top to bottom of the company can be obscured. While on-boarding and training do address FM prevention, it can be a challenge to avoid relearning the same lessons over time as staff changes. Another impediment exists when senior management is unable to embrace changing technology when leadership does not fully recognize its worth.

A strong culture of cross-functional teams engaged in problem solving at the plant level supports a consistent focus on FM prevention. The seek-and-destroy team model utilized to identify and eliminate microbiological niches in the ready-to-eat production environment can also be applied to a cross-functional team similarly tasked with addressing potential FM entry points.

Closing Thoughts

The safe procurement, processing, and distribution of the world's food supply promises to remain a hot-button issue. Unfolding climate crises, political unrest, and other unforeseen events can only exacerbate the challenges inherent in safe food delivery on a global scale.

In many ways, the quality of consumer food safety in much of the world has never been better. Yet the constant threats of physical, chemical, and biological hazards demand unceasing vigilance and constant improvements in food safety processes.

Now more than ever, any enterprise engaged in the food industry must make safe food practices an essential element of its corporate culture. We hope that the insights we have provided here, based on real-world experience, offer guidance to any company seeking to embed safe food handling practices into the hearts and minds of every employee. A hungry world demands it. ■

***Lone Jespersen, Ph.D.**, is principal at Cultivate and a member of the Editorial Advisory Board of* Food Safety Magazine; ***Matt Henderson, M.Sc.**, is the director of food safety at Land O'Frost; and **Wade Fluckey, Ph.D.**, is vice president of technical and regulatory affairs at Clemens Food Group.*

References

1. www.mygfsi.com.
2. seafoodhaccp.cornell.edu/Intro/blue_pdf/Chap12Blue.pdf.

Resources

St. Jeor, VL, et al. "Identifying Foreign Material Contamination in Food and Food Ingredients." Cargill Global Food Technology Group. www.sciencedirect.com/science/article/pii/B9780081005965034375.

Edwards, BR. 1980. "Method of Determining Foreign Material in Food Products Using Ultrasonic Sound." *J Acoust Soc Am* 68:1913.

Prince, G. 2014. "Controlling Foreign Material Contamination." *Snack Food Wholesale Bakery* 103(8):36.

Qu, CC. *A Research on Method and System for Foreign Material Detection In-Process* (Tsinghua University: ProQuest Dissertations Publishing, 2006).

Burd, SB. *Guidelines to Detect Foreign Material Contamination for Food Processors* (California State University: ProQuest Dissertations Publishing, 2007).

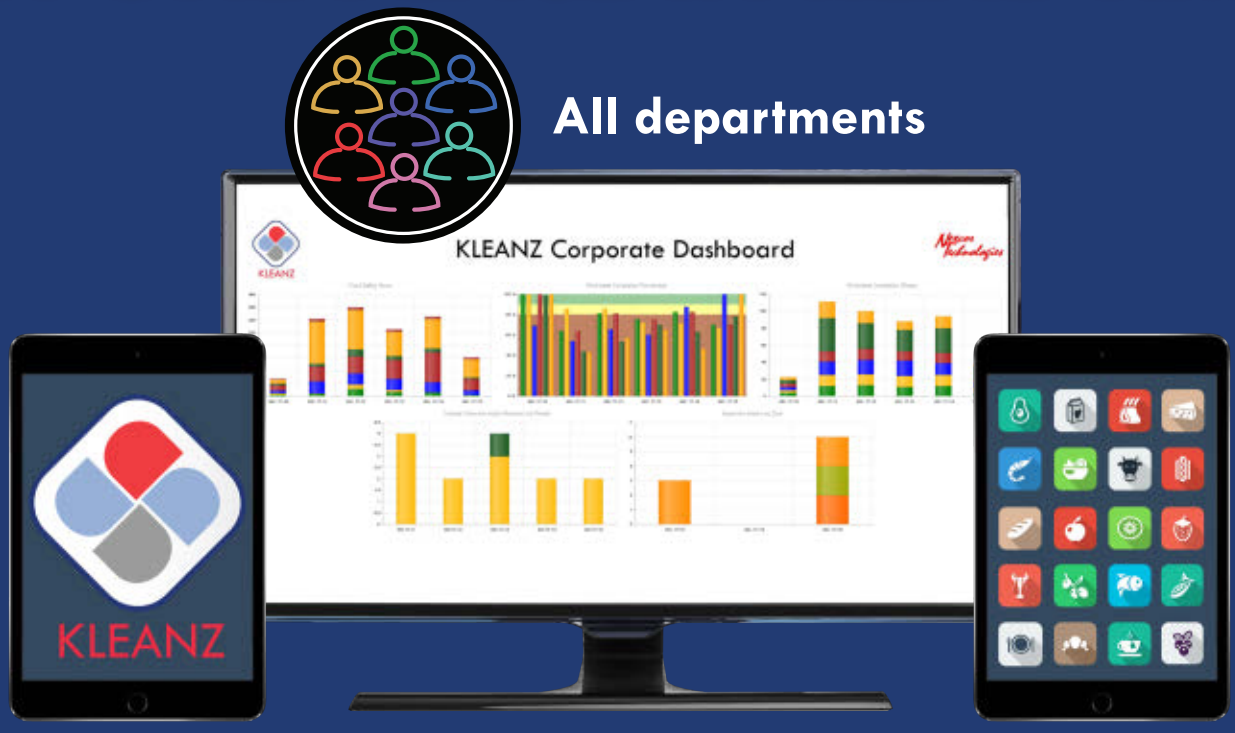
Kennell, B. 2015. "Why Food Safety Matters." *Food Manufacturing* June 10.

Payne, J. 2015. "Track and Trace Technology: One Cure for the Common Recall." *Food Manufacturing* June 12.

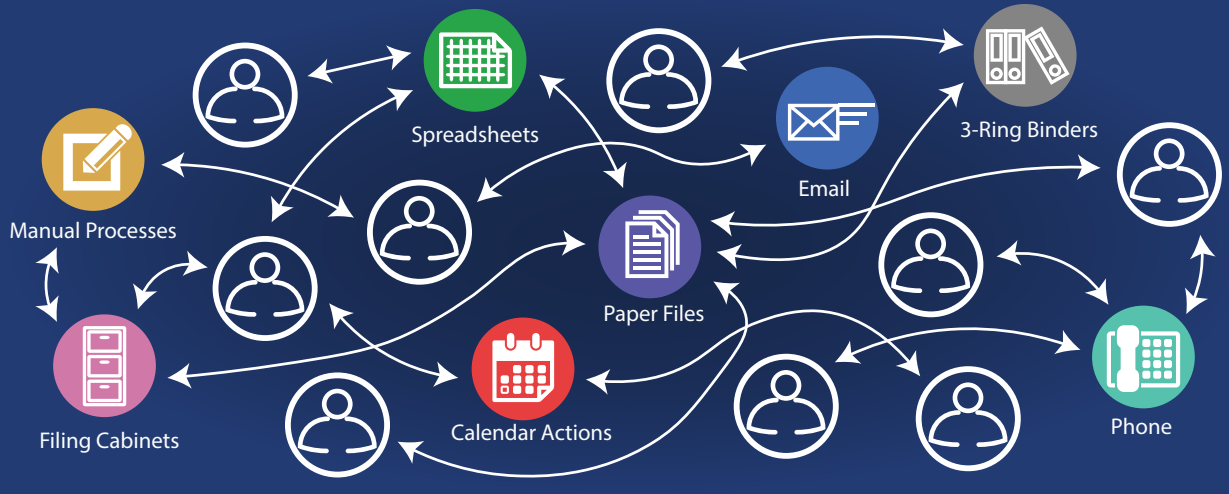
www.fda.gov/consumers/consumer-updates/whole-genome-sequencing-cracking-genetic-code-foodborne-illness.

Advertisers Index

EVERYTHING FOOD SAFETY IN ONE PLACE IN REAL-TIME



VS.



KLEANZ

By Nexcor Food Safety Technologies

770.831.9191 • info@kleanz.com

KLEANZ.com

The KLEANZ Team will be speaking at

ASB

BakingTECH Vision 2020

8th Annual American FOOD SURE Summit

2nd – 3rd March, 2020 Chicago