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Risk Resilience: Navigating Hazards and Recalls in Food Industries

In the dynamic world of food and agribusiness, where success hinges on the ability to navigate complex regulatory landscapes, mitigate risks, and ensure consumer safety, our combined expertise serves as your compass and shield.

About Cottingham & Butler: Your Trusted Risk Management Partner

Cottingham & Butler brings decades of experience as a leading provider of risk management and insurance solutions. Special izing in the unique challenges faced by the food and agribusiness sector, Cottingham & Butler is dedicated to empowering organizations to proactively manage risks, enhance operational resilience, and protect their bottom line.

About The Acheson Group: Regulatory Experts Pioneering Food Safety

The Acheson Group is synonymous with excellence in food safety and regulatory consulting. With a team of seasoned experts who have played pivotal roles in shaping global food safety policies, The Acheson Group is committed to elevating industry standards and ensuring that businesses are not just compliant, but resilient in the face of evolving challenges.

Your Gateway to Operational Excellence

This eBook is not just a compilation of best practices; it is a tailored guide designed to meet the specific needs of food and agribusiness operations. Whether you are a seasoned industry veteran or a newcomer navigating the regulatory landscape, "Safeguarding Success" is a comprehensive resource that promises to:

Illuminate Key Hazards and Risks
Dive deep into the intricacies of your industry with insights that identify and demystify the critical hazards and risks affecting your operations. Our collaborative effort ensures a nuanced understanding of the challenges unique to your sector.

Elevate Recall Readiness Strategies
In an era where product recalls can make or break a brand, our eBook equips you with proven strategies to not only prepare for recalls but to navigate them with finesse. From crisis communication plans to rapid response frameworks, "Risk Resilience" is your go-to resource.

Instill Contamination Best Practices
Stay ahead of the curve by embracing contamination best practices endorsed by industry leaders. From supply chain integrity to facility-level controls, this eBook delves into the strategies that fortify your defense against contamination threats.

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Dairy Food Safety, Supply Chain And Risk Management Services

The vast range of subsectors in the dairy industry - from liquid milk to cheeses, ice cream, frozen desserts, butter, yogurts/fermented products, dairy powders - means there is also a vast range of processes, procedures, related hazards and risks.

In Partnership with tag THE ACHESON GROUP

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KEY HAZARDS & RISKS

- **Supplier issues**, including incoming goods contamination from the field, processing, and/or transportation, antibiotic residues used in the treatment of livestock and animal welfare.
- **Process controls**, including environmental contamination, sanitation issues, CIP/COP procedures, time/temperature controls, etc.
- **Pasteurization errors/lack of validation** carries extreme risk of pathogenic contamination (e.g., Brucella, Campylobacter, Cryptosporidium, E. coli, Listeria, and Salmonella).
- **Post-process contamination** of milk-derived products, including product deterioration from water activity in certain milk products (such as cheeses), added contamination or allergen risk from additives/inclusions (e.g., herbed butter, nut ice creams, etc.).
- **Intentional adulteration**, particularly related to bulk supply, transportation, storage, and processing; including economic adulteration/food fraud of incoming goods.
- **End use** of certain products (such as milk powders in infant formulas) require higher sanitation and care.

SPECIALIZED SERVICE OFFERINGS

- **Insurance and Risk Transfer Program Design** - Dedicated Food & Agribusiness team specializes in analyzing, structuring, and procuring optimal insurance programs.
- **Supply Chain Risk Management** - Proprietary and customizable tools enable full-chain risk identification and mitigation strategies for food safety.
- **Environmental Control and Monitoring Programs (Ecp/Emp)** - Assess your facility and documentation to determine pathogenic contamination risk, provide solutions, and mitigate issues.
- **Hazard Analysis and Risk Assessment** - Conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to sanitation, allergens, process controls, etc.
- **Regulatory Compliance** - Help food companies ensure their compliance with FDA, USDA, and foreign food safety regulations through document and facility reviews and assessments.
- **Recall / Crisis Management** - Helps food facilities ensure they are prepared for a recall or crisis through interactive simulations, development/review of recall plans, and crisis assistance.
- **Intentional / Economic Adulteration** - Insider or external intentional contamination is a real risk in today's world. TAG's onsite vulnerability assessments for intentional and/or economic adulteration, and IA Rule training, help keep food operations safe.

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Dairy Update

An overview on recent recalls, regulatory updates (past, current and future), issues impacting the dairy sector, and other pertinent items of interest to a Risk Manager of a large-scale commercial producer.

DAIRY ISSUES AND STATUS

The dairy industry is facing a number of issues in 2022, from increased feed and operational costs to competition from animal-free milks and cheeses. However, some are projecting the year to be the most profitable for the industry over the last decade.

With both Russia and Ukraine being major wheat exporters, Ukraine being a critical corn and fertilizer exporter, and energy costs rising as well, the conflict is having a significant impact on America's agriculture industry. As discussed in a TAG article, with the food supply chain still in disruption from the pandemic, the war in Ukraine will only further stress food production. Not only will overall shortages continue to be an issue, but commodities that are at the very heart of our foods are becoming more scarce and more expensive.

The continuing increase in plant-based and lab-grown ("animal-free") milk products is due, at least in part, to the increasing number of lactose-intolerant and vegan consumers, animal welfare concerns, as well as:

- Lab-grown milk involves a process known as "precision fermentation" by which a cow-DNA-replicating genetic code is inserted into yeast or other micro-organisms, which are then fed sugars and brewed so that they multiply. (Financial Times)
- A UK-based company is developing animal-free cheeses using precision fermentation (similar to beer brewing) to produce products that are molecularly identical to traditional dairy. The company is targeting hard cheeses, a process that is more complex than soft cheeses. (Tech Crunch)
- A new kind of "milk", made from whey proteins produced by microflora, has been engineered to produce the same proteins found in milk from a cow. (New Atlas)

Even with all this, a Progressive Dairy article notes that producers showed optimism at recent trade shows which was matched by projections for farm profitability in 2022, based on predicted feed and milk prices. Thus, "following several years of tight margins, it seems that 2022 could be the most profitable in a decade."

The article supported the prediction with user data from Zisk, a downloadable free app that projects farm enterprise profitability – with app users representing almost 3 million dairy cows from 2,100 U.S. dairies. Additionally, milk prices are expected to be "bullish," and U.S. exports are strong, with significant growth in China consumption.

FIRST QUARTER DAIRY RECALLS

- January 30, 2022 - A Yelm, Wash.- based dairy recalled retail raw goat whole milk displaying because it may be contaminated with Escherichia coli bacteria (E. coli). The recall was initiated after routine sampling conducted by the Washington State Department of Agriculture (WSDA) revealed the presence of toxin-producing E. coli in retail raw milk dated 2/1.

- February 11, 2022 - A Manchester, Conn., ice cream company expanded its recall to include all products manufactured at the facility within expiry, because they have the potential to be contaminated with Listeria monocytogenes. The effected ice cream was distributed in retail stores in MA, CT, RI, VT, NY, LA, FL, TX, NH.

- February 16, 2022 - Whole milk produced by a Fallon, Nev.-based dairy was voluntarily recalled due to inadequate pasteurization. The problem was detected during a routine check by officials from Nevada Department of Agriculture on February 15.

- March 23, 2022 - A sample of unpasteurized raw milk collected from a New York farm by a State inspector was discovered to be contaminated with Salmonella. Further laboratory testing confirmed the presence of Salmonella in the raw milk sample. The producer is now prohibited from selling raw milk until subsequent sampling indicates that the product is free of harmful bacteria.

REGULATORY NEWS

- January 21, 2022 - A Senate bipartisan bill, the Dairy Pricing Opportunity Act, was co-sponsored in January 2022. According to co-sponsor U.S. Senator Angus King (I-Maine) the legislation would direct the USDA to begin holding Federal Milk Marketing Order (FMMO) hearings by this summer, to give milk producers a greater voice in dairy pricing. The hearings would reevaluate how the price of Class I (or fluid) milk is calculated and pave the way for changes to better support the dairy industry. The bill was initiated due to the unnecessarily complicated pricing formula, changes included in the 2018 Farm Bill, and the effects of an unprecedented pandemic have resulted in the loss of significant revenues for these farms over the last two years.

- February 10, 2022 - FDA's Milk and Milk Product Branch (MMPB) issued a coded memoranda on the Grade "A" Milk Search System (GAMS). The searchable database contains FDA's Grade "A" Milk Memoranda documents. It is intended to provide an efficient application to users with advanced search capabilities allowing stakeholders to access a library of information within the Grade "A" Milk Program. GAMS supports FDA's Milk Safety Cooperative Program by providing assistance to state and local milk regulatory/rating agencies, the dairy industry and other interested parties in the safe production of milk and milk products through the application of science-based food safety principles on the farm and at all stages through the processing chain. The document update includes sections with information on Interstate Milk Shipments, HACCP, National Milk Drug Residue Database Annual Reports, Guidance for Industry and Additional Resources.

- March 25, 2022 - Currently, although whole milk dairy products are good sources of nutrients, they cannot be labeled "healthy" because they don't meet FDA's criteria for a healthy claim. However, on March 25, FDA issued a Procedural Notice on Consumer Research on "Healthy" Symbol. The notice is for preliminary quantitative consumer research it plans to conduct on voluntary symbols that could be used in the future to convey the nutrient content claim "healthy." The FDA intends the symbol to be a stylized representation of "healthy." The update also provided notice that the FDA is developing a proposed rule that would update when manufacturers may use the "healthy" nutrient content claim on food packages. The agency intends to publish the proposed rule with the definition update soon. It is yet to be seen if there will be an impact on the labeling of dairy products.

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Egg Industry

The range of subsectors in the egg industry – from shelled (table eggs), unshelled, liquid and frozen – means there is a vast range of processes, procedures and related hazards and risks.

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KEY HAZARDS & RISKS

- **Shelled (raw) eggs** can pose particular hazards, including on-farm chemical and water contamination, as well as farm-level contamination of Salmonella and campylobacter passing into the egg from the flock.
- **Supplier issues**, including on-farm contamination, along with incoming goods contamination from the field, processing, and/or transportation, antibiotic residues used in the treatment of livestock, and animal welfare. Temperature maintenance is also extremely important throughout the supply chain for all eggs.
- **Organic production** can reduce the risk of pesticide and cleaning chemical contamination but does not reduce pathogenic risk.
- **Process controls**, such as out-of-temperature contamination potential, table egg wash water quality and safety, and environmental contamination, particularly that of Listeria.
- I**nvalidated cooking processes** carries extreme risk of Salmonella contamination.
- **Post-process contamination of egg-derived products**, including added contamination or allergen risk from additives/inclusions.
- **Intentional adulteration**, particularly related to bulk supply, transportation, storage, and processing; including economic adulteration/food fraud of incoming goods.
- **Caged & cage-free eggs** have some varying risks, but there is not a scientific basis for the claim that cage-free are more susceptible to risk due to environmental exposure. There can be some higher risk of Salmonella contamination of caged eggs due to greater volume of fecal dust, gut colonization and shedding, rodent and insect disease vectors, stress due to confinement, and disinfection difficulty.

SPECIALIZED SERVICE OFFERINGS

- **Supply Chain Risk Management** - TAG's proprietary and customizable tools enable full-chain risk identification and mitigation strategies for food safety – including that of farm assessments and sanitary transportation.
- **Environmental Control and Monitoring Programs (ECP/EMP)** - TAG will assess your facility and documentation to determine pathogenic contamination risk, provide solutions, and mitigate issues.
- **Hazard Analysis and Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to sanitation, allergens, process controls, etc.
- **Hygienic Design** - The sanitary design of equipment and the facility are critical for food safety, but its assessment can be a complex undertaking — TAG can help.
- **Regulatory Compliance** - TAG helps food companies ensure their compliance with FDA, USDA, and foreign food safety regulations, including labeling requirements, through document and facility reviews and assessments.
- **Recall / Crisis Management** - TAG helps food facilities ensure they are prepared for a recall or crisis through interactive simulations, development/review of recall plans, and crisis assistance.
- **Intentional / Economic Adulteration** - Insider or external intentional contamination is a real risk in today's world. TAG's onsite vulnerability assessments for intentional and/or economic adulteration, and IA Rule training, help keep food operations safe.

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Feed & Grain

The range of subsectors in the feed & grain industry means there is a vast range of processes, procedures and related hazards and risks.

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KEY HAZARDS & RISKS

- **Heavy Metals** - Feeds and grains can also be subject to risk from naturally occurring heavy metals (e.g., lead, arsenic, etc.), which can become toxic to humans at high or repeated exposures.
- **Mycotoxins** - Naturally occurring mycotoxins (such as aflatoxins, fumonisin, etc.) produced by certain molds and fungi can grow on grains, particularly those subject to warm, humid conditions. FDA has established maximum tolerance levels for some, but not all, mycotoxins.
- **Chemicals** - The use of pesticides on feeds and grains can add a risk of residue remaining in the final product.
- **Foreign Material** - (e.g, sticks, stones, bone fragments, etc.) is always a risk in the harvesting and sourcing of raw agricultural commodities.
- **Medications** - Adding medication to feed also adds risk, due to the growing incidence of antibiotic resistance in humans, as handling risks for medications such as progestins. Cross-contamination or incorrect dosing of medications can cause severe animal health issues.
- **Intentional Adulteration** - Intentional adulterations, as well as economically motivated adulteration (the addition of alternative low-cost/low quality ingredients), by dishonest persons can be a significant risk, particularly related to byproducts.

SPECIALIZED SERVICE OFFERINGS

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- **Hazard Analysis and Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to contamination/adulteration from heavy metals, mycotoxin, pesticide residues, foreign objects, and allergens.
- **Hygienic Design** - The sanitary design of equipment and the facility are critical for food safety, but its assessment can be a complex undertaking — TAG can help.
- **Regulatory Compliance** - TAG helps food companies ensure they're compliant with FDA, USDA, and foreign food safety regulations through document and facility reviews and assessments, including a review of animal/human food preventive controls and the Food/Feed Safety Plan.
- **Recall / Crisis Management** - TAG helps food facilities ensure they are prepared for a recall or crisis resulting from contamination through the use interactive simulations, development/review of recall plans, and crisis assistance.
- **Intentional / Economic Adulteration** - Insider or external intentional contamination is a real risk in today's world. TAG's Food Defense Plan review and onsite vulnerability assessments for intentional and/or economic adulteration, and IA Rule training, help keep food operations safe.

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Fresh Produce

The range of subsectors in the produce industry means there is a vast range of processes, procedures and related hazards and risks.

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KEY HAZARDS & RISKS

- **Water & Fertilizer** - Both agricultural and processing water can be the source of produce contamination, so this must be closely monitored and controlled. Similarly, biological soil amendments of animal origin, such as manure, are specifically addressed in the Produce Safety Rule as potential safety risks.
- **Chemicals** - The use of pesticides and herbicides can leave residues on produce above safe and legal limits.
- **Heavy Metals** - Produce can be subject to risk from naturally occurring heavy metals (e.g., lead, arsenic, etc.) which can be taken up by the produce and can become toxic to humans at high or repeated exposures.
- **Environment** - Processing facilities, livestock operations, and wild animals in close proximity of a farm have been known to cause environmental contamination impacting growing produce. Cryptosporidium, Cyclospora, E. coli, and various parasites are all potential foodborne contamination issues of produce.
- **Transportation & Storage** - Temperature control is essential for the quality and safety of produce, particularly while in transport and storage.

SPECIALIZED SERVICE OFFERINGS

- **Environmental Control and Monitoring Programs (ECP/EMP)** - TAG will assess your facility, processes, and documentation for potential process-related biological, chemical and physical hazards, provide solutions, and mitigate issues.
- **Hazard Analysis and Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to contamination/adulteration from heavy metals, mycotoxin, pesticide residues, foreign objects, and allergens.
- **Hygienic Design** - The sanitary design of equipment and the facility are critical for food safety, but its assessment can be a complex undertaking — TAG can help.
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Grain & Feed

The second quarter of 2022 did not hold much in the way of surprises for the grain and feed industries, but there were a number of issues of continuation from previous quarters or even previous years, including those relating to the climate, technological innovation, and the pursuit of "zero."

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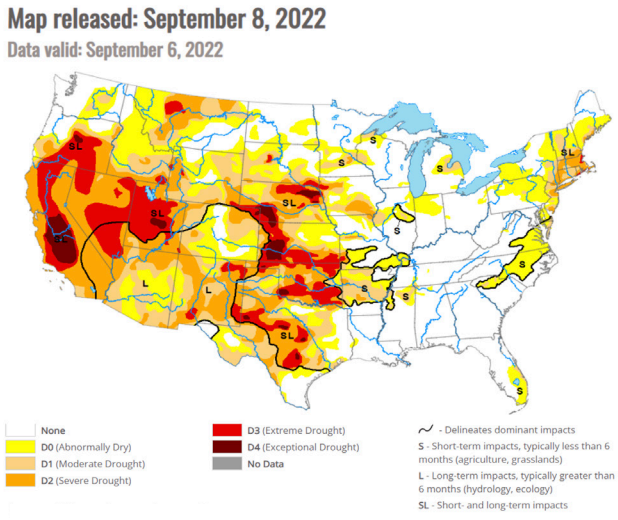
THE CURRENT ENVIRONMENT

As described by the Washington Post, the summer's drought has placed a "hefty toll on American crops." Climate change is impacting agricultural products across the board and across the country, with corn and wheat taking particularly significant hits. With the U.S. Drought Monitor showing much of the Western U.S., in particular, facing severe to extreme drought conditions (as show on the map below) during the growing season, many crops are expected to have reduced yields – by as much as 1/3 compared with last year, according to the American Farm Bureau Federation.

Adding to this is the fact that it is not just the U.S. seeing the impacts. Rather water levels have dropped around the world, not only impacting crops, but also major shipping supply routes.

Additionally, because climate change is impacting weather patterns overall, with extreme weather events becoming more frequent and more intense, it is expected that the poor yields are "more than a one-year blip," and food prices are likely to stay high for at least the near future.



Source: U.S. Drought Monitor

REGULATORY UPDATES

While USDA's recently published Ag Export Outlook 2023 increased its forecast for 2022 feed grain exports to $47.8 billion, it has decreased its forecast for wheat exports for 2022 by $300 million from the previous quarter's estimates, as more tons are sent abroad at a lower price. "Global wheat prices have fallen over the last quarter, reflecting the ongoing winter wheat harvests as the new-crop wheat supply situation becomes more favorable," the report states. With more supplies available next year, the total value of exports is expected to fall to $7.8 billion.

Meanwhile USDA's Agricultural Marketing Service (AMS) is seeking comment on its proposal for a new internal process "meant to facilitate the introduction of new and improved inspection technology that promotes competition and transparency." The primary focus of the proposal is on the need and suitability of the technology for official grain inspection, and includes a description of the proposed Inspection Technology Evaluation (ITE) Process which would begin with written proposal by a manufacturer of technology for a specific inspection factor. This is first evaluated by an AMS team then run through an evaluation process that focuses on validating the performance of the submitted technology using AMS' developed criteria or specifications for the specific inspection factor. The full proposal is available in the Federal Register.

FOOD SAFETY: EVEN CLOSER TO ZERO

With wheat considered to be highly prone to heavy metal accumulation from soil and water, studies advocating for the regulation or complete removal of heavy metals in animal feed, and recalls related to heavy metals in baby foods, there is a continuing effort to detect ever-lower levels of the metals, particularly arsenic and lead in foods and feed.

The detection of a heavy metal above the regulated limits can have severe repercussions. Take, for instance, the recall of Beech-Nut Stage 1, Single Grain Rice Cereal tested above the guidance level for naturally occurring inorganic arsenic set by the FDA in August 2020. Not only did Beech-Nut issue a voluntary recall of the product, the company decided to exit the market for single grain rice cereal due to concerned about the ability to consistently obtain rice flour well-below the FDA guidance level and its own specifications for naturally occurring inorganic arsenic.

This can have a significant impact on grain and feed producers as soil and water are a prime mode of heavy metal uptake and with consumer advocacy groups, regulators and Congress focusing on maximum levels, we can certainly expect new guidance, if not regulation, in the near future.

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Meat Processing and Packing

The vast range of subsectors in the meat processing industry - from pork, chicken, beef slaughter and/or processing - means there is also a vast range of processes, procedures, related hazards and risks.

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KEY HAZARDS & RISKS

- **Supplier issues** - Whether a facility slaughters animals or just processes meat and poultry products, animal health and welfare is of concern for the animals, the final quality of the meat, and consumer perception and resulting purchase of the final product.
    - Animal diseases (e.g., Avian influenza, Foot and Mouth Disease, Bluetongue. BSE, bovine tuberculosis, etc.) are a constant concern for this sector. Findings can lead to depopulations and trade restrictions.
    - Humane slaughter and humane transport are areas of particular concern and are increasingly closely regulated.
    - Because antibiotic use in animals can leave residues leading to antibiotic resistance in humans, the use has become a public health concern subject to stricter regulation in recent years.
- **Chemicals** - Unauthorized chemicals can be an issue in meat products, such as residues from non-food-grade cleaning products used in slaughtering facilities.
- **Pathogens** - The primary pathogen varying for different meats, e.g., Salmonella and Campylobacter of key concern in poultry, E. coli in beef, and Trichinella spiralis in pork; as well as general concerns with Listeria (particularly in RTE products) and other cross-contamination issues.

KEY HAZARDS & RISKS (CONT.)

- **Processing risks** - Foreign materials are of concern, including metal fragments from pr ocessing equipment, and physical hazards, such as bone shards in boneless products. Additives/inclusions used in meat/poultry products can add contamination or allergenic risk.
- **End use** - Improper consumer and foodservice handling/cooking of raw products can lead to foodborne illness that can come back on the manufacturer.

SPECIALIZED SERVICE OFFERINGS

- **Supply Chain Risk Management** - TAG's proprietary and customizable tools enable full-chain risk identification and mitigation strategies for food safety.
- **Animal Welfare Evaluations** - TAG can assess your, or your supplier operations, to ensure humane handling and transport for the welfare of the animals and safety and quality of the foods.
- **Environmental Control and Monitoring Programs (ECP/EMP)** - TAG will assess your facility and documentation to determine pathogenic contamination risk, provide solutions, and mitigate issues.
- **Hazard Analysis and Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to sanitation, allergens, process controls, etc.
- **Regulatory Compliance** - TAG helps food companies ensure their compliance with FDA, USDA, and foreign food safety regulations through document and facility reviews and assessments.
- **Recall / Crisis Management** - TAG helps food facilities ensure they are prepared for a recall or crisis through interactive simulations, development/review of recall plans, and crisis assistance.
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Non-Alcoholic Beverages

The range of subsectors in the beverage industry means there is a vast range of processes, procedures and related hazards and risks.

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KEY HAZARDS & RISKS

- **Supply Issues** - The supply chain incurs risks, including incoming goods contamination from the field, processing, and/or transportation.
    - While naturally occurring, heavy metals (e.g., lead) from the soil can be taken up by produce used in juices.
    - Liquid and bulk supply, storage, and processing are particularly susceptible to intentional adulteration.
    - Be wary of fraud in labeling, e.g., of spring water vs. tap water use.
    - Flavors can carry allergens risks, so it is important to work with the suppliers and review their sourcing practices and allergen management programs.
    - If a beverage is to carry a claim such as organic or vegan, all ingredients must be compliant; and ingredients that are part of beverages such as teas, coffees, or other infusions must comply with ready-to-eat food safety requirements or have validated kill step during the process.
- **Chemicals** - Unauthorized chemicals and chemical residues can be an issue in non-alcoholic beverages, such as residues from cleaning products used in processing facilities, for example. Management of pesticides for commodities that will be used for beverages is required in compliance with FSMA.
- **Microbiological and Toxin Contamination** - Pathogens (including bacillus cereus, Salmonella, cryptosporidium, E. coli, Cyclospora, giardia, legionella, coliforms, etc.) are all potential foodborne contamination issues. Yeasts, molds, algae, and/or patulin contamination can be an issue in juices, waters, and other beverages.

KEY HAZARDS & RISKS (CONT.)

- **Foreign Materials** are of concern, including glass, metal, and plastic fragments from processing equipment or bottling.
- **Processing Risks** - If unvalidated, juice pasteurization (cold-press, HTST) carries a risk of pathogenic contamination which can cause serious health risks to consumers. Hot fill processing for non-alcoholic beverages requires a validation if any of the ingredients used in the process has not gone through a validated kill step.
- **Formulations** - Dietary supplement formulations can be an issue if overformulation/overfortification is not carefully controlled.

TAG PROVIDES:

- **Supply Chain Risk Management** - TAG's proprietary and customizable tools enable full-chain risk identification and mitigation strategies for food safety.
- **Environmental Control and Monitoring Programs (ECP/EMP)** - TAG will assess your facility and documentation to determine pathogenic contamination risk, provide solutions, and mitigate issues.
- **Hazard Analysis and Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to sanitation, allergens, and process controls.
- **Regulatory Compliance** - TAG helps food companies ensure they are compliant with FDA, USDA, and foreign food safety regulations through document and facility reviews and assessments.
- **Recall/Crisis Management** - TAG helps food facilities ensure they are prepared for a recall or crisis through interactive simulations, development/review of recall plans, and crisis assistance.
- **Intentional/Economic Adulteration** - Insider or external intentional contamination is a real risk in today's world. TAG's onsite vulnerability assessments for intentional and/or economic adulteration, and IA Rule training, help keep food operations safe.

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Pet Food

The range of subsectors in the pet food industry means there is a vast range of processes, procedures and related hazards and risks.

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KEY HAZARDS & RISKS

- **Species identification** - In addition to general risks, there are specific risks related to the animal species for which the food is being manufactured. So it is critical that the hazard analysis is determined per species that the food is intended for.
- **Human consumption** - The foreseeable risk of pet foods being consumed by humans must be considered (e.g., infants and toddlers getting into the food, and adults purchasing it as a cheaper food option).
- **Pathogens** (e.g., Salmonella, E. coli, Listeria, etc.) are all potential foodborne contamination issues. This includes exposure to environmental pathogens during processing if the finished product receives no treatment post-packaging.
- **Naturally occurring mycotoxins** (such as aflatoxins, fumonisin, etc.) produced by certain molds and fungi be a risk in pet foods. FDA has established maximum tolerance levels for some, but not all, mycotoxins.
- **Heavy metals** - Animal foods also can be subject to risk from naturally occurring heavy metals (e.g., lead, arsenic, etc.), which can become toxic to pets at high or repeated exposures. Vitamin toxicities and deficiencies also must be considered, again species specific.

SPECIALIZED SERVICE OFFERINGS

- **Supply Chain Risk Management** - TAG's proprietary and customizable tools enable full-chain risk identification and mitigation strategies for food safety.
- **Environmental Control And Monitoring Programs (ECP/EMP)** - TAG will assess your facility and documentation to determine pathogenic contamination risk, provide solutions, and mitigate issues.
- **Hazard Analysis And Risk Assessment** - TAG will conduct a document review and/or on-site assessment and gap analysis of hazards and risks related to sanitation, allergens, process controls,
- **Regulatory Compliance** - TAG helps food companies ensure their compliance with FDA, USDA, and foreign food safety regulations through document and facility reviews and assessments.
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Recall Readiness: Preparedness, Discovery, Action

Recalls in the food industry are a fact of life. If you have not had to deal with one, it is likely only a matter of time before you are part of a recall.

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Preparedness, discovery, and action are the three key components of FDA's recently issued final guidance on Initiation of Voluntary Recalls – fundamentally the same elements on which TAG has focused its consultation and training. It also is little changed from the proposed guidance of April 2019, beyond editorial changes for clarity, deletion of the References section, and two Terminology additions (correction and market withdrawal) – except for one key update.

As FDA has made clear over the last few years, particularly since the publication of its New Era of Smarter Food Safety Blueprint, it is encouraging the use of technology, especially for product traceability. Its emphasis in the new guidance is no different, as the guidance specifically states, "FDA encourages the use of electronic communications for conveying voluntary recall communications about FDA-regulated products." The guidance provides little direction on electronic communication beyond that, and does include the allowance for calls, written/paper or electronic communication in various sections of the guidance. But the agency's continuing emphasis on technology and the guidance focus on "timely communications" for quick action all continue to push the industry to integrate technology for traceability – which is the foundation of an effective recall.

The recommendations for recall preparedness and initiation are fairly straightforward and in line with what TAG sees as best practices for such events. But the publication of the guidance takes these "best" practices up a level to "expected" practices – although, as with any guidance, it is considered to be "nonbinding recommendations." FDA further strengthens its expectation for industry preparedness in both the guidance itself ("It is critical for firms in a product distribution chain to be 'recall ready'") and in the title of its guidance announcement ("FDA Urges Companies to be 'Recall Ready' to Protect Public Health as Part of Final Guidance for Voluntary Recalls").

In addition to this guidance, it is critical to note that FSMA's Preventive Controls Rule requires that facilities establish "a written recall plan for food that requires a preventive control" that includes "procedures that describe the steps to be taken and assign responsibility for taking those steps." (See Chapter 14: Recall Plan guidance for more on this.)

The new guidance takes this a step further, providing recommendations for preparedness to ensure a firm is "recall ready" for a voluntary recall and the issuance of communication. Following is a synopsis of the guidance steps:

PREPAREDNESS

- Identify appropriate personnel. The assigning of specific person(s) to recall roles is essential for quick implementation when an event occurs. Best practice is to establish a recall team that includes alternates for critical roles.

- Train personnel on their responsibilities. Regular training, including mock recalls, help to ensure that team members have a thorough understanding of the recall procedures they are being asked to perform.

Establish a recall communications plan. Identify specific contacts and develop templates for internal, FDA, and direct account communications, as well as public communications if the recall is deemed necessary. Keep these updated.

- Identify any reporting requirements for distributed products. For foods, it is required that a report be submitted through the Reportable Food Registry any time there is a reasonable probability that use of/exposure to a food will cause serious adverse health consequences or death to humans or animals.

- Use adequate product coding. Products should include coding that enables lot identification and facilitates the effective recall of all violative lots.

- Maintain distribution records. Recalled product location records should be retained at least as long as the expected shelf life and use of the product and the time specified in other applicable regulations concerning records retention.

DISCOVERY

- Identify the problem. Procedures should be in place to enable identification of an adulterated product, including those for testing, deviation reporting, consumer complaints, etc.

- Investigate the problem. Specific personnel assignments for investigating a problem should be in place and a timely investigation conducted of any problem, with prompt evaluation and action taking place.*

- Make decisions and take action. Once it is decided that a recall is needed, the scope and depth of the recall needs to be determined, and production and distribution of affected product ceased.

- Consult with FDA about the problem. FDA encourages firms to consult with FDA while it conducts its investigation if the firm has any questions about it.*

*The guidance specifically notes that a recalling firm need not delay initiation of a voluntary recall pending completion of the investigation or FDA's review of its recall strategy or communications.

ACTION (THE RECALL)

Note: While guidance is nonbinding, steps in this section refer to various regulatory provisions of 21 CFR 7.42 on Recall Enforcement.

- Ceasing distribution, shipment, and/or sales of affected product(s). With no further elaboration, FDA apparently sees this as self-explanatory.

- Developing a recall strategy. This should consider various factors (e.g., potential risk, ease of product identification, etc.), address the depth of the recall as well as other factors of 21 CFR 7.42(b), and consider potential expansion should it be needed.

- Notifying direct accounts about the product being recalled, including what should be done with respect to the recalled product. To ensure prompt notification that enables direct accounts to act quickly and effectively to implement the recall, the guidance encourages the use of electronic communication, and recommends that any contact by phone be accompanied by written confirmation and documentation.

- Providing response instructions to notified direct accounts including contact information for and method by which the direct account should respond.

- Including instructions for appropriate disposition of recalled product to ensure the product does not remain a risk.

- When appropriate, notifying the public about a product that presents a health hazard. FDA simply references its guidance on Public Warning-Notification of Recalls which provides recommendations for when warnings should be issued, by whom, how, and the information to be contained.

Despite one's best efforts, things can go wrong through an unintentional contamination in processing or another link in the supply chain, or through the intentional and/or economic adulteration of a food. Regardless of the origination of the problem, it is essential that a facility act quickly to initiate a recall when public health is at risk, and the only way to ensure that is for the facility to have procedures in place that enable it to be prepared to take action.

Although being recall ready based on the specifics of the FDA guidance is "nonbinding," it is an FDA expectation – and having a written recall plan is a FSMA requirement – for the protection of consumers – and your brand. To ensure that your recall plan not only meets FDA expectations and requirements, but also protects your brand, give TAG a call. We can assess your plan, train your team, or work your facility through a mock recall or crisis scenario to ensure it is as protective as it can be.

Should you find yourself in a potential or actual recall situation, TAG has a great deal of experience in helping companies navigate the various challenges of getting a recall right. Being prepared is key, as noted above; but in the heat of the moment, TAG has supported many companies in making the best out of what is a very stressful situation.

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Salmonella Contamination Focus Continues to Increase

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The rates of Salmonella illness in the US have been a vexing challenge for many years. Despite setting goals for Salmonella reduction, the number of cases has remained stubbornly high. While a lot has been done to focus on Salmonella in recent years, it has been a challenge on many fronts to drive the numbers down.

Salmonella is a problem that impacts both FDA and USDA regulated food products but has recently become a major focus for USDA. As detailed in a 2014 GAO Report to Congress, USDA had taken a number of actions since 2006 to reduce contamination from Salmonella in poultry products: They reduced allowable Salmonella contamination in young poultry carcasses; developed an action plan to prioritize actions to reduce Salmonella; and published a final rule in August 2014 to modernize poultry slaughter inspections. Despite those actions, the September 2014 report was not only entitled USDA Needs to Strengthen Its Approach to Protecting Human Health from Pathogens in Poultry Products, it stated "Poultry products contaminated with pathogens cause more deaths than any other commodity."

Fast forward seven years later to October 2021, and little seems to have changed, with CDC estimating that Salmonella still causes more foodborne illnesses than any other bacteria (about 1.35 million infections, 26,500 hospitalizations, and 420 deaths in the U.S. every year), and it is estimated that over 23% of those illnesses are due to consumption of chicken and turkey.

In an October press release, USDA itself conceded that: "Far too many consumers become ill every year from poultry contaminated by Salmonella"; and "Time has shown that our current policies are not moving us closer to our public health goal. It's time to rethink our approach." And this was after issuing the Guideline for Controlling Salmonella in Raw Poultry in July to help poultry establishments identify and implement pre- and post-harvest interventions to control Salmonella as part of their HACCP system and utilize microbial testing results to monitor the performance of the HACCP system and inform decision-making.

So USDA is at it again: "mobilizing a stronger, and more comprehensive effort to reduce Salmonella illnesses associated with poultry products." With a goal to drive the industry closer to the national target of a 25% reduction in Salmonella illnesses, USDA has (again) set reducing Salmonella infections attributable to poultry as one of its top priorities. Included in its action items are:

- Seek stakeholder feedback on specific Salmonella control and measurement strategies, including pilot projects, in poultry slaughter and processing establishments.
- Encourage preharvest controls to reduce Salmonella contamination coming into the slaughterhouse.
- Consult with the National Advisory Committee for Microbiological Criteria in Foods for building on the latest science.
- Examine how quantification can be incorporated into its approach.
- Focus on the Salmonella serotypes and the virulence factors that pose the greatest public health risk.

While it seems that USDA has been attempting to reduce Salmonella since the turn of the century (because it has been nearly that long), it is not just the U.S. that is contending with the issue. Salmonella has become a major cause of foodborne infection outbreaks worldwide with estimates of 93.8 million cases of non-typhoidal Salmonellosis and 155,000 deaths occurring every year in the world; 86% of these illnesses due to the consumption of Salmonella-contaminated food items. The most common serotype is enteritidis, especially in Europe, where it accounts for 85% of Salmonella cases, Asia (38%), and Latin America and the Caribbean (31%).

Both the Center for Science in the Public Interest and a prominent plaintiff attorney have submitted petitions to USDA pointing out the importance of declaring specific Salmonella serotypes adulterants. So far USDA has not moved in that direction but likely they are heading that way.

The recent announcement from USDA around Salmonella reduction is a cry that has been made before – so what is different this time? My view is that some members of the poultry industry have done a great deal to reduce Salmonella and have focused heavily, and appropriately, on the live side of the operation. After all, the greater the load of Salmonella that arrives on the birds, the harder it is to control it during processing. Time will tell where USDA goes this time; and at this point, they appear to be embarking on asking for data and pursuing more science. But as that process moves along, it would be wise for the poultry industry to continue to look at ways to mitigate Salmonella to the greatest extent possible.

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