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Article

Food Safety Insights to Stay a Step Ahead in 2022 and Beyond

June 09, 2022

As 2022 progresses full of hope for a post-pandemic new normal, it is of no surprise that the food industry continues facing unprecedented challenges requiring quick, and in some cases, comprehensive changes to the way food safety is approached. These challenges range from the obvious and evolving to the obscure and emerging.

This article will highlight some areas of regulatory focus and will provide some tips for staying a step ahead in 2022 and beyond.

Current Risks May Be Re-Directing Focus Away from Food Safety

The current risk landscape impacting food producers and retailers ranges from the “here-and-now” to the “soon-to-be”. Supply chain challenges, albeit with some promise for improvement, continue to be a present-day challenge compliments of COVID, climate change, consolidation and geo-political conflicts**[1]**. Ongoing pandemic management measures impacting employers such as managing the labor crisis**[2]** and COVID-control expectations require continued attention –attention which may take focus away from effectively preventing food safety issues and / or appropriately responding to them.

How can the food industry reset and refocus as we continue to operate under these pressures in 2022? A good place to start is by focusing on what we know the regulators are focusing on. We summarize a few key initiatives, programs and regulations on the regulatory agenda for 2022 below and provide some strategies and tips to help your company stay a step ahead of some of these changes.

2022 Regulatory Focus

Below is a list of five key areas that food regulators are targeting, serving as a useful roadmap for industry to reference in 2022 and

beyond.

1. New Era of Smarter Food Safety

There has been much discussion about FDA's New Era of Smarter Food Safety. Since this comprehensive initiative alone is easily the subject of a dedicated and in-depth review, a few salient points are offered to help industry better understand why it's an important reference in 2022.

- It is much more of an initiative—a blueprint, or aspiration-- rather than a regulation itself. This said it serves as an excellent crystal ball for what is likely to come from FDA in the next decade.
- Its focus is to enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models such as ecommerce food delivery, reduce contamination of food, and foster the development of a food safety culture.
- This "Smarter Food Safety" blueprint will dominate the conversation for the foreseeable future if your company is regulated by FDA.
- Implementing key aspects of this blueprint will aid in demonstrating your company's ability to stay informed and in-step with current and future regulatory thinking. Give it a read. **[3]**

2. Proposed Traceability Rule

As mentioned, one of the four core elements of the New Era of Smarter Food Safety focuses on enhancing traceability across the supply chain to expedite root cause investigations and outbreak identification, all with the goal of protecting human and animal health and safety.

Even today, traceability records across the supply chain are largely paper based. As new regulations require more information to be documented for specified retention periods and in an electronic format, our physical filing cabinets are no longer sufficient to support the volume of information and speed of traceback needed to protect human and animal health and safety. FDA's focus on tech-enabled traceability is intended to address this reality.

It is important to note a couple key aspects of this proposed rule:

- The proposed rule only applies to specific products deemed high risk on what is referred to as the Food Traceability List (FTL). https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability.This said, industry appears to be preparing to apply the ultimate requirements for all products not just those on the FTL list, which is recommended. Your company may be one outbreak or recall away from making the FTL high risk list. Why wait when you can stay a step ahead?
- FDA is not requiring a specific technology. Rather it is and has pledged to work with stakeholders to explore low- or no-cost options so that its approaches are inclusive of and viable for food operations of all sizes. A pilot project with several traceability system providers is currently underway in support.**[4]**

3. Smarter Tools to Enhance Speed to Root Cause and Resolution of Outbreaks

One of the areas FDA is focused on in its New Era Blueprint is to leverage smarter tools to improve the speed and accuracy of traceback capabilities and root cause analyses and identification to further the prevention-based framework that FSMA established. Such tools are to enhance speed, accuracy, simplicity, and efficiency of traceback and ultimately offer some level of predictability to foresee and mitigate future events. Information sharing to feed AI and machine learning is being requested and advocated for in this plan. These are certainly lofty goals. However, information sharing agreements between the agency and private industry that provide incentives and protections for the industry to share information without fear of retribution or liability will be needed to some degree before these aspirations will likely be achieved.

4. New Allergens to Manage

And then there were nine. Under the FASTER *Act* of 2021, sesame is being added as the 9th major food allergen effective January 1, 2023. In November 2020, , the FDA issued a draft guidance to encourage manufacturers to voluntarily declare sesame in the ingredient list when it is used as a "flavoring" or "spice" or when the common or usual name (such as tahini) does not specify sesame. Some exceptions apply. If you produce sesame-containing products, read up. Until the effective date manufacturers do not have to list it as an allergen, however in most cases it must appear in the ingredient statement so as to not be considered mislabeled. See the following link for details on sesame and the other "Big 8" allergens at https://www.fda.gov/food/food-labeling-nutrition/food-allergies and The FASTER Act at https://www.congress.gov/bill/117th-congress/senate-bill/578?q=%7B%22search%22%3A%5B%22S.+578%22%5D%7D&s=1&r=1

5. FDA 2022 Budget Request

Much of regulators' future focus is no secret. Often the best place to look for the roadmap is in fiscal years' budget requests. The 2022 FDA budget request identifies the key areas in which the agency intends to invest.**[5]**

One key topic for 2022 is focusing on emerging chemicals and toxicological issues and maternal and infant health and nutrition. The FDA has prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of contaminants that the agency feels has not been of focus by food manufacturers targeting this population, particularly certain chemical hazards. In April 2021, the FDA announced a comprehensive plan to further reduce levels of toxic elements such as lead, cadmium, mercury, and arsenic in foods for babies and young children. The "Closer to Zero: Action Plan for Baby Foods" identifies actions the agency will take to reduce exposure to toxic elements from foods eaten by babies and young children to as low as possible.**[6]**

Consider a Different Kind of “5G”- its Not Just for Your Cellular Service

We offer some tips to help navigate the post– pandemic regulatory landscape in the form of a “5G” approach that just may be even more reliable that your current cellular service!

1. Gear up: For once there actually is a crystal ball. Two actually! The New Era of Smarter Food Safety and the agencies’ 2022 budget requests. Priorities for 2022 and beyond are laid out in black and white. Read them and be miles ahead of the rest.

2. Get ahead: The proposed traceability rule contains an excellent foundation on which to evaluate your current traceability and root cause analyses capabilities and to start preparing now to vet tech suppliers or make enhancements to your tech-enabled traceability programs. Run simulations to test your people, process and traceability systems to understand where gaps may lie and address them before a required effective date. While the proposed rule may change a bit in its final rule form, it will likely arrive at the same destination—a requirement for companies making ‘high risk’ foods to adopt certain traceability requirements that will only be able to effectively be implemented with technology (author’s opinion not stated as such in proposed rule language)

3. Guidance is Your Guide: FDA announced what industry guidance topics is expected to be released by the end of June 2022. While guidance does not equal regulation, we all know the agency often treats it as binding. Get a preview of what is expected and monitor agency alerts, so you do not miss announcements of guidance that impacts your organization. Some examples of expected Guidance are as follows:

    - Do you produce products intended for babies and toddlers? Perhaps you should keep your eye out for the guidance expected on “Lead action levels for categories of foods consumed by babies and young children: Draft Guidance for Industry”

    - Do you produce almond milk or other plant-based milk alternatives? FDA has been working on regulation expected in 2022 on “Labeling of Plant-based Milk Alternatives, Draft Guidance for Industry.”

        - For a complete list of anticipated guidance see https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development

4. Get an Outsider’s Perspective: Agencies have converted to whole-genome sequencing (WGS). Have you? Or have you at least considered the pros and cons of strain typing/serovar typing in certain instances? What is your SOP for taking duplicate swabs during an agency swab-a-thon? Do you have one? In writing? Did you weigh the risks of taking and testing duplicates verses only

documenting the location of the agency swab and hold associated product pending results? Getting an expert review of your existing environmental monitoring and pathogen testing program and related SOPs can help you gain a deeper understanding of the relative risks and potential regulatory actions that may occur as a result of your existing programs and SOPs.

- Outside experts can also help you gain a deeper understanding of relative health hazard associated with a potential product contamination issue. For example, your product may have a microorganism present in it that you didn't expect. Is it a food safety issue because it could cause harm to humans or animals? Or is it a spoilage organism that will not cause illness but may still be "bad" for your brand reputation. Indeed, there are some microorganisms that may cause illness and others that only lead to quality issues like spoilage. Both are harmful to your brand and bottom line, but only one may trigger your policy coverage. Working with outside experts in food safety and insurance—your broker and underwriters—will help you make the best decisions based on regulatory, operational, reputational and insurance related risks.

5. Guard Yourself: Even the most comprehensive food safety programs may not protect your company against a recall or outbreak. The saying "you are as strong as your weakest link" has never been truer as it is amidst a global pandemic. Supply chain disruptions, shortages and suppliers' closing doors or consolidating with others threw a proverbial wrench in the best of supply chain control programs. Significant labor shortages inevitably result in shorter sanitation and pre-op inspection times, even though these are the last tasks that should be shorted in a food facility. Despite best intentions, things can and will go wrong. Product contamination insurance and adverse publicity insurance may be a wise addition to your risk management toolkit.

Although 2022 is well underway, this article is intended to shed light on key emerging topics and considerations to help the industry stay a step ahead in protecting its regulatory, operational and brand risk exposure while placing public health and safety as the central focus.

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3 https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint
4 https://www.fda.gov/news-events/press-announcements/fda-brief-fda-announces-winners-food-traceability-challenge.
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