May 24, 2024

Submitted electronically via regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 11: Food Allergen Program, Draft Guidance for Industry (Docket No. FDA-2016-D-2343)

Dear Sir or Madam,

The Food Industry Association (FMI) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) Draft Guidance, "Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 11: Food Allergen Program" ("Draft Guidance").[1] As the Food Industry Association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain—from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services—to amplify the collective work of the industry. Read more about us at www.FMI.org.

FMI appreciates FDA's release of the Draft Guidance and the agency's efforts to explain how to establish and implement a food allergen program through multiple, detailed recommendations regarding good manufacturing practices (GMPs), food allergen controls (including cross-contact controls and label controls), and supply chain programs. This Draft Guidance is critically important, as undeclared food allergens continue to be the leading cause of food recalls. Therefore, FMI appreciates the opportunity to provide comments on this important topic.

Flexibility and Facility-specific Risk Assessments Are Fundamental to Allergen Control

Given the importance of the Draft Guidance, we are concerned that rather than provide intended flexibility to food manufacturers, it will have the effect of limiting how manufacturers control allergens. Specifically, we are concerned that in many respects, the Draft Guidance is not sufficiently flexible, nor risk based, and fails to allow food manufacturers to design an allergen program that is appropriate for their facility, products, and processes. Certainly, the key principle

[1] 88 Fed. Reg. 66457 (Sept. 27, 2023).

of the FDA Food Safety Modernization Act (FSMA) and the Current Good Manufacturing Practices, Hazard Analysis and Risk-Based Preventive Controls (Preventive Controls) rule is that food safety programs must be risk-based.

Similarly, flexibility and risk-based assessments are fundamental to allergen control. There is not a "one-size-fits-all" approach. Indeed, effective allergen control depends on many factors which are specific to each facility, equipment, and food. Therefore, even within a single company, allergens may be controlled differently at different facilities or in different foods produced at the same facility.

FMI appreciates that in several respects the Draft Guidance takes a risk-based approach to allergen control, which is consistent with the framework of risk-based preventive controls generally. In particular, the guidance emphasizes the flexibility facilities have in managing allergen controls such as the recognition that an activity can be both a monitoring and verification activity, and that "exception records" can serve as monitoring records. FMI also is pleased that the Draft Guidance explicitly states that the purpose is to provide as many examples as possible so that companies can develop their own food allergen program as appropriate to their operations, "not to imply that a food allergen program should have all the CGMP measures, preventive controls (including supply chain controls), monitoring/verification activities, corrective action procedures, and records that [it] describe[s] for illustrative purposes."[2]

Nonetheless, although the Draft Guidance includes flexibility language in some areas, as discussed below, we would also like to see flexibility language incorporated in other sections throughout the document to ensure that food manufacturers have the ability to take a risk-based approach to allergen control that is tailored to their operations. In the comments that follow we address some of the areas of the Draft Guidance our members identified as most critical for ensuring that allergen programs are risk-based and effective:

- Allergen management should leverage good manufacturing practices (GMPs) and Preventive Controls (PCs) as distinct tools
- Label control risk is company and facility specific
- Supply chain programs and supplier verification activities must consider the potential hazard and the supplier's food safety practices
- Allergen advisory statements are the product of a risk-assessment
- Allergen thresholds play a key role in risk-based decision making

We also provide some additional suggestions on ways to streamline the Draft Guidance. Our detailed comments are below.

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[2] We recommend FDA repeat this disclaimer throughout the guidance so that the examples are not misinterpreted as prescriptive requirements.

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Allergen Management Should Leverage GMPs and PCs as Distinct Tools

FMI welcomes the agency's discussion of the complimentary role that good manufacturing practices (GMPs) and preventive controls (PCs) each play in a risk-based food allergen program. We appreciate that the agency encourages firms to continue to use GMPs to manage certain aspects of allergen control, while reserving PCs for other aspects of the program. FMI agrees allergen management should be balanced between these two distinct tools and firms should have the flexibility to use the tools appropriate to their risk levels.

The Draft Guidance provides manufacturers with the opportunity to apply management components to GMP activities to elevate the GMP to an allergen preventive control. Although this is intended to provide flexibility to manufacturers to utilize existing programs, which we support, it is not sufficiently clear that all GMPs need not be elevated in this way. In fact, many GMP activities are more appropriately maintained as GMPs rather than managed as PCs. FDA should consider clarifying that elevating GMPs to a PC may be a solution in lieu of adding additional or new practices in order to satisfy the need for a PC; however, GMPs are the bedrock of a strong food safety program and there is no expectation that GMPs as a whole should require PC-level management. Such an approach would not be risk-based. Moreover, doing so could have the unintended effect of diluting the function of PCs, which serve not only to manage a hazard, but also to signal that the hazard is one that requires additional attention and focus.

We also ask that the agency add language to Appendix 11-1 where the agency provides examples of GMPs that can be part of allergen program. Specifically, we recommend that the agency clarify that, like preventive controls, GMPs are selected based on the determination of the hazard analysis which takes into account the products, processes, and facility. The GMP activities listed are not appropriate or practical for all operations. For example, some of the measures such as separate storage rooms, separate break areas for use by personnel who work in processing areas with different food allergens, and creation of a buffer room or clean area between areas handling foods with different food allergen profiles would not be feasible without construction or engineering changes to a facility, nor may they be necessary. We recommend FDA revise the section on GMPs to state "examples include" in order to emphasize the flexibility manufacturers have when selecting measures to meet GMP requirements.

Label Control Risk Is Company and Facility Specific

With respect to label controls, the Draft Guidance acknowledges that label content controls and label management controls are treated as separate controls within the document solely for organizational purposes and that the purpose of the Draft Guidance is "not to imply that a food allergen program should have all the controls." However, the Draft Guidance appears to suggest both categories of label controls will always be in place, with no mention of how companies can determine appropriate food allergen label controls (i.e., label content or label management processes) based on the hazard analysis and assessing risk by evaluating other

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factors such as facility recall history, number of products produced, number of allergens in the facility, use of dedicated lines, and other factors. For example, a facility with a history of management-related recalls (wrong-product-wrong-package) likely would implement preventive controls for label management but may consider its label content risk to be low such that it does not warrant a PC. In order to align the Draft Guidance with the risk-based principles in the Preventive Controls rule, FDA should include language in this section expressly noting that the determination of whether a label content or label management control is needed is the product of a risk assessment which may conclude that preventive controls are not necessary.

In addition, the Draft Guidance seems to set an expectation that companies verify label content against the product specification at label receipt/delivery. Depending on the facility, this may not be feasible or efficient. In the first instance, a majority of sophisticated companies receive label shipments multiple times per week. The man hours required to identify and track at the warehouse level the expected incoming shipments and the associated specifications would be prohibitive. In the second instance, in some cases personnel receiving labels at the facility/warehouse are not in the best position to compare the received labels against the product specifications and confirm that allergens are appropriately identified. This work is performed by corporate personnel with relevant expertise. Finally, reconciling labels with the specification at the receiving step may not be the most efficient use of resources, especially when labels have been approved at the corporate level, in which case performing reconciliation against the specification twice would be duplicative.

Supply Chain Programs and Supplier Verification Activities Must Consider the Potential Hazard and the Supplier's Food Safety Practices

FMI is concerned that the Draft Guidance introduces new expectations for supply chain programs to address food allergens that are overly prescriptive, disconnected from risk, and inconsistent with FSMA. Specifically, the Draft Guidance recommends that receiving facilities conduct testing on incoming ingredients both to approve suppliers and verify allergen cross-contact controls whenever the supplier uses shared equipment regardless of the supplier's practices in place. Quite simply, this is not a risk-based approach and is inconsistent with the Preventive Controls regulations.

FSMA and the Supply Chain Program regulations at 21 CFR Part 117 Subpart G require manufacturers to take a risk-based approach when approving suppliers and selecting verification activities. Manufacturers must consider the supplier's food safety programs, practices and procedures. Therefore, conducting ingredient testing regardless of the supplier's food safety practices would conflict with the regulations and would not be grounded in risk. Subpart G also requires manufacturers to consider the nature of the potential hazard (public health impact and likelihood of occurrence) when approving suppliers and selecting verification activities. One important consideration is that the risk of allergen cross-contact at supplier may not necessarily be one for which there is a reasonable possibility that exposure to the hazard will cause serious adverse health consequences or death. Supply chain programs must take this into account.

Separately, FMI is concerned that the reliance on testing may be misplaced. Particularly for allergen cross-contact, where allergen residue may not be homogenously distributed, a testing scheme would have to be carefully designed. For example, standard representative sampling using beginning/middle/end sampling may not be effective in identifying cross-contact, if present. Thus, sampling and testing for allergens would have to be separate and distinct from any other routine lot testing. This additional sampling complexity increases time spent on sample collection, and costs associated with testing. Additionally, FMI is concerned that fit-for-purpose testing is not available for all major food allergens in many food matrices. When a validated method is not available for a matrix, such method must be developed or validated for that matrix (which is costly and time consuming), or a method is used that may not be validated for the specific matrix, which calls into question the reliability of the results. There also is extensive information demonstrating that current allergen test kits have several weaknesses that can drive inaccurate results, such as heterogeneity of an allergenic material in food, susceptibility to temperature abuse in transport and storage, potential for user or equipment error, and matrix interference, leading to inaccurate results. Significantly, one positive test result may not be a true indicator of the actual presence of an allergen.

The Draft Guidance should be revised to include examples demonstrating the flexibility manufacturers have to design supply chain programs for managing allergen cross contact based on public health impact, likelihood of occurrence, supplier practices, and supplier history. The Draft Guidance also should make clear that manufacturers have the flexibility to determine, based on risk, the appropriate emphasis on supply chain programs within their overall approach to allergen controls in their facilities.

Advisory Statements Are the Product of Risk-Assessments

FMI appreciates FDA recognizing in the Draft Guidance that there may be circumstances where despite the implementation of GMPs and PCs, a manufacturer may not be able to ensure protection against allergen cross-contact. In those instances, the manufacturer may choose to provide an allergen advisory statement on the label of the product, disclosing the possible unintended allergen presence. FMI agrees that advisory statements are not an appropriate substitute for implementation and adherence to a strong GMP program and preventive controls. We encourage FDA to include additional information and examples in the guidance regarding circumstances where the risk of cross-contact remains despite implementation of GMPs and PCs.

We also recommend FDA include additional examples of how a manufacturer may document its approach to cross-contact risk-assessments and decisions to use precautionary labeling (including supplier provided allergen advisories). Currently, the Draft Guidance recommends that these determinations and written justifications for them appear in the Food Safety Plan. We maintain that other approaches may be appropriate, such as a company's written policy that applies to all foods or a labeling procedure. FDA should revise the Draft Guidance to provide additional flexibility for these decisions, so long as they are the product of a risk-assessment.

FMI is concerned that the Draft Guidance's expectations regarding supplier use of allergen advisory statements are not feasible at scale or risk-based. The Draft Guidance states "we recommend you discuss the reasons for the allergen advisory statements with the potential supplier. . . you should approve a supplier that provides allergen advisory statement only if you determine that such statements are not being used in lieu of adherence to CGMPs or in lieu of adherence to the requirements for allergen cross-contact controls." This could be read to mean the agency expects customers to conduct a detailed assessment of a supplier's allergen cross-contact controls and confirm that "even after implementation of appropriate CGMP measures and allergen cross-contact controls, that a food can[not] be protected from allergen cross-contact." This exceeds the customer's role and responsibility under supply-chain applied controls, which is rooted in the assurance that suppliers will meet their legal obligations. Manufacturers should not be expected to serve as informal regulatory gatekeepers for upstream allergen controls. Suppliers are in the best position to determine whether advisory labeling is appropriate for the products they produce, and manufacturers should be able to rely on those risk-based decisions.

Allergen Thresholds Play a Key Role in Risk-Based Decision-Making

FMI supports the agency's openness to the use of threshold dose response as part of a risk assessment in determining appropriate allergen controls. The food industry has, and continues to, support the establishment of thresholds for major food allergens. The Draft Guidance notes that "published data on population dose responses to various food allergens are becoming increasingly available." Furthermore, the "published data raise the possibility that some low-level exposures to food allergens, and the presence of certain allergen-derived ingredients, may not cause allergic reactions in most consumers who have that food allergy." Despite the fact that FDA has not established a maximum amount of food allergen that may be present in labeled food products without the need for declaration, the Draft Guidance acknowledges that "food manufacturers/processors could evaluate such data in light of their specific products, such as through risk assessments or other scientifically valid assessments, in making decisions on appropriate food allergen controls."

This flexibility to make decisions based on risk assessments or other scientifically valid assessments is in line with the growing published literature and is also consistent with the overall risk-based approach to preventive controls. It is critical that companies are given the flexibility to consider this information, along with factors associated with their facility, the product, and other variables to make a risk-based determination that is appropriately protective of human health.[3] FMI encourages FDA to build on these statements to recognize allergen

[3] CODEX Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)

thresholds more formally.[4] Allergen thresholds would help industry assess cross-contact risk, determine when allergen advisory statements are appropriate and evaluate products affected by allergen cross-contact for safety to ensure affected product does not enter commerce or is removed from commerce. Moreover, establishing thresholds would create standards for allergen advisory labeling, provide consistency to consumers and allow them to make informed food choices.

Opportunities to Streamline Draft Guidance

In addition to the substantive comments above, we believe the following steps could be taken to streamline the draft guidance, which is lengthy and in places repetitive.

- Distinction between monitoring and verification activities. The agency discusses at length and in detail in several sections the fact that some activities could be monitoring or verification activities including allergen cleaning procedures, allergen cross-contact controls, and label controls. The interplay between monitoring and verification activities is a helpful and important reminder that PC management components should be site specific, but could be limited to one section, which is then cross referenced throughout to shorten the Draft Guidance.

- Replace Allergen Cleaning Procedures Section with Cross-Reference to Chapter 10: Sanitation Controls. We understand Chapter 10: Sanitation Controls is currently under development and identified as "coming soon." To this end, we encourage the agency to consider when drafting Chapter 10 and revising Chapter 11, how the two chapters can best and most efficiently cover their relevant topics. For example, the discussion in Chapter 11 related to allergen cleaning procedures includes SSOP details that may be better the addressed as a sub-section of Chapter 10, which is then cross-referenced in Chapter 11, rather than being addressed as comprehensively in Chapter 11.

- Relocate Appendix 11-1 Content to a Different Guidance Document. As noted above, GMPs and PCs are distinct tools. While GMPs may compliment a strong Food Allergen Program, issues such as personnel apparel, employee movement, design and construction of a facility, equipment material, warehousing, and the like, may be better addressed under separate Guidance focused on GMPs than on preventive controls.

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[4] FDA should incorporate the thresholds established at the Food and Agriculture Organization of the United Nations and the World Health Organization meeting on thresholds referenced in the Draft Guidance for clarity and consistency.

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FMI supports the agency sharing its thinking on the important issue of allergen controls and robust Food Allergen Programs. We encourage FDA to continue efforts to engage with industry as it moves forward with these efforts. We also recommend FDA develop training programs regarding the allergen Draft Guidance and allergen control programs, as this is a critical area of food safety.

Should you have questions about these comments, please feel free to contact me.

Sincerely,

Hilary S. Thesmar

Hilary S. Thesmar, PhD, RD, CFS
Chief Science Officer and SVP Food and Product Safety

Ashley Eisenbeiser

Ashley Eisenbeiser, MS, CFS
Senior Director, Food and Product Safety Programs

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