January 21, 2025

Submitted electronically via regulations.gov

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

Re: Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Docket No. FDA-2024-N-3609.

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) proposed process and Discussion Paper: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (Discussion Paper). 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 the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

FMI applauds FDA for outlining its proposal to enhance its approach of Post-Market Assessments of chemicals in food and for holding the September 25, 2024 public meeting. We believe transparency is key to an initiative like this one and appreciate the visibility into the process FDA intends to undertake. To reiterate the oral comments we delivered at the public meeting, FMI and its members are committed to ensuring a safe food supply and we welcome FDA's efforts to engage in Post-Market Assessments of chemicals in food using an approach that is both transparent and grounded in sound science. We believe that as the agency charged with protecting public health, FDA has the scientific expertise to undertake this important work. The agency has the unique ability not only to carefully evaluate scientific data and information on a particular substance, but also to make risk-based decisions and then communicate those to consumers and industry alike. Having FDA at the helm of this systematic process will help ensure a uniform, federal approach to these issues and strengthen consumer confidence in the food supply.

FMI supports the basic framework outlined in the Discussion Paper, as it enables the agency to use its resources effectively and efficiently. At the same time, FMI would welcome additional detail and specificity regarding the agency's process, so it and other stakeholders can fully understand how the process will work in practice. There are three areas in particular where FMI

sees opportunities to enhance the proposed process with additional clarity and refinement to ensure a transparent process grounded in sound science and risk-based decision-making:

(1) External Engagement: There are additional opportunities for stakeholder involvement in the Post-Market Assessment process, particularly with respect to Focused Assessments, assessments involving risk-management actions, as well as incorporating the use of well-balanced, multidisciplinary Advisory Committees.

(2) Risk-Based Assessments: FMI supports FDA's commitment to using a risk-based approach, rather than a hazards-based approach, as it develops the Post-Market Assessment process. FDA should further clarify the Prioritization of Risk model and publish the criteria for public comment.

(3) Public Education and Communication: Clear and consistent communication to the public about any Post-Market Assessment action taken by FDA and what it signifies is necessary to effectively convey potential risks and to reassure consumers of the security of our food supply.

Although we urge FDA to consider and incorporate our recommendations into the Post-Market Assessment process, our members recognize that implementation of the agency's activity in this area may be an iterative process. A unified, systematic approach to post-market reviews is critical to minimize the disruption and confusion caused by the patchwork of state-by-state legislation. Therefore, the recommendations proposed in these comments should not delay the proposed December 2025 implementation date.

We provide additional detail in the comments that follow.

1. There are Additional Opportunities for Stakeholder Involvement in the Post-Market Assessment Process

As evidenced by the comments delivered during the September 25 public meeting, academia, industry, and consumer groups are aligned with respect to the need for transparency and stakeholder involvement throughout the Post-Market Assessment process. We appreciate FDA's approach to stakeholder engagement as outlined in the Discussion Paper and FMI agrees with FDA's proposal to engage the public during the Scope/Problem Formulation and Draft Scientific (Risk and Safety) Assessment phases in Comprehensive Assessments. We recognize that there are other avenues for engagement that are not captured by the paper. For example, a member of the public may submit data and information to the agency through other channels, such as a Citizen Petition or through open dockets that are relevant to the particular chemical at issue.[1] We recommend FDA remind the public of these engagement vehicles. Additionally, FMI

[1] 21 CFR § 10.30.

recommends that FDA incorporate additional opportunities for external involvement as discussed below:

- Public Engagement for Focused and Comprehensive Assessments: Under the current proposal, there are no formal public engagement opportunities for Focused Assessments, although FDA may seek external peer review "on an ad hoc basis." We agree with many of the speakers from the public meeting who advocated for public engagement during Focused Assessments. However, we recognize FDA is constrained by limited resources and ensuring a timely review of chemicals while simultaneously seeking and incorporating public comment into a Focused Assessment may not be feasible.

  We therefore propose modifying FDA's two-pronged approach to include a decision node for Focused Assessments at the Scientific (Risk and Safety) Assessment Step (Step 2). Under our proposal, if FDA determines that a chemical does not meet the "reasonable certainty of no harm" standard or, in the case of a contaminant, it suggests a public health concern and risk management action may be necessary, the chemical will be converted from a "Focused" to a "Comprehensive" Assessment, where the Draft Scientific Assessment will be subject to public comment before FDA initiates the risk management review steps, thus providing for public engagement. Alternatively, if FDA concludes the available information about the chemical does not suggest a public health concern that may require risk management, then the Focused Assessment would proceed to the Communication of Conclusions step. Our proposal is contemplated, in part, by the Discussion Paper, which states that at the current Risk Management Review step for Focused Assessments, FDA "may also identify the need for additional research or the need for a full comprehensive assessment."[2] Converting a Focused Assessment to a Comprehensive Assessment if there are public health concerns with the chemical is risk-based and will ensure external engagement in select circumstances where a public health risk has been identified, while ensuring the proper depth of assessment and thoughtful allocation of FDA resources.

- Risk Management Actions: When an assessment includes specific risk management actions, public engagement should be sought prior to initiating the actions to ensure they are adequately designed to protect public health and will not cause disruption to the food supply chain. Furthermore, in instances where the risk management implementation plan would result in a change to the regulatory status of a food ingredient, the time needed for manufacturers to evaluate their formulas and reformulate and/or relabel their products as appropriate should be incorporated into the

[2] FDA, Discussion Paper, Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (August 2024), p. 4, available at https://www.fda.gov/media/180942/download.

implementation timeline. These actions are critical to ensuring a safe and stable food supply.

- Advisory Committees: FMI supports FDA's willingness to incorporate external engagement into its Post-Market Assessments, particularly through peer review. With respect to advisory committees, we support the incorporation of advisory committee review into the Post-Market Assessment process. Although advisory committee review could occur at several potential points in the process, one logical place would be at the end of the "Scientific (Risk and Safety) Assessment" (Step 3) of the Comprehensive Assessment. Incorporating review by a well-balanced, multidisciplinary advisory committee will ensure that the assessment is developed with the benefit of a variety of viewpoints. We advise, if deciding to move forward with an advisory committee, that the committee should be utilized to aid in the assessment process and not create a bottleneck by slowing down the process.

FMI believes that the aforementioned proposed steps will help to balance the need for external engagement with competing timing and resource constraints.

2. The Prioritization of Risks Scheme Would Benefit from Further Clarity and Refinement

The opening paragraphs of the Discussion Paper state that the proposed systematic process would allow FDA to "proactively identify and target chemicals currently in the food supply for assessment in a structured manner *based on risk*" (emphasis added).[3] We support this statement and ask FDA to confirm its commitment to using a risk-based approach, rather than hazards-based approach, as it develops the Post-Market Assessment process. Although FMI generally supports the Prioritization of Risk scheme outlined in Section IV of the Discussion Paper, additional refinement is warranted, as detailed below:

- Proposed Criteria and the role of "public interest": We understand that the Prioritization of Risk scheme is designed to determine the priority ranking for each chemical that will be subject to a Comprehensive Assessment. The Discussion Paper identifies several criteria that FDA can consider as part of this process. These criteria include science-based public health factors and, other "decisional factors, such as "interest and/or attention to this chemical by other organizations or the public" (emphasis added). FMI agrees that public interest and/or attention is a factor that should be considered when determining the priority of a given chemical, as it indicates consumers' need and desire for additional information and guidance from FDA. However, unlike the other public

[3] FDA, Discussion Paper, Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (August 2024), p. 3, available at https://www.fda.gov/media/180942/download.

health factors listed in the scheme, such as toxicity, exposure information, or intended population, there is no direct relationship between public interest and the health or safety risk posed by a chemical. To suggest that public interest plays a role in the risk profile of a chemical has the potential to generate consumer confusion and misplaced skepticism in the safety of the food supply. We therefore recommend that FDA revise the title for the current Section IV to "Prioritization of Review." This change will help improve clarity and reduce the potential for consumer confusion about the Post-Market Assessment review process.

Public interest is also discussed in the context of the Fit for Purpose Decision step, noting that if FDA has "reason to suspect an assessment will be…of significant public interest, the assessment is likely to be Comprehensive."[4] However, even if a Comprehensive Assessment is not indicated, public interest in a chemical and its safety may warrant addressing it with a Focused Assessment. Providing a timely response to consumer/public concerns (which may or may not rest on a scientific foundation) through a Focused Assessment may help build public confidence in the food supply and in FDA's leadership on these issues.

- MCDA Model: With respect to the proposed risk-ranking model, although we generally support the use of a Multi-Criteria Decision Analysis (MCDA) method for prioritizing the review of chemicals, we urge FDA to publish the specific criteria and scoring approach that will be used for public comment prior to implementation. We understand that FDA intends to use an approach similar to the method used by the U.S. Environmental Protection Agency (EPA) for prioritization of chemicals for risk evaluation.[5] However, given the differences between the FDA and EPA regulatory regimes and nature of the chemicals of interest, we caution FDA from simply implementing a carbon copy of the EPA model. Publishing the specific methodology for public comment will help ensure public understanding of the approach and that it is comprehensive, objective, and scientifically sound.

3. Public Education and Communication is Critical for the Success of the Post-Market Process and to Ensure Consumer Confidence in the Food Supply

Clear and consistent communication to the public about any Post-Market Assessment action taken by FDA such as, the reasons for that action and what it signifies, is necessary to effectively convey potential risks and to reassure consumers of the safety of our food supply. We agree

4 *Id*. at 4.

5 EPA, Prioritization of Existing Chemicals Under TSCA, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritization-existing-chemicals-under-tsca.

with FDA that "risk communication will be critical throughout this process."[6] Below we provide recommendations about when and how FDA should incorporate communication throughout the Post-Market Assessment process.

- Post-Market Assessment Website: We encourage FDA to communicate with stakeholders about the Post-Market Assessment process, where each substance currently resides in the process and the significance of when a food chemical is the subject of a post-market review. The public-facing website FDA currently uses to publicize the List of Select Chemicals in the Food Supply Under FDA Review is a step in the right direction.[7] The website identifies the chemicals that are currently being reviewed by the agency and where they are in the review process. It also includes educational information about the food ingredients, food contact substances, and contaminants listed in the table, and an explanation that FDA may initiate these Post-Market Assessments in response to requests by stakeholders (e.g., petitions) or on the agency's initiative. Although the information is helpful and provides necessary context, the website should more clearly communicate to consumers that a chemical's presence on the list alone is not dispositive of a food safety risk. We urge FDA to continue using this or a similar website for the new Post-Market Assessment process as a method for communicating to the public while incorporating additional statements emphasizing that except as specifically noted (e.g., bromated vegetable oil (BVO)) the agency's review of the listed chemicals is ongoing and no final conclusions as to safety or the appropriate risk management action, if any, have been taken. FDA should make clear to the public the agency's Post-Market Assessment of a chemical does not mean it is unsafe. Additionally, as progress is made on the assessment of chemicals, step-wise updates of each chemical will help grow confidence in the agency and this program.

- Clarification of the GRAS Process: Several speakers at the public meeting commented on Generally Recognized as Safe (GRAS) ingredients, urging FDA to "reform" the GRAS notification program. The comments indicated that there is disagreement and confusion among stakeholders regarding what the GRAS process entails and FDA's legal authority (or lack thereof) to reform it.[8] We appreciate that FDA has several webpages dedicated to educating the public on how FDA regulates food additives and GRAS ingredients.[9]

---

6 FDA, Discussion Paper, Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (August 2024), available at https://www.fda.gov/media/180942/download.

7 FDA, List of Select Chemicals in the Food Supply Under FDA Review, available at https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review.

8 21 U.S.C. §321(s).

9 *See* e.g., FDA, Understanding How the FDA Regulates Food Additives and GRAS Ingredients; available at https://www.fda.gov/food/food-additives-and-gras-ingredients-information-consumers/understanding-how-fda-regulates-food-additives-and-gras-ingredients; FDA, How U.S. FDA's GRAS Notification Program

Moreover, we appreciate FDA's recent decision to publish memoranda documenting FDA's determination that the use of a substance in food does not meet the statutory criteria for GRAS.[10] We urge FDA to continue educating the public on the meaning of GRAS and emphasize that all GRAS substances, whether self-determined or reviewed by FDA, are eligible for FDA review through the Post-Market Assessment process.

We also think it is important to emphasize that FDA has ample authority under current law to address GRAS substances that pose a risk to the safety of consumers. FDA can act immediately to address a product that is dangerous to consumers, regardless of whether it has gone through the Post-Market Assessment process. For example, FDA can issue Public Health Alerts and has the authority to order an administrative detention if there is reason to believe that an article of food is adulterated, which then may be subject to seizure or injunction action under certain circumstances.[11] Continuing to incorporate these concepts into consumer outreach and education will help to strengthen the integrity of the Post-Market Assessment process and consumer trust in the food supply.

4. FDA Should Narrow the Scope of the Post-Market Assessment Framework

FDA has decided to integrate both chemical contaminants (such as toxic elements) and intentionally added substances into the same post-market assessment framework. However, we believe it would be beneficial to separate the processes for these two categories. The risk assessment methodologies and risk management strategies differ significantly between them, justifying this separation. Moreover, contaminants often require multiple rounds of adjustments to risk management actions as new mitigation options become available and the feasibility of reducing contaminants improves.

- Separation of Contaminants: We suggest that the reassessment work should primarily focus on intentionally added substances, while contaminants should continue to be managed through existing initiatives like FDA's Closer to Zero program. If the combined approach is maintained, it will be crucial to help stakeholders understand that the frameworks (including prioritization criteria) and risk management options for these two groups may differ. Specifically, the FDA should clarify how the cycles of reassessing the feasibility of reducing contaminant action levels will fit into the post-market assessment prioritization process.

Works (Dec. 2005), available at https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works.

[10] FDA, Post-market Determinations that the Use of a Substance is Not GRAS, available at https://www.fda.gov/food/generally-recognized-safe-gras/post-market-determinations-use-substance-not-gras.

[11] 21 U.S.C. §334(h)(1)(A); § 344(a).

5. FDA Should Consider Timing When Releasing Risk Assessments and Proposals for Risk Management

While we recognize the potential value of public comment, we feel that it is important FDA consider the timing between any public release of a Draft Scientific Risk and Safety Assessment and a Draft Proposal for Risk Management or an indication that no further risk management steps are needed. More specifically, by issuing risk assessments and risk management plans within close temporal proximity, FDA will help industry avoid potential disruptions and efficiently facilitate appropriate risk management procedures. Without similarly timed release, new risks may unintentionally be created for industry. For example, issuing a risk assessment significantly earlier than its corresponding risk management plan could lead to increased actions by states, retailers/customers, and risk Plaintiff lawyers that may not align with FDA's risk management positions when later released.

* * *

FMI greatly appreciates the opportunity to provide comment on the Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food. We look forward to further dialogue and collaboration with the agency and would be pleased to provide any further information that would be helpful to the agency.

Sincerely,

Shelby Hollenbeck

Shelby Hollenbeck, PhD
Director, Food and Product Safety Programs

Dana Graber

Dana Graber
Associate General Counsel & Senior Director, Legal and Regulatory Affairs
FMI – The Food Industry Association