IDFA
International
Dairy Foods Association

January 21, 2025

Via Regulations.Gov

U.S. Food and Drug Administration
Docket No. FDA-2024-N-3609

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3.2 million jobs that generate $49 billion in direct wages and $794 billion in overall economic impact. IDFA's diverse members make most of the milk, cheese, ice cream, yogurt and cultured products, and dairy-derived ingredients produced and marketed in the United States and sold throughout the world. Safe, nutritious, affordable, and sustainable, dairy foods offer unparalleled health and consumer benefits to people of all ages.

IDFA appreciates the opportunity to provide our feedback on questions posed in the "Discussion Paper, Development of an Enhanced Systemic Process for the FDA's Post-Market Assessment of Chemicals in Food" (Discussion Paper, henceforth). We believe this is the first step necessary to establish a robust, science-based and transparent program that supports the use of innovative substances in food with the necessary level of oversight to ensure public trust in our nation's food supply. We urge the Food and Drug Administration (FDA or agency) to continue seeking public comments as the agency continues to refine this program.

Given IDFA's membership and the nutritional benefits of dairy products, it should be no surprise that consumer trust in the safety of dairy products is a top priority for dairy processors as is oversight by a credible and robust *federal* food regulatory agency. The lack of a proactive, robust, federal post-market oversight system for food substances that undergo pre-market safety assessments, and for substances that are Generally Recognized as Safe (GRAS), has led state legislatures to pass laws to ban these food substances through state political systems instead of through rigorous science, review, and assessment by the FDA. The result is a patchwork of state laws that makes compliance a challenge for companies processing and selling dairy products in multiple states. It also stifles innovations that can bring healthy nutrient dense dairy products to Americans of all ages. IDFA supports regulations founded on reliable science and robust risk assessments that apply nationwide.

IDFA's comments below reflect our perspectives on the Discussion Paper and next steps. We appreciate our industry's collaboration with FDA and look forward to working with the incoming Trump Administration to develop and implement a robust post-market assessment program for food substances given we collectively share the goal of a safe and affordable food supply.

Before responding to the questions posed by the FDA on its Discussion Paper, we first want to urge the agency to move forward with the utmost transparency as it establishes new processes and protocols for science-based decision making regarding chemical substances used or found in food. Continuation of the FDA's insular approach to decision making could further erode consumer confidence in the agency and its ability to assure Americans have access to safe food. IDFA believes the FDA needs a cultural transformation to pivot to an organization that is decisive and action-oriented with much greater transparency and an enhanced desire to collaborate with all stakeholders, including the food industry. IDFA is generally supportive of the approach outlined in the FDA's Discussion Paper and our comments below are aimed at being constructive. Our industry desires a credible, nimble, and robust agency with strong science-based regulatory oversight.

1. When and how should the FDA engage the public on post-market assessments?

IDFA believes the FDA's post-market assessment program will lack credibility and transparency unless the agency provides more opportunities for public engagement and avoids arbitrary decision making. At the same time, public engagement should be targeted and designed to be useful to the FDA while facilitating timely decision making. To achieve this balance, we recommend utilizing a public-facing workplan and developing and implementing a set of criteria that triggers FDA public engagement in lieu of establishing a rigid, one-size-fits-all process for public engagement.

A. <u>A public-facing workplan as a communication tool is the best way for FDA to share information and provide much needed transparency and accountability.</u>

As a communication tool, IDFA strongly recommends that the FDA utilize a public-facing workplan(s) that includes information such as data needs, comment opportunities and deadlines, milestones, review status, and an overall timeline for completing activities for both Focused and Comprehensive post-market assessments. Selected substances should be included in a workplan following prioritization based on an established set of criteria. A workplan should include a general explanation of the basis for inclusion of a substance (e.g., petition, new scientific studies, actions by other nations, extended time since prior review). The FDA should update the workplan at a regular cadence and as needed so that the public can track progress and stakeholders can understand when opportunities for engagement arise.

Importantly, to avoid undue public stigmatization and potential consumer confusion, the FDA should explicitly state that food substances prioritized for Focused or Comprehensive post-market assessments and included on a workplan continue to be considered safe for human consumption. Moreover, FDA must convey that the purpose for inclusion in a workplan is to communicate about substances that are priorities for post-market assessment, and that until the assessments are complete, these

substances can continue to be used as per existing limitations in the manufacturing of food.

B. FDA should establish criteria to trigger public engagement at specific points in its post-market assessment program

The FDA's Discussion Paper includes an opportunity for public engagement and comment as part of the Comprehensive assessment process delineated (see response to question 2 below) but not as part of the processes for Focused assessments or the prioritization of substances for assessments. Because the FDA must balance resources and timeliness regarding post market assessments, IDFA recommends the agency consider providing opportunities for public engagement, review, and comment at other defined points in its post-market assessment program.

Further, we suggest that decisions to provide opportunities for stakeholder engagement not be based on a rigid one-size-fits-all framework but instead based on a specific set of criteria. To provide more predictability for the FDA and the public, we recommend that the agency develop these criteria with public input and that it put in place guardrails on where in the process it would even consider public engagement. The FDA should always seek public input, or input from specific stakeholders, when data or information is needed to further the agency's post-market assessment decision making. This is particularly important when the data or information needed is related to the prioritization of food substances for assessments and the conduct of Focused and Comprehensive assessments.

IDFA specifically recommends the FDA consider seeking public input in the following instances:

First, FDA actions that serve gatekeeping functions provide an important opportunity for public input. In its Discussion Paper, the FDA does not provide an opportunity for public input during the Triage phase, which is the first gatekeeping function of the agency's proposed post-market assessment framework. IDFA believes public comment is needed during the Triage phase, because the FDA states in its Discussion Paper that it is during this phase that the agency develops its initial priority list for a fit for purpose decision on the need to conduct a post market assessment. Unrelated but relevant, the Discussion Paper lacks information and details about the criteria the FDA will use to make these initial decisions, specifically how the Triage phase will be carried out, and if and how the public can provide input. IDFA recommends that the FDA provide stakeholders with additional information on the Triage phase and consider public input at this point in the process.

Second, the FDA should seek public input before it makes a final risk management decision on a risk assessment, especially if the decision is to delist a substance. More specifically, if a Focused or Comprehensive assessment results in specific risk

management actions, IDFA strongly recommends the FDA seek public input *before* implementation of such actions to ensure they are feasible and practical to implement and that supply chains remain resilient, while most importantly protecting public health. To do otherwise could result in unintended consequences including major supply chain disruptions and ingredient and product shortages. IDFA also urges the FDA to consider the time needed for manufacturer reformulation and relabeling of products for retail circulation should a substance be delisted or banned. We believe that stakeholder engagement and input on risk management actions the agency is considering in response to the results of Focused assessments is particularly important and we are concerned that the FDA does not include this as a possibility in their proposed framework. We understand there will be times when an immediate action must be taken to mitigate an acute public health risk, but other than that we do believe the agency needs to be transparent and engage stakeholders before it implements risk management actions in response to its post market assessments.

2. Is the frequency and mechanisms of the envisioned public engagement described in Section V of this document appropriate? If not, please provide alternative areas for engagement/communication, additional information that you believe should be shared publicly, and rationale for the change.

IDFA urges the FDA to align its method and nature of public engagement for post-market assessments conducted by the agency on its own accord to the public engagement that is mandated for food additive petitions and /citizen petitions, to the extent practical.

When discussing public engagement regarding Comprehensive post-market assessments, the FDA cites to regulations for color additive petitions and citizen petitions which mandate opportunities for public comment; IDFA urges the agency to align the method and nature of public engagement for Comprehensive post-market assessments conducted on FDA's own accord to the extent practicable with the public engagement mandated for food additive and citizen petitions.

IDFA also supports the FDA providing opportunities for public comment during Comprehensive post-market assessments as provided in the Discussion Paper, but as noted in question 1, we believe additional opportunities for public comment should also be considered and offered. IDFA understands that public engagement through public meetings and open comment periods can slow down FDA processes, but without this transparency and stakeholder engagement and input, post-market assessments at the agency will remain insular and opaque and may further erode stakeholder confidence in the work the FDA is doing in this very important arena. As stated in our response to question 1 above, we believe criteria for assessing when to seek public input would serve the FDA well.

3. Should the FDA integrate an advisory committee review into its post-market assessment process? If yes, at what stage, and what should the committee's role be?

Advisory committees can serve an important function in supporting science-based government decision making by inviting diverse expertise and input that augments that of an agency. IDFA's members, however, do not agree that an advisory committee would benefit the proposed FDA post-market assessment program, nor where in the post-market assessment process an advisory committee would be most valuable. We also understand that the FDA expressed opposition to the use of an advisory committee in any aspects of its post-market assessment program at the September 26, 2024, public meeting.

IDFA members expressed concerns that establishing and utilizing an advisory committee would slow down a process that needs to move quickly. Our members are also concerned that an advisory committee would not include diverse representation and would in fact exclude experts from the food industry. In contrast, some of our members do believe an advisory committee could also serve to help prioritize chemicals for assessment and provide advice with respect to Triage and program performance.

If the FDA determines that an advisory committee is appropriate, IDFA strongly urges the agency to ensure the committee includes experts from multiple sectors, including industry. Food industry representatives could be selected with expertise in the food chemicals under review, supply chains, and manufacturing thus bringing a valuable perspective to the advisory committee and the FDA. Comprehensive assessments would notably benefit from industry experts with specific knowledge of the chemicals under review. We recommend that the FDA look to the multi-sector advisory committees that have proven effective at the Environmental Protection Agency (EPA) and determine if a diverse committee could also be valuable to the agency.

4. Are the Fit for Purpose Decision Tree questions in Section III of the document appropriate? If not, what questions would you add or how would you modify the questions to be more appropriate to the task?

IDFA generally agrees with the Fit for Purpose Decision Tree questions. With that said, we believe these questions would also prove useful not only for selecting chemicals, but for prioritization of chemicals for post-market assessments.

The first Fit for Purpose Decision point is whether the assessment would require significant resources outside of the FDA's Office of Post-market Assessment (for example, resources for lab work and/or data collection). We acknowledge that this criterion is important because the FDA must work within the confines of the resources it has been given by Congress and the agency will need to weigh risk against available resources. However, the FDA should expect criticism if it declines to conduct a post-

market assessment because it would take too many resources. We recommend that the FDA provide more transparency in how it would weigh risk and associated costs-benefits when prioritizing post-market assessments of food chemicals.

IDFA agrees with the second criterion that examines whether there is scientific consensus and/or strong weight of evidence suggesting the substance's potential to impact the prevailing conclusion of reasonable certainty of no harm under its conditions of use in food. We also agree that the FDA should look to whether multilateral organizations, U.S.-bilateral organizations and/or scientific organizations recently reviewed the risks associated with a food substance and identified potential safety concerns. However, identification of safety concerns by these other entities needs to be reviewed carefully given the different constructs for assessing risk in different regions of the world. The FDA will need to ensure that it considers and follows the standards and regulatory frameworks in the U.S. when examining safety concerns raised by non-U.S. entities.

IDFA agrees that the FDA should determine if there is evidence of a change in dietary exposure to a food chemical that could impact consumer health when identifying and prioritizing food substances for post-market assessments. With that said, we would like the FDA to provide additional details on how it plans to determine if a substance poses a significant public health interest. Will the level of public health interest be based on how much of the substance is in the marketplace? Or is this criterion really the same as those noted above?

Relatedly, the FDA's current website lists 21 chemicals as under agency review, including environmental contaminants, color additives, food additives and food contact substances. The FDA's public facing website is an improvement, but it lacks prioritization and timelines for the initiation and expected completion dates for the assessments. IDFA recommends a public workplan(s) to fill these information gaps as noted above in question 1. We also suggest that the FDA limit the number of substances on any priority list to those that will actually be under active review by the agency based on the availability of resources. Otherwise, these lists do not change and instead highlight what appears to be FDA inaction; this apparent lack of progress could fuel state legislatures to continue to take their own actions and fuel further consumer distrust.

5. Is the Prioritization of Risks scheme the FDA outlines in Section IV of its Discussion Paper appropriate for ranking food chemicals (including contaminants, food ingredients, and those substances used in contact with food) for post-market assessments? If not, please explain why and how you would modify the Prioritization of Risks scheme. Please provide supporting rationale for the changes.

IDFA supports the use of a multi-criteria decision analysis (MCDA) as an appropriate method of weighing and prioritizing risks. The risk prioritization criteria for a public health ranking are generally appropriate as well, but as the FDA further refines its MCDA, we recommend that the agency seek additional public input. More specifically, as the FDA moves forward in developing a MCDA, we caution the agency to ensure that the MCDA is appropriate for food and distinct from the MCDA utilized to review chemicals under EPA's Toxic Substances Control Act (TSCA). We do not believe there is a scientific basis to use a "similar approach and criteria" as TSCA for food chemicals given that the chemicals reviewed under TSCA pose the potential for far more harm than those substances intentionally or indirectly added to food that have already undergone a pre-market safety assessment or GRAS determination (see Discussion Paper page 7). As part of that pre-market safety review, food substances and chemicals must meet the reasonable certainty of no harm standard for their intended use. This contrasts with TSCA's goal of regulating chemical substances and mixtures that present an unreasonable risk of injury to the health of the environment (15 U.S.C. §2601). That said, we recommend that the FDA also consider the resources needed to complete a post-market assessment, as considered in the first criterion in the Fit for Purpose Decision Tree. This would allow the FDA to weigh speed with human health risk and make decisions that may prioritize reviews that can be done more quickly to maximize public health outcomes.

6. Is the FDA's two-pronged approach of Focused Assessments and Comprehensive Assessments appropriate to assess public health risks of chemicals in food? If not, please explain why.

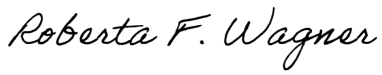
IDFA agrees with the two-pronged approach for post-market assessments outlined in the FDA's Discussion Paper. However, the FDA includes unintentionally added and unavoidable environmental contaminants in the same category as approved food and color additives, food contact substances, and GRAS substances. It is not clear to IDFA how environmental contaminants would fit into the FDA's post-market assessment program, given these contaminants are not subject to pre-market assessments and are not GRAS. Furthermore, environmental contaminants will require different processes, prioritization, decision criteria, and risk communication and management actions from substances subject to pre-market review or that have been determined to be GRAS.

IDFA urges the FDA to develop an independent surveillance and assessment program for environmental contaminants and provide an opportunity for public comment. We believe a program for environmental contaminants would require surveillance, data collection and processes that differ from a post-market assessment program. Also, given the FDA has legacy programs, such as its Total Diet Study and pesticide residue monitoring programs, we suggest the FDA reexamine those programs to determine how they could be integrated and made more effective for conducting surveillance and data collection in addition to other methods of surveillance noted in the Discussion Paper.

Moreover, in developing a program for addressing environmental contaminants, IDFA recommends that the FDA establish and share its decision-making and prioritization processes and criteria and seek public input. These processes and criteria should be informed by and align, where appropriate, with the agency's post-market assessment program. IDFA recognizes that the scientific approach for the assessment of environmental contaminants and other intentionally added food substances may be similar and would likely require the same technical expertise. With that said, the risk management measures for intentionally versus unintentionally present substances would differ and therefore may have an impact on certain aspects of the risk assessment approach.

Lastly, the manner in which the FDA responds to and communicates about environmental contaminants will also differ from post-market assessments of food substances that have undergone a pre-market safety review. Responding to risks posed by environmental contaminants may require research to identify appropriate mitigation strategies and typically will not only require risk management actions by the FDA but may also require coordinated involvement of other federal agencies, including the EPA, USDA, and even state regulators. This contrasts with the regulatory processes and risk management actions that can be taken by the FDA with regard to substances subject to pre-market review and thus authorized for specific uses in food. IDFA urges the FDA to establish a standalone program for environmental contaminants and to provide details on how it will perform surveillance and gather data, identify, prioritize, and assess the risks associated with these contaminants. As stated, we would appreciate an opportunity to comment on this program and these details once available.

Thank you for the opportunity to comment on the FDA's proposed framework for the systematic review of food chemicals. Should you have any questions on our comments, please reach out to Roberta Wagner.



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