U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

The Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food

May 2026

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Abbreviations

ADI (Acceptable Daily Intake)
DAI (Division of Additives and Ingredients)
DCC (Division of Chemical Contaminants)
Discussion Paper (Discussion Paper: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food)
DRAP (Division of Risk Assessment and Prioritization)
EFSA (European Food Safety Authority)
FAO (Food and Agriculture Organization of the United Nations)
FD&C Act (Federal Food, Drug, and Cosmetic Act)
FDA (U.S. Food and Drug Administration)
GRAS (Generally Recognized as Safe)
HFP (Human Foods Program)
JECFA (Joint FAO/WHO Expert Committee on Food Additives)
OFCSDSI (Office of Food Chemical Safety, Dietary Supplements, and Innovation)
OPMA (Office of Post-Market Assessment)
OPMAS (Office of Pre-Market Additive Safety)
OSSRP (Office of Surveillance Strategy and Risk Prioritization)
WHO (World Health Organization)
WILEE (Warp Intelligent Learning EnginE)

I. Background and Purpose

In August 2024, the U.S. Food and Drug Administration (FDA or we) published a Discussion Paper on the development of an enhanced systematic process for the post-market assessment of chemicals in food, including food additives, color additives, generally recognized as safe (GRAS) substances, food contact substances, and chemicals that are present as contaminants.

The Discussion Paper broadly outlined a proposed approach for a systematic process for the FDA to proactively identify and target chemicals currently in the food supply for assessment. The paper included six questions for public consideration, and we opened a docket for public comment, FDA-2024-N-3609, at the time of its publication. In September 2024, we held a public meeting to share more details about the systematic process and hear stakeholder perspectives on the proposal. We received and granted one request to extend the comment period, which closed on January 21, 2025. We received over 70,000 comments, which we carefully reviewed to inform our thinking and assist us in further developing the process.

Here we present the revised systematic process for the post-market assessment of chemicals in food, which incorporates stakeholder feedback from both the public meeting and the submitted comments. This paper describes the process, including how we will identify food chemicals for review, prioritize identified food chemicals for assessment, structure scientific assessments, and communicate risk management plans. We also address common themes from public comments submitted to the docket. A companion paper detailing a tool to help us prioritize food chemicals for post-market scientific assessments was published alongside this paper.

What do we mean by "Chemicals in Food"?

The goal of this process is to ensure that all substances in food are safe for people to consume. Everything in food is made up of chemicals – whether natural or synthetic.

Chemicals in food include:

- Individual elements like calcium (an essential nutrient) or lead (a contaminant)
- Chemical compounds like table salt, vitamin C, or butylated hydroxyanisole (BHA)
- Complex mixtures of chemical compounds like chocolate or rosemary extract

Whether a substance in food is safe depends on how much of it we eat over time and how its chemical components interact with our bodies when we eat the food. These substances are often regulated in various ways under the Federal Food, Drug, and Cosmetic Act (FD&C Act). For consistency in this document, we will use the term "food chemical" to describe any substance found in or added to food including nutrients, food additives, contaminants, and natural ingredients. For information about how FDA regulates chemicals in food, see the following links:

- Food Ingredients and Packaging
- Chemical Contaminants and Pesticides

Overview of Major Changes from Discussion Paper

We carefully reviewed the comments we received from stakeholders during the 2024 public meeting and in the public docket. We thank all those who commented. Your feedback has been helpful in revising our systematic process for post-market assessment of chemicals in food. We have made the following major revisions to the process:

- We have added additional public engagement opportunities throughout the process, such as requesting information from the public prior to conducting most scientific assessments, making preliminary scientific assessments available for public comment, and plans to include public nomination of candidate food chemicals for post-market assessment.
- We have included the option to have preliminary scientific assessments peer reviewed in some cases.
- We have streamlined the process by removing the split between focused and comprehensive assessments.
- We have provided additional details regarding how we will receive and identify potential safety concerns during signal detection, triage signals to determine how they should be handled, and prioritize food chemicals for scientific assessments.

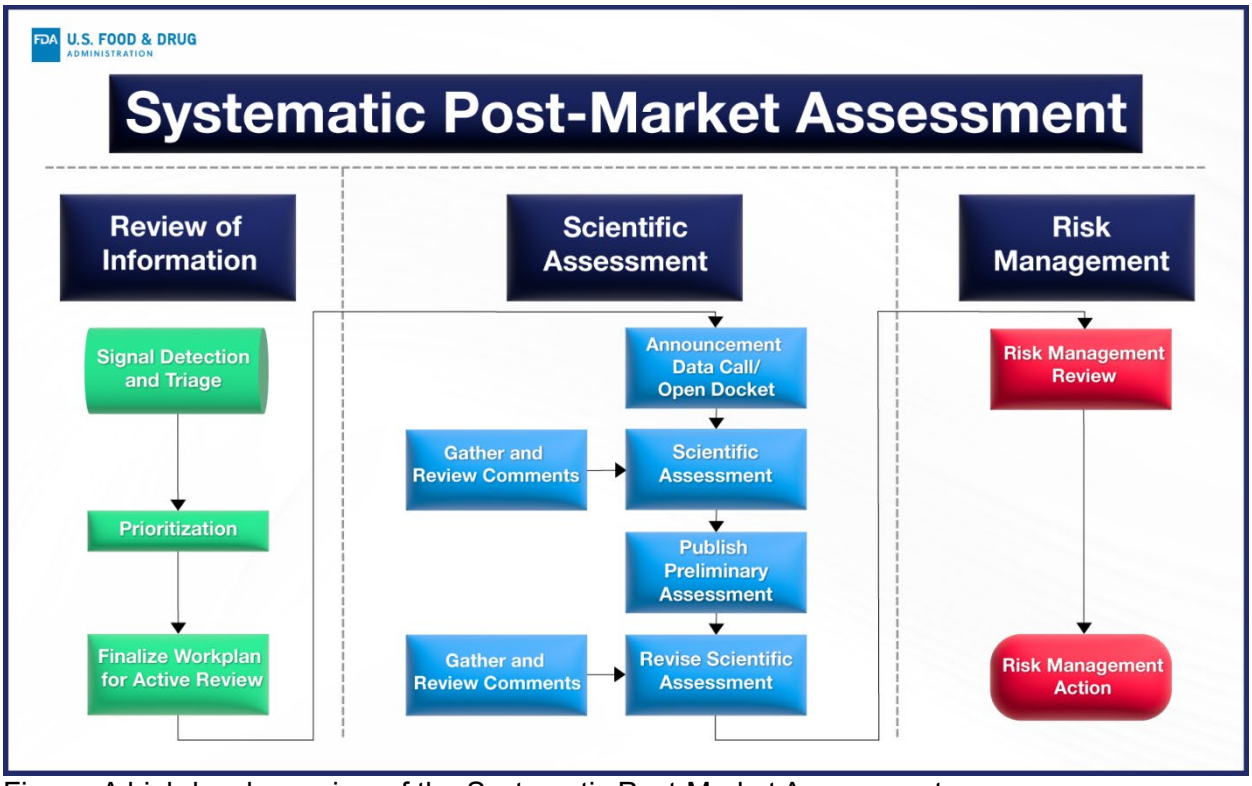


Figure: A high-level overview of the Systematic Post-Market Assessment process

In October 2024, FDA underwent a major reorganization with the creation of the Human Foods Program (HFP). HFP's Office of Post-Market Assessment (OPMA) within the Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI) will operate the systematic post-market assessment process with support from the Office of Surveillance Strategy and Risk Prioritization (OSSRP). OPMA's Division of Additives and Ingredients (DAI) is responsible for the

post-market assessment of chemicals intentionally added to food or food contact materials, such as food additives, color additives, or other types of intentionally added food chemicals. The Division of Chemical Contaminants (DCC) within OPMA collaborates with the Division of Risk Assessment and Prioritization (DRAP) in OSSRP to conduct post-market assessments of contaminants, which are chemicals that are unintentionally present in food or food contact materials.

II. Process

Identifying and Prioritizing Chemicals in Food

1. Post-Market Signal Detection

a) What is a Signal?

The systematic process for post-market assessment of chemicals in food begins with monitoring for and identifying signals. For this process, a signal[1] is any data or information suggesting potential hazard, changes in use, or changes in exposure related to chemicals in food, packaging, or processing that may pose a health risk (also referred to as food chemical safety signals):

- A potential food chemical hazard (e.g., reported contamination exceeding regulatory action levels) or reported adverse reaction to food;
- New uses of a chemical or combination of chemicals in food, food packaging, or food processing that could significantly increase exposure to the chemical(s);
- Substantial changes to a food, food contact substance, or food ingredient due to economic or supply conditions that increase the likelihood of adulteration; or
- Significant changes in dietary exposure or safety information for a particular chemical or combination of chemicals used or found in food, food packaging, or food processing.

b) Signal Detection Methods

We will use several approaches to identify new and existing signals.

One approach uses the Warp Intelligent Learning EnginE (WILEE), which is an artificial intelligence platform that uses established machine learning techniques to process large volumes of publicly available data and synthesize useful information, including information about chemicals in food. WILEE scans for information from various sources, including PubMed and similar databases, international food safety organizations, trade groups, the press, and the open web, to find emerging information on food chemicals. This information is then categorized by commodity, chemical, and other associated information that may indicate a concern, such as adverse health consequences. Signals detected by this tool will be regularly triaged (See Section 2, Triage), and the classification algorithm will be continuously improved by subject matter experts to enhance the tool's performance.

[1] Adapted from Hauben and Aronson (Drug Safety 2009; 32(2): 99-110) and informed by a 2013 Food Advisory Committee Meeting on Detecting Signals for Chemical Hazards of Concern in HFP-regulated Products.

We will also receive and triage signals detected by traditional methods, such as signals received directly from other FDA offices and scientists, information in new submissions to the FDA, domestic and international regulatory activities, adverse event reports, news reports, and trade press. We also intend to solicit public nominations of food chemicals for assessment, which will be part of our identification process, and will announce details on how we will solicit such nominations at a later date.

Through the public comment process, we received suggestions for specific sources we should consider when monitoring for food chemical safety signals. These included: new scientific publications, international regulatory actions, adverse event reports, and other publicly available scientific information. We agree that these are all important sources of information and will include them in our signal detection efforts. Multiple commenters expressed concern that we may miss or discount existing signals because the process described in the Discussion Paper appeared to be exclusively focused on new signals. However, we will not discount any sources of signals, including those already identified by the FDA and others. For example, we will consider the food chemicals that were mentioned in the public comments as signals, provided the chemical and its use(s) are within the FDA's food regulatory authority.

2. Triage

After identifying food chemical safety signals, FDA scientific staff will review the information to determine if the systematic process is the appropriate assessment pathway for each signal. Signals meeting the following criteria will not be prioritized for a scientific assessment since they are handled by alternative processes.

- **Insufficient information:** Some signals may not contain enough information to clearly indicate a potential health risk. We will refer these for enhanced monitoring using WILEE to detect additional clarifying signals. In other cases, where signals do not indicate changes in the science but rather increased public attention or potential misinformation, we may publish communications on the safety of the relevant food chemicals.
- **Current FDA assessments:** Some signals may involve chemicals that are currently under review. Those signals will be provided to the scientific reviewers as appropriate.
- **Immediate health risks or compliance cases:** Some signals may indicate immediate health risks or potential violation of regulations and statutes. These may be specific products, such as poisonous mushrooms used as an added ingredient, lead contaminated apple cinnamon puree products, or undeclared major food allergens. We will handle these signals through existing processes for urgent health risks and compliance issues.

All other signals will enter the post-market prioritization process (see next section) with two exceptions that receive immediate assessment:

- **Cancer evidence for approved additives:** Federal law prohibits certain chemicals found to cause cancer in humans or animals from being approved as food or color additives. For food additives and color additives intended for use in food, such additives are not deemed safe if found to induce cancer when ingested by humans or animals, or if found, after tests which are appropriate for the evaluation of the safety of such additives, to induce cancer in humans or animals. These restrictions do not

apply to prior-sanctioned or GRAS uses of the chemical. If a signal provides new evidence that a chemical approved for use as a food or color additive induces cancer in humans or animals when ingested (or after appropriate tests), we will conduct a cancer hazard assessment through an expedited process. However, prior-sanctioned or GRAS uses would require a full scientific assessment to determine their safety.

- **Regulatory actions by other food safety authorities:** We may identify signals from state, federal, and international food regulatory or advisory agencies. Examples include the European Food Safety Authority (EFSA), Health Canada, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Because these agencies sometimes conduct extensive scientific assessments, any adverse findings from these scientific assessments are of great importance to FDA and their findings may lead to an immediate scientific assessment to ensure that FDA's assessments are timely and relevant.

3. Prioritization

In our Discussion Paper, we proposed developing a process to prioritize food chemicals for assessment. Public comments generally requested more details on our prioritization methods, with some suggesting we publish the prioritization criteria and have the methods peer-reviewed. Some commenters proposed that prioritization should occur before all assessment types. Commentors also had differing opinions on whether prioritization should only consider public health risk factors or include other decision factors, as well as differing views on how these factors should be weighted.

Since the public meeting and comment period, we have further developed a tool for Prioritization of Food Chemicals for Post-Market Assessment. FDA scientists will use the tool for detected signals that complete triage and are sent to prioritization. We opened a public docket (FDA-2025-N-1733) on the prioritization tool to collect public comments. The docket closed on August 18, 2025. We determined the prioritization tool constitutes "influential scientific information" that will impact agency decision making by helping us set priorities for the annual post-market work plan. We submitted the prioritization tool for external peer review. We shared public comments submitted to the docket with the peer reviewers for their consideration. We posted the Peer Review Plan on FDA's Peer Review Agenda. Once the peer review was completed, we revised the prioritization tool based on feedback from the public comments and peer reviewers. We posted documents from the peer review, along with the revised prioritization tool, on FDA's web page for Completed Peer Reviews.

Full details of the revised prioritization tool, the scoring criteria, and the score weighting calculations can be found here: Prioritization of Food Chemicals for Post-Market Assessment. The prioritization tool is not a full scientific assessment and is not used to determine the safety of chemicals in food or as a basis for post-market risk management. The prioritization tool will help establish priorities for the annual post-market work plan. However, the work plan will not be determined solely on the prioritization tool since other internal and external factors may contribute to the FDA's year-to-year priorities.

Executing a Work Plan

1. Establish and Publish a Yearly Work Plan

Each year, we will announce a post-market work plan, such as in an HFP Constituent Update. The work plan will list the food chemicals selected for scientific assessments. We will regularly update the status of ongoing assessments as they reach milestones on our List of Select Chemicals in the Food Supply Under FDA Review webpage.

Including an intentionally added chemical on the work plan or the List of Select Chemicals Under Review does not mean that the food chemical's current use in food is unsafe. It only means that FDA is conducting a scientific assessment of the food chemical and its current uses. Similarly, including a contaminant on the work plan or the List of Select Chemicals Under Review does not mean that the contaminant is currently present at harmful levels in the food supply or that FDA is not already taking risk reduction steps, including enforcement actions. It only means that FDA is assessing whether new information requires further investigation, a change in assessment or regulatory conclusions, or whether there are additional or new actions FDA should take to ensure the continued safety of the U.S. food supply.

We received several comments concerning the bifurcation of the post-market assessment process into focused and comprehensive assessments that we proposed in our Discussion Paper; some commenters were in favor, while other commenters suggested a more streamlined design. After considering the public feedback, we agree that it will be more efficient, more flexible, and simpler to use a streamlined design. We will now use a single type of post-market assessment, and the scale of each assessment will depend on the state of the available science for that chemical, as well as its uses or presence in food or food contact materials. The number of food chemicals we can assess at one time and the duration of each assessment will be determined by the scale of ongoing and planned assessments, agency resources, and related factors.

Additional assessments outside of the systematic process will take place as necessary, such as those initiated through a petition, during immediate public health emergencies, or due to violations of regulations and statutes. These additional assessments will necessarily extend the timelines of ongoing assessments and may limit the number of new assessments that can be initiated in the next work plan, depending on agency resources. We received many comments arguing against the consideration of agency resources when determining the scale of an assessment. We agree that an assessment's scope should be based only on the state of the science and the regulatory context; however, agency resources and related factors will determine how many concurrent assessments we can undertake and the completion time for any given assessment.

2. Scientific Assessment and Stakeholder Engagement

Scientific assessments are evaluations of scientific and technical knowledge and an analytical synthesis of that knowledge. When conducting scientific assessments, we use a case-by-case approach. FDA may conduct several different types of scientific assessments to address safety, risk, hazard, or other aspects, depending on the specific chemical, our existing knowledge about it, and why it is present in food.

Commenters on the Discussion Paper requested extensive stakeholder engagement during post-market scientific assessments and details on how frequently and through what mechanisms the FDA would provide public engagement opportunities. We have included more details on our post-market assessment process and the opportunities for stakeholder engagement in the revised process as described in this section.

a) Initial Stakeholder Engagement

Once a food chemical has been selected for scientific assessment, we will engage external stakeholders in several ways:

- We will announce the scientific assessment in the annual post-market work plan or other announcement, such as an HFP Constituent Update. The FDA website will be updated to reflect the beginning of the assessment on the List of Select Chemicals in the Food Supply Under FDA Review.
- We will publish a data call requesting information in the Federal Register and announce it on the FDA website, such as in an HFP Constituent Update. We will open a public docket on Regulations.gov for stakeholders to respond to the data call. The data call will explain the specific information we are requesting. For intentionally added food chemicals, we may request information on how the chemical under assessment is currently being used by manufacturers, including conditions of use, manufacturing processes, use levels in food, packaging migration data, specifications for contaminants or impurities, other data required to estimate dietary exposure, unpublished toxicology data, other unpublished safety data, and whether the chemical has been abandoned for its authorized intended use by manufacturers. For contaminants, we may request information on sources of the contaminant, levels of the contaminant in foods, unavoidability of the contaminant, and mitigation measures available to reduce levels of the contaminant in food.
- To ensure a timely assessment, we intend to open public dockets for data calls for 60 days with no extensions.
- If we determine during triage or while establishing the work plan that there is sufficient information to conclude that a chemical presents a clear or urgent health risk or that an authorized food additive or color additive has been found to cause cancer in humans or animals, then we may bypass the data call step.
- We may request specific information from certain stakeholders and other entities when appropriate. For example, such requests may occur in cases related to effective Food Contact Notifications, which are manufacturer-specific authorizations, or when we have questions related to a manufacturer's GRAS conclusion. Other examples include when there are data specific to contaminant levels in a specific product or class of products or if we are seeking information that may be in the possession of other regulatory agencies or international standard setting organizations.
- To encourage information sharing, we will, as always, protect trade secrets and confidential commercial or financial information to the extent allowed by law. We encourage industry stakeholders to coordinate data sharing through trade organizations when responding to data calls to help protect confidential information while still assisting us in conducting an informed, quality scientific assessment. For example, only high-level information on approximate use levels in general food categories is needed to estimate dietary exposure for intentionally added food chemicals. Information on specific product composition is likely not necessary for our scientific assessments. The participation of industry stakeholders in these data calls is essential for food safety. We use

conservative assumptions to estimate dietary exposure, and without refinements enabled by manufacturer use information, this may lead to overestimation of dietary exposure and unnecessary risk management actions. For more information on how dietary exposure is estimated, see Guidance for Industry: Estimating Dietary Intake of Substances in Food.

b) Preliminary Scientific Assessment

Once we have collected relevant information, including through stakeholder engagement, FDA scientists will begin working on a preliminary scientific assessment, which may include all or some of the following steps as appropriate:

- Review of available scientific information about the food chemical under assessment, including published scientific literature, FDA's internal records, and any additional information provided to us through a data call;
- Evaluation of how reliable and scientifically sound the available studies are, including whether they use appropriate methods and meet current scientific standards;
- Estimating how much of the food chemical people may consume (dietary exposure) by combining data on what Americans eat with measurements or estimates of chemical levels found in those foods, while considering both the general U.S. population and specific groups that may have higher exposure (e.g., children who consume foods specifically marketed to them) or greater vulnerability to health effects (e.g., individuals with kidney disease who may process chemicals differently);
- Assessment of toxicological hazards, evaluation of potential adverse health effects associated with the identified hazards, determining populations that may be more susceptible to these effects, and identification of areas where more information is needed to fill data gaps;
- Establishment or refinement of an Acceptable Daily Intake (ADI), Toxicological Reference Value, or other health-based guidance value for the food chemical based on quality toxicology or other safety data with a dose-response study design and using the most sensitive adverse outcome; and
- Combining the available information to determine the risk, safety, and/or human health impact of the estimated dietary exposure to a chemical.

c) Stakeholder Engagement on Preliminary Scientific Assessments

Once we have completed a preliminary scientific assessment, we will engage external stakeholders in several ways before finalizing the assessment:

- We will publish the preliminary scientific assessment for work plan chemicals on the FDA website.
- We will open a public docket for the preliminary assessment on Regulations.gov where interested parties can submit comments. To ensure a timely assessment, we intend to open these dockets for 60 days with no extensions. This docket is for the public to express opinions on the assessment and make recommendations for revisions, introduce new or alternative data for FDA's consideration, or offer a differing scientific interpretation or methodology.

d) Finalize and Publish Scientific Assessment

After seeking stakeholder feedback on the preliminary scientific assessment, we will carefully review public comments. We will also review feedback from peer reviewers when applicable. The final scientific assessment will be announced and published on the FDA website.

3. Risk Management

Once the scientific assessment is complete, we will determine if any action needs to be taken to ensure the safety of the food supply. Examples of actions FDA may take to protect public health include revoking or amending authorizations for certain uses, working with industry on voluntary market phase-out agreements and recalls, refusing imported food products, developing action levels or specified limits for contaminants, and issuing alerts. Regardless of whether action is necessary, we will publish all final scientific assessments so that the public and other stakeholders will have access to our analyses.

Many of the commenters expressed interest in public comment opportunities on proposed risk management strategies, and we will provide the opportunity to do so when appropriate. For example, if FDA proposes to revoke, amend, or issue a regulation, we will obtain comments on this proposed action. Another example where we would solicit public comments on a proposed risk management action would be issuing draft guidance for contaminant action levels. However, there may be cases where public comments on risk management actions are unnecessary, such as when the results of our scientific assessment indicate that there is no safety concern, or cases where public comments would not be appropriate, such as when FDA takes enforcement action.

A common concern received in the public comments was including intentionally added food chemicals and contaminants in the same risk management process. The comments expressed that these two categories of chemicals exist under different regulatory frameworks which means that they require different risk management tools and have different standards for action. We are aware of these distinctions, which is why separate divisions within the FDA will handle the assessment and risk management of each category (see Section II, Process). This new post-market process is not intended to replace our current mechanisms for safeguarding the food supply, such as Closer to Zero, but rather to provide a new mechanism to identify chemicals that need assessment and to enhance the transparency of our post-market assessments.

III. Science-based Decisions

FDA will emphasize sound science and make decisions strictly based on quality scientific data when conducting post-market assessments. In the Discussion Paper, we did not describe the details of our data quality criteria for scientific assessments, and several commenters raised concerns about the lack of discussion on this topic. Some commenters also raised concerns about FDA using data provided by industry stakeholders, citing possible bias, and some raised concerns that our description of "focused assessments"[2] implied that these assessments would be restricted to only include newly published information, while ignoring the total body of scientific evidence.

[2] Note that the revised process no longer uses the term "focused assessment." The use of this term refers to the context in which it was used in the Discussion Paper.

FDA's standards for evaluating data quality during post-market scientific assessments will be no different from those that are used by FDA for pre-market assessments or for any other scientific assessment. Post-market scientific assessments use the best available science and include a critical evaluation of the available scientific knowledge, data, and information. This scientific knowledge base encompasses all published and unpublished resources available to HFP, including, but not limited to, information submitted by petitioners (e.g., industry research and contracted studies), data developed by the U.S. and other governments, publicly available scientific literature, and information provided to FDA through data calls. Scientific assessment conclusions will be made based on the weight of scientific evidence.[3]

We may consider publishing additional guidance on data quality and study evaluation criteria for post-market scientific assessments in the future. However, our current guidance documents available on FDA's Food Chemical Safety webpage can serve as a valuable resource for understanding how FDA applies science to regulate Food Ingredients & Packaging or Chemical Contaminants and Pesticides.

IV. Addressing Additional Comments from the September 2024 Public Meeting and Docket

1. Use of an Advisory Committee

In the Discussion Paper, we asked if we should integrate an advisory committee review into our post-market assessment process, and, if yes, what the role of that committee should be. There was no clear consensus among commenters on either question. The comments were split on whether we should convene a committee, and even those in favor were not in agreement on what its role should be. The commenters who opposed integrating a committee into our systematic process were concerned that it would take away from internal resources and delay the process. There were also concerns about selecting committee members and accounting for their potential biases or conflicts of interest. Given the overwhelming support for timely post-market assessments, we have decided not to integrate an advisory committee for post-market assessments. Subject matter experts are encouraged to provide their feedback to FDA during public comment periods for data calls, preliminary assessments, and proposed risk management actions.

2. Separation of Risk Assessment and Risk Management

Some comments suggested separation at the staff level, with different staff conducting risk assessments and risk management activities. Even prior to HFP's October 2024 reorganization, risk assessment and risk management of chemicals in food have been and will continue to be conducted by separate staff based on different expertise and responsibilities. Technical experts, including chemists and toxicologists, evaluate the available data and information relevant to the safety of a chemical in food and generate scientific memoranda summarizing their findings. Risk

[3] See, for example, Principles and methods for the risk assessment of chemicals in food, World Health Organization, 2009.

management staff, including regulatory experts, policy experts, attorneys, and agency leadership, develop and execute a plan to manage the risk described by the technical experts based on FDA's priorities and within the authorities set by the FD&C Act. We will continue this practice of separating risk assessment and risk management activities between separate staff.

Some comments suggested that staff conducting post-market assessments should not have been involved in the pre-market assessment of the same chemical. These comments suggested that this separation would reduce the potential for bias that could occur in post-market assessments by a person who conducted the pre-market assessment of the same food chemical. As part of HFP's October 2024 reorganization, the responsibility to manage and conduct post-market safety assessments of food chemicals was assigned to OPMA with support from OSSRP. While subject matter expertise may require consultation of experts from other FDA offices, OPMA and OSSRP are functionally and structurally separated from the offices operating FDA's pre-market food chemical safety programs.

3. Managing Responses to Petitions

One comment raised concerns that the systematic post-market assessment program may compete with the existing petition programs in terms of resources and that petitioners could leverage food additive or color additive petitions requesting the removal or restriction of an existing approval to bypass the work plan decisions. We do not have discretion to deny filing or review of a complete petition. However, such petitions and any additional assessments not announced in the work plan will necessarily delay ongoing assessments. Because the assessments selected in our work plan are expected to be the highest public health priorities, it will be more beneficial to public health for most assessments to occur through this systematic process. Future food additive, color additive, and citizen petitions requesting post-market action will be handled by OPMA. Petitions requesting pre-market approval will continue to be handled by the Office of Pre-Market Additive Safety (OPMAS).

4. Adopting Post-Market Actions of Europe or Other Nations

Many commenters mentioned their desire for FDA to adopt decisions on food chemical safety made by the European Union or certain other nations, such as the United Kingdom or Canada. We must conduct our own scientific assessments and make risk management decisions based on the criteria mandated by federal law, including the safety standards provided by the FD&C Act, regulations implementing the FD&C Act under Title 21 of the Code of Federal Regulations, and U.S. federal court decisions.

However, FDA routinely reviews scientific assessments and regulatory decisions regarding food chemical safety made by international organizations, such as EFSA, Health Canada, JECFA, and the Codex Alimentarius Commission, as well as other U.S. federal agencies, such as the Environmental Protection Agency and the National Toxicology Program. Review of such activities by national and international scientific and regulatory bodies is incorporated into several components of the systematic process for post-market assessment. First, recent actions by such organizations are received as signals during signal detection and triaged along with other signals. Additionally, when another food safety authority publishes adverse findings in a scientific assessment, FDA may also immediately reassess the chemical (as described in Section 2, Triage) to ensure that FDA is addressing potential public health issues when they are timely and relevant to the U.S. population. Finally, as FDA has done historically, scientific data or assessments published by scientific or regulatory organizations are weighed and evaluated during our scientific assessments by considering the total weight of scientific evidence.

5. Recommendations for Specific Chemicals in Food and Other Concerns

Many commenters highlighted concerns about specific chemicals in our food supply. Not all chemicals mentioned are within FDA's regulatory authority, however. Pesticide tolerances, for example, are set by the Environmental Protection Agency, although FDA enforces those limits. Additionally, many concerns were about food chemicals already under assessment or being addressed by FDA, which can be found on our List of Select Chemicals in the Food Supply Under FDA Review. Those food chemicals that were not already part of an ongoing FDA assessment were received as signals for consideration in the systematic process.

Other concerns were focused on susceptible subpopulations, such as infants, children, and pregnant women. We would like to assure our stakeholders that we consider relevant susceptible subpopulations for all pre- and post-market assessments. Infant formula, for example, has different considerations than other foods because it serves as the sole source of nutrition for many infants throughout a critical period in their growth and development (for example, infants are more susceptible to dietary exposures due to their small body size). Where appropriate, we shared comments relating to specific chemicals with other HFP offices. For example, we forwarded comments relating to the labeling of specific chemicals to the Office of Nutrition and Food Labeling in HFP's Nutrition Center of Excellence.

6. Concern about Potential Conflicts of Interest at FDA

We received comments expressing concerns about potential conflicts of interest at FDA and industry influence over FDA decision making. Federal employees are held to strict principles of ethical conduct. FDA staff are subject to additional requirements to prevent even the appearance of a conflict of interest. For example, FDA employees are prohibited from holding financial interests in organizations that are significantly regulated by FDA and are required to report all conflicts of interest and seek approval to participate in outside activities. They are not permitted to seek employment with regulated entities unless they recuse themselves for a period of time from work that would have a direct and predictable effect on their financial interests. Once they leave FDA, they are barred for two years from making representational communications to or appearances before the government regarding matters under their official responsibility while at FDA and are additionally restricted from certain forms of compensation and conflicts of interest. Senior and Very Senior FDA employees are held to additional standards. The FDA website contains information regarding Ethical Standards for FDA Employees and lists of Prohibited Financial Interests for FDA Employees.