U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Tool for the Prioritization of Food Chemicals for Post-Market Assessment

May 2026

1. OVERVIEW

In August 2024, the U.S. Food and Drug Administration (FDA) published a discussion paper on the development of an enhanced systematic process for the post-market assessment of chemicals in food.[1] The systematic post-market assessment of food chemicals[2] consists of the following steps: signal detection, triage, prioritization, scientific assessment (safety, risk, and/or hazard), and risk management. A full description of the process is published alongside this paper and describes each of these steps within the context of the systematic post-market assessment process.[3]

FDA has sought to develop a science-based, data-driven, systematic, and reproducible process for the prioritization of chemicals in food that are candidates for post-market assessments. This document describes FDA's method for prioritizing chemicals[4] identified for post-market assessment using existing information about the food chemical. In 2023-2024, FDA developed and internally piloted a draft prioritization tool (Version 1) for that purpose. The pilot was used to evaluate the prioritization approach, including details such as scoring criteria, and determine whether this method was suitable for future prioritization of chemicals for review. Internal review supported the pilot approach. Based on results from the pilot, public comment,[5] and stakeholder input including at FDA's public meeting entitled "Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food" held in September 2024,[6] FDA updated the prioritization tool (Version 2). The most notable change to the tool at this stage was the development and inclusion of the toxicity rubric for scoring the 'Toxicity' criterion. In 2025, Version 2 of the prioritization tool, including the toxicity rubric, underwent

---

[1] https://www.fda.gov/media/180942/download

[2] For consistency in this document, we use the term "food chemical" to describe any substance found in or added to food including nutrients; food additives; color additives; generally recognized as safe (GRAS) substances (including GRAS substances that have not been notified to FDA); food contact substances; and chemicals that are present as unintentional contaminants

[3] https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review; https://www.fda.gov/media/192046/download?attachment

[4] 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; or complex mixtures of chemical compounds such as rosemary extract.

[5] https://www.regulations.gov/document/FDA-2024-N-3609-0001

[6] https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food

additional review, including an opportunity for public comment[7] followed by external scientific peer review[8] in compliance with the Information Quality Act. The prioritization tool has since been further revised (Version 3), considering public comment, the external scientific peer review, and additional internal testing. Modifications to the tool based on feedback include removal of Other Decisional criteria, adjustment to calculation of the overall score (now based on only Public Health criteria), revisions to clarify criteria definitions, and increased communication regarding how the prioritization tool fits into FDA's overall systematic process.

The details of the revised prioritization tool (Version 3) are described in the following sections.

The Post-Market Assessment Prioritization Tool focuses on potential risk to public health using a Multi-Criteria Decision Analysis (MCDA) method.[9] Subject Matter Experts (SMEs) from a variety of disciplines within FDA's Human Foods Program (HFP) will use the prioritization tool to score a set of criteria evaluating candidate chemicals in food for priority for further review. From the individual criterion scores, an overall score is determined. In our MCDA method, the higher the total score, the higher the priority of that chemical for post-market assessment.

For Public Health criteria, a chemical that would receive the highest score is one for which:

- The chemical may produce severe health effects (e.g., cancer, cardiovascular toxicity);
- Dietary exposure to the chemical has increased;
- The chemical is found in or could potentially be present in food intended for susceptible subpopulations (e.g., infants); and
- Newly available information, data, or science could potentially impact or change conclusions.

The methodology presented below is part of a broader systematic post-market assessment process which is detailed in a companion paper.[33] Briefly, the systematic process for post-market assessment of chemicals in food begins with monitoring for and identifying signals.[10] Approaches to identify new and existing signals include using well-established machine learning techniques to ingest and synthesize large volumes of publicly available information as well as traditional methods such as signals directly received from other FDA offices or adverse events reporting systems. After identifying food chemical safety signals, FDA scientific staff will triage each signal to determine if the systematic process is the appropriate assessment pathway or if an alternative pathway should be pursued. For example, during triage, signals indicating an immediate public health risk exit the systematic process and are handled separately through established mechanisms. Signals determined to be appropriate for the systematic process will

---

[7] https://www.regulations.gov/docket/FDA-2025-N-1733

[8] https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/peer-review-tool-ranking-chemicals-food-post-market-assessments; https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews

[9] Belton V, Stewart TJ. *Multiple Criteria Decision Analysis: An Integrated Approach*. Norwell, MA: Kluwer Academic Publishers; 2002.

[10] For this process, a signal 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 impact food safety or public health.

then be prioritized based upon the updated prioritization tool described below. Importantly, the score a chemical receives and the ultimate position of that chemical in the prioritized list provided by the Post-Market Assessment Prioritization Tool is *not* an evaluation as to whether that chemical poses a public health risk. The potential impact to public health of exposure to any chemical through food is determined during the pre- and post-market scientific assessment processes. The Post-Market Assessment Prioritization Tool, along with other factors, will help establish priorities for the annual post-market work plan by ranking chemicals for post-market assessments. We acknowledge there may be updates to the tool in the future, as HFP deems appropriate, such as in response to scientific advancement (e.g., artificial intelligence), efficiency analyses (e.g., analyses conducted after initial implementation of the full systematic process), or changes in resources (e.g., funding, personnel).

2. DESCRIPTION OF THE POST-MARKET ASSESSMENT PRIORITIZATION TOOL

2.1 Public Health Criteria

The Post-Market Assessment Prioritization Tool considers decisional criteria relating to public health. Specifically, the Public Health criteria include information on the toxicity of a food chemical, exposure to the food chemical, consideration of susceptible populations who may be exposed to the food chemical, and impactful new scientific information. Taken together, high scores in these criteria would increase the priority of a food chemical for post-market assessment.

2.1.1 Toxicity:

- The 'Toxicity' criterion is scored by utilizing a toxicity rubric that consists of seven different data types: acute toxicity; carcinogenicity/mutagenicity/genotoxicity; developmental and reproductive toxicity; neurotoxicity; other organ-specific toxicity; immunotoxicity; and bioaccumulation/biopersistence (See Appendix A, Table A1). There is also an optional eighth category to assist in the scoring of data-poor chemicals. The rubric incorporates elements of the U.S. Environmental Protection Agency's (EPA) data-driven criteria for evaluation of toxicity[11] while also considering the wide variety of chemicals found in food.
- Each chemical receives a score, based on the weight of the available evidence, for each of the seven data types in the rubric (i.e., information for all data types is sought). Data-poor chemicals may additionally receive the optional eighth category score. Similar to the EPA's approach, the highest score a chemical receives for any single toxicity data type becomes its score for the 'Toxicity' criterion in the Post-Market Assessment Prioritization Tool (See below and Appendix A, Table A2).

[11] https://www.epa.gov/sites/default/files/2014-03/documents/work_plan_methods_document_web_final.pdf

Highest toxicity data type score from the rubric	Toxicity criterion score
High (9)	9
Moderate (5)	5
Low (1)	1

- Note: The evaluation of potential toxicity of a food chemical using the toxicity rubric and its ultimate toxicity criterion score should not be considered a comprehensive safety assessment.

2.1.2 Change in exposure:

Description	Scoring
Have there been changes in exposure since the last assessment, such as use level (e.g., above regulatory level), new or increased sources of contamination, consumption (e.g., consuming populations, amount consumed, products consumed, how prepared), production volumes, and/or conditions of use?	9 = Exposure has considerably increased because data indicate considerably higher use levels in food OR considerably higher contamination levels or prevalence in food OR considerable increase in consumption (e.g., due to considerable increase in consumption patterns or market trends such as indicated by production volume); 5 = Exposure has moderately increased because data indicate somewhat higher use levels in food OR moderately higher contamination levels or prevalence in food OR moderate increase in consumption (e.g., due to moderate increase in consumption patterns or market trends such as indicated by production volume); Not previously assessed or reviewed by FDA; 3 = Unable to assess change in exposure since the last assessment due to insufficient information; 1 = Exposure has not changed or has decreased because data indicate decreased or no change in use levels OR decreased or no change in contamination levels and prevalence in food OR decreased or no change in in consumption (e.g., similar consumption patterns or market trends such as indicated by production volume)

2.1.3 Use or presence in food for susceptible subpopulation:

Description	Scoring
Is the chemical found (e.g., using label information from consumer-packaged goods database or FDA monitoring systems) or could potentially be present (e.g., occurs naturally, is introduced or formed during manufacturing, or based on proposed intended uses or technical effects) in food specifically marketed to or intended for susceptible subpopulations (e.g., infants; young children; pregnant and nursing women; older adults)?	9 = Yes 5 = Unable to assess due to insufficient information 1 = No

2.1.4 New scientific information and potential impact:

Description	Scoring
Is new scientific information available (e.g., new toxicity or adverse health effect data or studies; improvement in detection methods or limits; new data or studies on biopersistence) that would impact or change the conclusions of the previous assessment or review by FDA? If yes, what is the potential impact?	9 = Yes, new scientific information available with potential high impact; 5 = Yes, new scientific information available with potential moderate impact; Scientific information available but the chemical has not been previously assessed or reviewed by FDA; 3 = Yes, new scientific information available with uncertain impact; 1 = Yes, new scientific information available with potential low impact; No new scientific information available that would impact or change the previous assessment or review; No scientific information available and the chemical has not been previously assessed or reviewed by FDA

2.2 Description of Calculation of the Post-Market Assessment Prioritization Score for Each Chemical

The overall Post-Market Assessment Prioritization Score is calculated by summing the weighted criterion scores across the four Public Health criteria (i.e., 'Toxicity'; 'Change in exposure'; 'Use or presence in food for susceptible subpopulation'; 'New scientific information and potential impact') and then multiplying by 100 (for convenience):

$$score_{overall_i} = \left(\sum_{j=1}^{4} w_j \times score_{publicHealthCriteria\ j,i} \right) \times 100$$

Where:

w_j = weight assigned to Public Health criterion j

$score_{publicHealthCriteria_{j,i}}$= criterion score for the j[th] Public Health criterion associated with i[th] chemical

$score_{overall_i}$= Prioritization Score associated with i[th] chemical

The tool can accommodate equal and unequal weighting schemes. However, based on results from sensitivity analysis, equal weighting among the Public Health criteria is currently used to determine the overall Post-Market Assessment Prioritization Score. The selection of equally weighting for overall score determination is consistent with previously peer-reviewed MCDA methodology developed for food safety public health prioritization (e.g., FDA's Risk-Ranking Model for Food Tracing).[12]

Using "Chemical Y" as an example, with Public Health criterion scores of {9, 3, 9, 3} for the four criteria (i.e., 'Toxicity'; 'Change in exposure'; 'Use or presence in food for susceptible subpopulation'; 'New scientific information and potential impact'), respectively, and each given a public health sub-criterion weight of $\frac{1}{4}$, the Prioritization Score = $\left(9 \times \frac{1}{4} + 3 \times \frac{1}{4} + 9 \times \frac{1}{4} + 3 \times \frac{1}{4}\right) \times 100 = 600$.

[12] https://hfpappexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracingfinalrule/

3. APPENDIX

Appendix A. Toxicity rubric and scoring for the Post-Market Assessment Prioritization Tool

Table A1. Toxicity rubric[13, 14]

Data Type[15, 16]	**Species and/or Study Type**	**High[17] (9)**	**Moderate (5)**	**Low (1)**
Acute toxicity	Animal oral LD50 or similar (mg/kg bw[18])	<300, ***or…*** *see human data for equivalent Data Type*	300 to <2000, or insufficient data to evaluate in animals, ***or…*** *see human data for equivalent Data Type*	≥2000, ***or…*** *see human data for equivalent Data Type*
Acute toxicity	Human	Evidence/reports of poisonings or adverse events in humans	Insufficient data to evaluate adverse events in humans	Sufficient human data available to evaluate but no apparent adverse effects (history of safe consumption)

[13] For purposes of prioritization, toxicity studies will be considered for the chemical under review only. Determining chemicals that may serve as appropriate surrogates for data-poor chemicals is out of scope for the prioritization process.

[14] Essential nutrients and minerals should receive a final score of "1" from the toxicity rubric, which should advance to the main tool. Because essential nutrients and minerals are not inherently toxic under most circumstances scoring these chemicals as "1" for the toxicity rubric allows exposure and new information to be the primary factors contributing to their final score in the main tool.

[15] Exposure by the oral route is strongly preferred. Data from studies with intravenous or intraperitoneal exposure should not be used except to support weight of evidence determinations, and data from studies with dermal or inhalation exposure should only be used in rare cases (e.g., studies of sensitization that assist in identifying immunotoxic potential).

[16] For all categories scored, a weight of evidence approach should be taken and the totality of the database considered.

[17] Indicated dose ranges in animals reflect levels at which effects have been observed (e.g., lowest observed adverse effect level (LOAEL)/lowest observed effect level (LOEL)). Negative data (lack of effects) such as no observed adverse effect level (NOAEL)/no observed effect level (NOEL) should not be used to score the chemicals. There may be cases where the highest dose tested did not produce a LOAEL/LOEL. In such cases, a different study should be selected to clarify scoring. If another study is not available, the NOAEL/NOEL may be used, but the chemical should also receive an optional Database Compensation score. For repeated dose animal studies, the upper-bound (1000 mg/kg bw/day) was informed by the limit dose from relevant guideline studies (e.g., OECD, EPA OPPTS 870 Series). The lower-bound (250 mg/kg bw/day) was informed by select criteria from the Toxic Substances Control Act's prioritization scheme, then the appropriateness of the indicated dose ranges for the scores were verified using food additives and contaminants with adequate databases to support scoring.

[18] Milligram per kilogram bodyweight

Data Type[15, 16]	**Species and/or Study Type**	**High**[17] **(9)**	**Moderate (5)**	**Low (1)**
Carcinogenicity/ mutagenicity/ genotoxicity	Various	Weight of evidence across all available data streams (*in vitro*, *in silico*, animal, human), including opinions of authoritative entities, testing batteries, and other relevant data indicates that the chemical is a probable or likely carcinogen, mutagen, or genotoxin in animals (human-relevant tumor types only)[19] or humans	Weight of evidence across all available data streams (*in vitro*, *in silico*, animal, human) is equivocal, or there is insufficient data to assess genotoxicity, mutagenicity, or carcinogenicity in humans or animal evidence exists but its relevance to humans is unclear	Weight of evidence across all available data streams (*in vitro*, *in silico*, animal, human), including opinions of authoritative entities, indicates that the chemical is not genotoxic, mutagenic, carcinogenic
Endocrine, and developmental and reproductive toxicity (DART) or signals	Animal (mg/kg bw/day)	<250, ***or…*** *see human data for equivalent Data Type*	250 to <1000 or insufficient data to evaluate in animals, ***or…*** *see human data for equivalent Data Type*	≥1000, ***or…*** *see human data for equivalent Data Type*
Endocrine, and developmental and reproductive toxicity (DART) or signals	Human	Evidence in humans of endocrine or DART	Insufficient data to evaluate endocrine or DART	Sufficient human data available to evaluate but no evidence of endocrine or DART
Neurotoxicity or neurological signals	Animal (mg/kg bw/day) Acute, repeated dose or delayed neurotoxicity studies	<250, ***or…*** *see human data for equivalent Data Type*	250 to <1000 or insufficient data to evaluate neurotoxicity in animals, ***or…*** *see human data for equivalent Data Type*	≥1000, ***or…*** *see human data for equivalent Data Type*
Neurotoxicity or neurological signals	Human	Evidence in humans of irreversible neurotoxicity	Evidence in humans of reversible neurotoxicity; or insufficient data in humans to evaluate neurotoxicity regardless of reversibility	Sufficient human data available to evaluate but no evidence of neurotoxicity

[19] Food and color additives are subject to the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (§§ 409(c)(3)(A) and 721(b)(5)(B)). Food chemicals that have intended uses as food and color additives and are carcinogens will exit the systematic post-market assessment process even if the data in humans in negative or equivocal. After exiting the process, those uses will receive a cancer hazard assessment and any remaining uses will be prioritized.

Data Type[15, 16]	**Species and/or Study Type**	**High**[17] **(9)**	**Moderate (5)**	**Low (1)**
Other organ-specific toxicity (e.g., cardiovascular) or signals	Animal, repeated dose (mg/kg bw/day)	<250, ***or…*** *see human data for equivalent Data Type*	250 to <1000 or insufficient data in animals, ***or…*** *see human data for equivalent Data Type*	≥1000, ***or…*** *see human data for equivalent Data Type*
Other organ-specific toxicity (e.g., cardiovascular) or signals	Human	Evidence in humans of organ-specific effects (e.g., exposure associated with greater odds of disease outcome)	Insufficient data in humans to evaluate organ-specific effects	Sufficient human data available to evaluate but no evidence of organ-specific effects in humans
Immunotoxicity or immune signals	Various	Evidence (animal or human) of immune effects	Insufficient data (animal or human) to evaluate immune effects but reason for concern exists (e.g., structural similarity to chemicals with immune effects, belongs to family of chemicals with known effects)	Sufficient animal or human data available to evaluate but no evidence (animal or human) of immune effects, ***or…*** Insufficient data exist to evaluate, but there is no reason for concerns of immune effects
Bioaccumulation / biopersistence	Various	Evidence or estimates (animal, human or *in silico*) of high biopersistence (e.g., bioconcentration factor [BCF] ≥1000, or half-life in mammals on the order of months to years)	Evidence or estimates (animal, human or *in silico*) of moderate biopersistence (e.g., half-life in mammals on the order of weeks), ***or…*** Unable to evaluate biopersistence	Evidence or estimates (animal, human or *in silico*) of low biopersistence (e.g., BCF < 1000, or half-life in mammals on the order of hours to days)
Database compensation for data-poor food chemicals (optional)	EDT based	Food chemical assigned EDT Class V or VI	Food chemical assigned EDT Class III or IV	Food chemical assigned EDT Class I or II

Table A2. Calculation of toxicity criterion score using "Chemical X" as an example.

	Toxicity data type scores for Chemical X
Acute toxicity	5
Carcinogenicity/ mutagenicity/ genotoxicity	9
Endocrine, and developmental and reproductive toxicity (DART) or signals	5
Neurotoxicity or neurological signals	5
Other organ-specific toxicity (e.g., cardiovascular) or signals	5
Immunotoxicity or immune signals	5
Bioaccumulation/ biopersistence	1
Database compensation for data-poor food chemicals (optional)	*Not scored*

For the above example, Chemical X would be assigned a toxicity criterion score of 9 in the Post-Market Assessment Prioritization Tool because the highest scoring toxicity data type in the rubric was a 9. All seven toxicity data types are always scored for each chemical (i.e., even if a chemical receives a 9 for one of the toxicity data types (which would immediately report a toxicity criterion score of a 9 in the main tool), the other data types will still be scored). In the above example, there is sufficient data for scoring the core seven parameters of the toxicity rubric, and as such the eighth parameter (Database compensation) is not scored here. However, for data-poor food chemicals, the database compensation parameter will also be scored, and the highest score likewise will move forward into the main tool.