FDA's Proposed Prioritization Tool: The Latest Step Toward a New Framework for Post-Market Assessment of Chemicals in Food

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On June 18, the FDA released a proposal for how it plans to prioritize food chemicals for post-market review. This proposal builds upon the FDA's work toward developing a transparent systematic process for post-market assessment of food chemicals, which the FDA outlined in an August 2024 discussion paper and hosted a public meeting to discuss in September 2024.[1] The FDA envisions a "systematic post-market assessment of food chemicals [that] consists of the following steps: signal detection, triage, prioritization, scoping, scientific assessment (safety, risk, and/or hazard), risk management review, and risk management action."

The proposal is essentially a set of rubrics that subject matter experts ("Experts") within the Human Foods Program ("HFP") would use to score chemicals that are candidates for post-market review (the "Proposed Tool"), and the resulting overall scores would be used to rank those chemicals in order of priority to inform the FDA of how to allocate its resources.[2]

What Does the Proposed Tool Ask Reviewers To Consider?

To use the Proposed Tool, Experts would score each chemical on the criteria listed below, which are divided between "Public Health Criteria" and "Other Decisional Criteria." These individual criteria scores will be used to calculate the chemical's overall score, as discussed in the section below. The individual criteria scores range from one to nine with nine indicating, for example, the highest risk of severe harm to public health or significant negative attention directed at the chemical from the public, media, or other regulators.

The Public Health Criteria

- **Toxicity** – Each chemical would be scored either high (9), moderate (5), or low (1) for seven types of toxicity (*e.g.*, acute, neuro, reproductive, etc.). The highest score of those seven would be used as the chemical's toxicity score for purposes of calculating the chemical's Public Health score and subsequent overall score.
- **Change in Exposure** – Experts would consider whether there has been a considerable increase in exposure levels or production of the chemical, or if it is used in highly consumed foods (9); a moderate increase in exposure or production, or if it is used in moderately consumed foods (5); if the FDA has not previously assessed exposure to this chemical, or cannot determine whether there has been a change since previous assessment (3); or if there has been no change in exposure or production, or if it is used in foods that are not often consumed (1).
- **Susceptible Subpopulation** – This criterion accounts for whether the chemical is found, or is likely found, in food specifically intended for vulnerable subpopulations (9), if it is unknown whether it is found in such food (5), or if it is not in food intended for vulnerable subpopulations (1).

[1] 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).
[2] FDA, Tool for the Prioritization of Food Chemicals for Post-Market Assessment (June 18, 2025) (available at: https://downloads.regulations.gov/FDA-2025-N-1733-0001/attachment_1.pdf).

- **New Scientific Information** – Experts will score chemicals for this criterion based on whether new scientific information has become available that has high potential (9), moderate potential (5), or low or uncertain potential (3) to impact the conclusions of the previous scientific assessment of the chemical. If there is no new scientific information available, the chemical will receive the lowest score possible for this criterion (1).

The Other Decisional Criteria

- **Attention** – Chemicals that are receiving significant attention from Congress, news, social media, or stakeholder organizations expressing concerns will score highly (9) or moderately (5) on this criterion depending on the level of attention and concern. This score will be lower if the chemical is receiving attention with mixed or conflicting opinions (3). If there is no attention or pressure on FDA or industry to specifically address this chemical, it will receive the lowest score possible for this criterion (1).
- **Other Government Action** – HFP Experts will review whether multiple other governmental agencies (e.g., states, international, or other federal agencies) have taken restrictive action against the chemical (9), whether any other governmental agency has taken restrictive action against the chemical (5), or if there has been no action or no conclusive action by other government agencies (3). If another governmental agency has taken *permissive* action in favor of the chemical, it will receive the lowest score possible for this criterion (1).
- **Impact on Public Confidence** – If Experts believe that failure to perform post-market assessment of the chemical has a high risk of causing the public to lose confidence in the safety of the U.S. food supply, the chemical will receive a high score (9). If there is a moderate (5) or low to no risk (1) of losing public confidence, the chemical will be scored accordingly.

How Would a Chemical's Overall Score Be Calculated?

The Proposed Tool provides a three-step calculation. First, the Public Health score will be calculated, then the Other Decisional score, then those results will be combined to determine the chemical's overall score ("Prioritization Score"). The Proposed Tool weighs all criteria scores equally, but this is one of the decisions that the FDA is specially soliciting feedback on.

The Public Health Criteria Equation

$$score_{publicHealth_i} = \sum_{j=1}^{4} w_j \times score_{publicHealthCriteria_{j,i}}$$

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

The Other Decisional Criteria Equation

$$score_{otherDecisional_i} = \sum_{k=1}^{3} w_k \times score_{otherDecisionalCriteria_{k,i}}$$

Where:
w_k = weight assigned to Other Decisional criterion k
$score_{otherDecisionalCriteria_{k,i}}$ = criterion score for the k[th] other decisional criterion associated with i[th] chemical

The Prioritization Score Equation

$$score_{overall_i} = w_{publicHealth} \times score_{publicHealth_i} + w_{otherDecisional} \times score_{otherDecisional_i}$$

Where:

$score_{publicHealth_i}$ = Total Public Health Criteria Score associated with i^{th} chemical

$score_{otherDecisional_i}$ = Total Other Decisional Criteria Score associated with i^{th} chemical

$w_{publicHealth}$ = weight assigned to the Total Public Health Criteria Score

$w_{otherDecisional}$ = weight assigned to the Total Other Decisional Criteria Score

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

Example Calculation

Chemical Y scores 9, 3, 9, and 3 on each of the Public Health Criteria.

Public Health score = $9 \times \frac{1}{4} + 3 \times \frac{1}{4} + 9 \times \frac{1}{4} + 3 \times \frac{1}{4} = \mathbf{6}$

Chemical Y scores 9, 5, and 5 on each of the Other Decisional Criteria.

Other Decisional score = $9 \times \frac{1}{3} + 5 \times \frac{1}{3} + 5 \times \frac{1}{3} = \mathbf{6.3}$

Chemical Y Prioritization Score = $6 \times \frac{1}{2} + 6.3 \times \frac{1}{2} = \mathbf{6.2}$

Is There an Opportunity for the Public To Offer Input?

Yes, the last day to submit public comments on the Proposed Tool is July 18, 2025, in docket FDA-2025-N-1733. Pages 10 through 12 of the proposal list five detailed questions that the FDA would like feedback on and extends an invitation for any additional comments. The proposal also contains additional details on the methodology, particularly how HFP Experts will examine toxicity.