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ALERT

FDA's Proposed Ranking Tool Gives Public Opinion a Seat at the Food Safety Table

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With food policy remaining a top priority for the Trump Administration, the U.S. Food and Drug Administration (FDA), acting under Health and Human Services (HHS) Secretary Robert F. Kennedy Jr., has swiftly advanced a number of policy initiatives focused on the safety of food additives and ingredients. As one of its first initiatives under the new Administration, FDA announced its intent to overhaul the agency's systematic safety review of food ingredients currently in the food supply chain. Specifically, the FDA released its proposal to advance a "robust, transparent post-market chemical review program to keep [the] food supply safe and healthy."

As a first step in its overhaul of the agency's post-market chemical review program, FDA released for public comment a proposed prioritization tool, otherwise known as the "Post-Market Assessment Prioritization Tool" (Prioritization Tool), for determining which food ingredients or food contaminants should be targeted for a post-market safety assessment by the agency. FDA recently announced a 30-day extension of the comment period giving interested stakeholders until August 18, 2025, to submit comments regarding the proposed Prioritization Tool.

Under the proposal, the Prioritization Tool would utilize a multi-criteria decision analysis (MCDA) approach for FDA to score each food ingredient or food contaminant based on the risk the substance poses to public health. The scores for each ingredient or contaminant would be based on Criteria derived from the following two categories:

1. **Public Health Criteria**, which includes chemical toxicity, dietary exposure, use by vulnerable subpopulations (e.g.

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infants), and any new information; and

2. **Other Criteria**, which includes interest and activity on the food ingredient or food contaminant from external groups, actions by other government agencies, and public confidence in U.S. food safety should the post-market assessment of the chemical not be completed.

Within each category, the criterion is scored on a standardized scale, and the overall prioritization score is calculated using equal weighting. Higher scoring ingredients or contaminants will be prioritized for post-market review over those with lower scores.

A major concern with the FDA's proposal is its plan to equally weigh the Public Health Criteria and Other Criteria, which could artificially inflate or diminish the ingredient or contaminant overall score for prioritization. For example, a contaminant with a high "Public Health" score based on a high level of toxicity may not otherwise be widely known by the general public, which would lower its "Other" score and, therefore, its overall score. That substance may then not be prioritized as highly as the potential toxicity or exposure dictate. Conversely, a food ingredient's overall score could be artificially inflated by the public's perceived risk of the ingredient, thereby increasing its Other score even if such perceived risk is unsupported by scientific data evaluated under the Public Health criteria.

One solution to assure that real risk outweighs perceived risk could be to prioritize substances based only on their Public Health score, and rank substances with the same Public Health score by their Other score. In this way, food ingredients or chemicals with higher Public Health scores are always prioritized over those with moderate or low Public Health scores, but high Other scores.

Most recently, on July 30, 2025, FDA released a new tool for toxicity screening of food ingredients or contaminants found in foods. In announcing the release of the Expanded Decision Tree (EDT), FDA stated it expects to use the EDT in both pre- and post-market evaluations of food ingredients and anticipates that the EDT will provide information that can be incorporated into FDA's prioritization of food ingredients or contaminants for post-market review. FDA states that the EDT chemical toxicity and risk screening tool will be used to assist the agency in evaluating the safe use of food ingredients or food contact substances and to monitor the food supply for chemical contaminants. The EDT was submitted by FDA for external peer review in March 2024, where input was collected from scientific experts and incorporated into the model. FDA states that it plans to provide opportunities for public engagement on the new tool, and it also plans to release an informational video on the EDT at some future date.

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As HHS continues to advance its food policy initiatives, we expect to see more changes in the current regulatory framework for FDA's chemical review program. Wiley will continue to monitor these changes and provide updates as policy decisions are made.