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Via Electronic Mail

Dockets Management Staff (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: FDA's Tool for the Prioritization of Food Chemicals for Post-Market Assessment. Docket No: FDA-2025-N-1733.

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments on FDA's draft Post-market Assessment Prioritization Tool, which aims to ensure FDA focuses on reviewing chemicals in food that pose the greatest public health risk. The draft tool uses Multi-Criteria Decision Analysis (MCDA) to determine a score for each chemical based on evaluation of information about a chemical against pre-established criteria; the higher the score, the higher the priority. The prioritization process is part of FDA's enhanced systematic process for the post-market scientific assessment of chemicals in food. As the goal is to develop a science-based, data-driven, systematic, and reproducible process, FDA should ensure components of the overall process meet this standard. Doing so would align with Executive Order 14303, Restoring Gold Standard Science, which requires that Federal decisions are informed by the most credible, reliable, and impartial scientific evidence available and that agencies weigh each piece of scientific evidence based on its quality and relevance.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 180 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org

CRN supports a science-based and risk-informed systematic process for the post-market prioritization and review of chemicals in food and offers the following responses to FDA's questions listed in Section 4 of the method description document, "Tool for the Prioritization of Food Chemicals for Post-Market Assessment."[2]

FDA should refine the Public Health Criteria

The Public Health criteria included in FDA's methodology should be refined by incorporating changes in each specific criterion and/or scoring for each criterion, as recommended below.

Section 3.1.1. "Toxicity"

FDA should remove acute toxicity data from the toxicity rubric used to score the toxicity criterion. Acute toxicity data are not relevant to the assessment of substances used in food because they typically reflect the effects of a single, high-dose exposure, versus chronic, low-level exposure that is more reflective of eating patterns.

Section 3.1.2 "Change in exposure"

A change in exposure to a substance does not necessarily increase public health risk. To determine if the change in exposure is relevant to risk, total exposure must be established. Therefore, this criterion should describe total exposure to a substance and the scoring should be based on determination of high, moderate, or low impact on toxicity, with each level defined. The defined terms should be used instead of the subjective terminologies "considerably higher levels;" "highly consumed;" or "considerable increase." When determining total exposure, FDA should be transparent about how exposure data were obtained and calculated to ensure the information used is accurate and credible.

Additionally, changes in production volume should be excluded from consideration because an increase in production volume does not necessarily mean an increase in consumer exposure. Some substances have other uses outside of the food industry. Increased production volume could also be a result of increased demand for export, not

[2] Food and Drug Administration. Tool for the Prioritization of Food Chemicals for Post-Market Assessment. Available at: https://www.regulations.gov/document/FDA-2025-N-1733-0001.

domestic use.

Section 3.1.3 "Susceptible subpopulation"

FDA should define "susceptible subpopulation" to clarify the characteristics of such a subpopulation.

Section 3.1.4. "New scientific information and potential impact"

To ensure that the prioritization of substances is based on credible scientific information, only scientific information published in peer-reviewed scientific journals or published by a recognized authoritative/regulatory body should be considered for evaluation of this criterion.

To determine the impact of any new scientific information that is published, FDA should assess the quality of the data and whether it is consistent with the existing body of evidence on the substance.

FDA should reconsider Other Decisional Criteria

While CRN appreciates FDA's acknowledgment that public confidence and stakeholder activity/attention are important to regulatory processes, we are concerned that incorporating qualitative criteria into the prioritization score would weaken the scientific rigor of the methodology.

Section 3.2.1. "External stakeholder activity/attention"

This criterion includes attention raising concerns by U.S. government representatives (e.g., Congress, GAO, HHS Secretary, FDA Commissioner), consumer organizations, public interest groups, and trade groups, as well as national news/social media coverage. CRN recommends removing this criterion for the following reasons:

- Any calls for action by U.S. government representatives should be based on new scientific information, which would be identified in the Public Health criteria. Therefore, inclusion of this criterion would essentially be counting the same information twice.
- Concerns raised by other external groups may not have a credible scientific basis and should not be used to prioritize substances for post-market assessment.

- Similarly, national news and social media coverage of a substance is not necessarily based on credible scientific information.

Section 3.2.2. "Other government decisions"

Any restrictive action by another governmental agency should only be considered if it is risk-based and supported by strong scientific evidence. Such evidence would already have been considered under the Public Health criteria. As such, including other government decisions would be redundant.

If FDA maintains this criterion, the international government agencies that will be considered should be specified. Only international government agencies that follow risk-based procedures and meet FDA's scientific standards should be included in the evaluation. FDA should also indicate whether actions by international government agencies will be weighted equally.

Actions by state or locality-level governmental agencies should be excluded from the evaluation. These agencies generally do not have the scientific expertise or resources to make risk-based decisions.

FDA should implement a prioritization methodology based on Public Health Criteria

The Public Health Criteria Score should be the basis for the numerical Post-market Assessment Prioritization Score. Public Health Criteria are driven by objective and quantitative scientific data, while Other Decisional Criteria are subjective and based on qualitative factors that are vulnerable to bias. While we recognize that FDA intends to consider public concerns and confidence in the food supply, such qualitative criteria should not be included in the numerical prioritization score. We recommend using numerical weighting for the Public Health Criteria and separate letter grading for the Other Decisional Criteria, e.g., A, B, C to indicate high, medium, and low level of external activity/attention. This approach allows for evaluation of a numerical score that forms the basis for prioritization and the capture of contextual considerations while avoiding conflation of the two.

Further, FDA states it is considering applying equal weighting between Public Health Criteria Score and Other Decisional Criteria Score. However, the draft methodology allows

Other Decisional Criteria to disproportionately influence the overall score. Each public health criterion contributes one-fourth of the total public health score (i.e., divided by four). Meanwhile, the other decisional criteria are divided by three, meaning each carries more weight individually. This imbalance—caused by an unequal number of criteria—skews the formula toward the other decisional factors.

FDA should publish an annual list of chemicals prioritized for post-market assessment

CRN appreciates that FDA is undertaking a systematic approach to prioritizing and reviewing chemicals in food post-market to continue to safeguard the health of consumers. We recommend that FDA publishes an annual list of chemicals that will have complete post-market scientific assessments; by focusing on a limited number of chemicals at a time, the agency assures it can consistently complete planned post-market assessments and increase public confidence over time. In contrast, publishing a lengthy list of chemicals without defined, realistic timelines for completion would undermine public trust.

Sincerely,

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