August 18, 2025

Marty Makary, MD, MPH
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Tool for the Prioritization of Food Chemicals for Post-Market Assessment (Docket No. FDA-2025-N-1733)

Dear Commissioner Makary,

Consumer Reports[1] is pleased to comment on the Food and Drug Administration's (FDA's) proposed tool for the prioritization of food chemicals for post-market assessment. We strongly supported the FDA's decision to develop an enhanced systematic process for the post-market review of the chemicals added to food, and think that this proposed tool represents a step in the right direction, though the tool could be significantly strengthened as explained below.

As we noted in our written comments about FDA' discussion paper on an enhanced post-market assessment of chemicals in foods, we support a risk-based system to identify the riskiest chemicals to prioritize. FDA's draft Post-market Assessment Prioritization Tool focuses on potential risk to public health (risk ranking) as well as including other decisional criteria (interest in a food chemical by the public or other food safety regulators) using a Multi-Criteria Decision Analysis (MCDA) method.

The risk ranking portion of the Prioritization Tool (Public Health Criteria Score) includes scores for four areas: toxicity, exposure, whether the chemical is or could be found in food consumed by vulnerable populations (e.g., infants, elderly, pregnant women, immuno-compromised people, etc.), and whether new scientific information would increase our concern about the toxicity of the chemical. The four components of the risk ranking portion of the Prioritization Tool are appropriate categories, and we are pleased FDA has included some of the suggestions we made in our comments earlier this year in developing the Tool.

[1] Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

However, several changes must be made to the entire Prioritization Tool to ensure that it prioritizes public health by giving far greater weight to public health criteria and to ensure there is full transparency in the process of developing and finalizing the Prioritization Tool.

First, the **Prioritization Tool should give significantly more weight to the Public Health Criteria score**. Presently, the Prioritization Tool is composed of a sub-score for Public Health Criteria and a sub-score for Other Decisional Criteria (interest in a food chemical by the public or other food safety regulators), with each sub-score being given equal weight. Thus, Public Health Criteria are given equal weight with non-public health criteria. We strongly disagree with this approach. The Public Health Criteria are risk-based measures, while the Other Decisional Criteria are not risk based measures, rather they are simply a measure of the interest in a food chemical by the public of other food safety regulators. While it is acceptable to include Other Decisional Criteria as part of the Prioritization Tool, these Other Decisional Criteria should not be given anywhere near equal weight as the Public Health Criteria. Indeed, for the Prioritization Tool to be considered a strong risk-based measure, the Other Decisional Criteria should only make up 10 percent to 20 percent of the overall score for the Prioritization Tool. **We urge FDA to modify the Prioritization Tool to give far greater weighting to the Public Health Criteria compared to the Other Decisional Criteria**.

Secondly, the **toxicity criterion of the Public Health Criteria should be given higher weighting compared to the other three criteria**. The toxicity criterion consists of seven different categories: acute toxicity; carcinogenicity/mutagenicity/genotoxicity; developmental and reproductive toxicity; neurotoxicity; other organ-specific toxicity; immunotoxicity; and bioaccumulation/biopersistence. Each of these seven categories will receive a score of 1, 5, or 9. The highest score a chemical receives for any single toxicity category becomes its score for the toxicity criterion. This approach means that a strong signal of severe toxicity in any one of the seven categories ensures the highest score. However, this approach does not allow for much differentiation among the chemicals. This approach would rank a chemical with 9s in all seven categories as the same as a chemical with 9 in one category and 1 in the other six categories. We urge FDA to revise the toxicity criterion so that it is both given a higher weighting than the other three criteria and can more readily differentiate chemicals with more systemic toxicity, e.g., those affecting multiple categories, and those with narrower toxicity, e.g., those affecting one or two categories.

Third, the **toxicity criterion should explicitly include hormonal disruption**. None of the seven categories of toxicity explicitly includes hormonal disruption, although a number of the categories of toxicity do include toxicological endpoints impacted by hormonal disruption (e.g., some carcinogenicity, developmental, reproductive, neurotoxicological, or immunotoxicological endpoints). We urge the FDA to explicitly include hormonal disruption as a category. For hormone disruptors, FDA should not use TTC (threshold of toxicological concern) to define

scores, since hormone disrupting chemicals can have low dose effects and have non-monotonic toxicity dose responses.[2]

Fourth, the **toxicity criterion should give far more attention to human epidemiological and clinical studies, especially for hormone disrupting chemicals**. The bulk of toxicity tests that are used to set "safe" exposure levels of chemicals are usually based on animal-based testing methods. The current chemical risk assessment approach to developing a "safe" level for a chemical is to combine a dose that does not cause adverse effects in animal studies using high exposure doses and safety factors (also known as uncertainty factors) to account for incomplete data and variability between and within species. The problem with this approach is that some of the effects seen in human populations via epidemiology or clinical studies are associated with health endpoints that are not usually assessed in animal toxicology studies. Thus, a 2021 study of five ortho-phthalates found that for four of them, human epidemiological studies found health endpoints that were well below the individual "safe" levels (e.g., the Reference Dose). As the study noted, "The significantly affected endpoints revealed by our analysis include metabolic, neurodevelopmental and behavioral disorders, obesity, and changes in hormone levels. Most of these conditions are not routinely evaluated in animal testing … We conclude that for DBP, DIBP, BBP, and DEHP current RfDs estimated based on male reproductive toxicity may not be sufficiently protective of other health effects. Thus, a new approach is needed where post-market exposures, epidemiological and clinical data are systematically reviewed to ensure adequate protection".[3] **We urge FDA to modify the Prioritization Tool to more explicitly incorporate human epidemiological and clinical data, especially for chemicals that are already on the market.**

Fifth, the **FDA should ensure transparency by making each step in this process of modifying the Prioritization Tool publicly available**. In other words, all the scoring criteria, data sources and chemical rankings should be made publicly available as well as open for comment. In addition, FDA should seek stakeholder input, from scientists, health organizations and the public at each stage of the process.

Sixth, the **FDA should solicit input from the public on which chemicals to prioritize**. As the FDA notes, this Prioritization Tool "is also intended to work with FDA's surveillance and signal detection tools, which will assist in generating an inventory of candidate chemicals for prioritization."[4] In addition to FDA's internal process, they should solicit input from the public on which chemicals to prioritize.

Consumer Reports supported the FDA's decision to develop an enhanced systematic process for the post-market review of the chemicals added to food and encouraged that some progress has

[2] https://academic.oup.com/edrv/article-abstract/33/3/378/2354852?
[3] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-021-00799-8
[4] https://downloads.regulations.gov/FDA-2025-N-1733-0001/attachment_1.pdf

been made in the development of a Post-market Assessment Prioritization Tool. We look forward to more opportunities to comment on the FDA's process to enhance the post-market framework for assessing chemicals found in food.

Sincerely,

Michael Hansen, Ph.D.
Senior Scientist