Comment on Docket No. FDA-2025-N-1733: Tool for the Prioritization of Food Chemicals for Post-Market Assessment
August 18, 2025

On behalf of FoodFight USA, we appreciate the opportunity to comment on FDA's proposed tool for the prioritization of food chemicals for post-market assessment.

Founded by entrepreneurs Todd Wagner and Lori McCreary, FoodFight USA is a nonprofit, nonpartisan movement dedicated to cleaning up America's tainted food supply. Our mission is threefold: to stop self-regulation by food companies, empower consumers, and collaborate with American farmers to grow healthier foods that are economically viable and beneficial to consumers' health.

At FoodFight USA, one of our cornerstone initiatives – a Post-Market AI-driven Analysis of GRAS Chemicals – reflects our entrepreneurial, tech-forward approach to complex problem-solving and a commitment to using AI for good. We are developing a system that leverages AI to more efficiently and effectively evaluate the approximate 10,000 post-market GRAS chemicals and prioritize those that are commonly used and pose the greatest risk to public health.

Our team has been scraping multiple databases and using AI technologies like Operator - an advanced data extraction and analysis tool - to build a model that will estimate food additive health risk based on a combination of toxicity, prevalence, and scientific consensus. Starting with the 50-80 most used and the most toxic ultra-processed food (UPF) chemicals, we are cross-referencing those against the 10,000+ GRAS chemicals to find patterns of molecular overlap with any that are known to be carcinogens or endocrine disruptors. From there we can flag a list of the "worst offenders" and recommend them for expedited removal from U.S. foods.

We have been collaborating with universities, industry partners, and research organizations focused on food and chemical safety, and we are ready to assist FDA to develop a scalable solution to a complex problem. With our work aligning well with FDA's post-market assessment efforts, we would like to address the following questions from Docket No. FDA-2025-N-1733:

1. *The purpose of the Post-market Assessment Prioritization Tool is to assist in making decisions about which chemicals, including both intentionally added substances and unintentional contaminants in food, are a priority to review. Is the modeling approach we proposed appropriate for this purpose? If not, please explain your reasoning and provide alternatives for FDA to consider. Please be specific and provide references, as appropriate.*

While the intention behind this prioritization tool is commendable, it highlights a broader concern of the extremely slow progress of chemical evaluation. Without integration of machine learning or automation, the FDA tool risks becoming yet another bureaucratic step that delays necessary assessments and regulation. To assign priority scores before conducting post-market assessments, the proposed tool requires reviewing all 10,000+ food chemicals, looking into current studies and evidence on them, and having Subject Matter Experts (SMEs) from FDA's Human Foods Program (HFP) score each criterion for each chemical.

Not only is this process time-consuming, but the inclusion of SMEs as evaluators introduces a high degree of subjectivity. A 2018 study of 63 regulatory agencies found that FDA's qualitative judgment-based approach often leads to divergent interpretations, whereas agencies like EFSA use quantitative frameworks with measurable criteria that produce more reliable and reproducible outcomes. This underscores the need to minimize subjectivity and move toward more systematic, objective evaluation methods.

Given these time-consuming steps, it would be more efficient to integrate the prioritization and assessment processes into a single workflow. The resulting priority scores for each chemical should directly inform regulatory decisions, eliminating the need for a separate, lengthy post-market assessment phase.

As proposed, the prioritization process resembles the EPA's chemical prioritization approach under the Toxic Substances Control Act (TSCA), which takes 9-12 months and still leads only to risk evaluation. EPA risk evaluations themselves can take up to 3.5 years each, and the EPA has only completed one per year as of FY 2020. If FDA wants to move faster and more effectively, it needs a more agile system. FDA's proposed model lacks sufficient speed and scale to address public health risks in a timely manner. We hope to collaborate with FDA to further develop this tool and incorporate AI/ML resources so that the prioritization and assessment processes for the 10,000+ chemicals do not take a minimum of one year *per chemical* to complete. Ultimately, our goal is to compress the timeline significantly – from years to potentially weeks – so that regulatory actions can keep pace with emerging risks.

2. *The draft scoring definitions for all criteria were developed to consider the expected variability in the types and extent of data available for the wide variety of food chemicals that may be considered for review.*
    a. *Given this context, are the scoring definitions for the Public Health criteria appropriate for the purpose of the tool?*
        i. *Are the definitions appropriately defined? If not, please describe changes that might be considered and why.*

The scoring under the Toxicity criterion should incorporate more advanced tools like EPA's Toxicity Forecaster (ToxCast), which detects effects across biological processes (e.g., mitochondrial, developmental, cell cycle function). ToxCast data encompasses multiple data types under the current Toxicity rubric, so it could either be factored into each relevant data type or stand alone as its own data type under the rubric. We suggest scoring ToxCast data by percentage of active assays (i.e., High for >5%, Moderate for 1% - 4.9%, Low for <1%).

Additionally, WHO's International Agency for Research on Cancer (IARC) classifications should also be incorporated into carcinogenicity scores on top of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Chemicals classified as Group 1 (carcinogenic to humans), 2A (probably carcinogenic to humans), or 2B (possibly carcinogenic to humans) by IARC should score high under Toxicity.

The scoring for the "Change in Exposure" criterion is also inconsistent and potentially misleading. For example, a chemical that FDA has never assessed automatically receives a low score of 3, even if it is widely consumed at potentially harmful levels. Meanwhile, the criteria also allow a high score of 9 for chemicals found in highly consumed foods. This raises a key ambiguity: if a chemical is both unassessed by FDA and found in commonly consumed foods, it is unclear which score it should receive. To ensure more accurate prioritization, the scoring system should be revised to reflect both the lack of prior assessment **and** the potential for high population exposure.

There is also a need for transparency about data sources. For instance, the "Change in Exposure" criterion considers variables like consuming populations, amount consumed, products consumed, and preparation methods, but it is unclear whether this is based on NHANES, industry data, or other sources. Understanding the population samples and datasets used is essential, especially as average diets may overlook vulnerable or high-risk groups.

b. *Are the scoring definitions for the Other Decisional criteria appropriate for the purpose of the tool?*
    i. *Are the definitions appropriately defined? If not, please describe changes that might be considered and why.*

We believe that the "Other Governmental Decisions" criterion should place greater emphasis on international regulatory actions, which often reflect a precautionary approach grounded in emerging science and public health protection. These global decisions, such as bans or restrictions by regulatory bodies in the European Union, Canada, or Japan, should not be grouped and scored equally with state, local, or even federal agency actions. Instead, they merit their own distinct scoring framework to reflect their significance and the broader international consensus they may signal. More specifically, if a chemical has been banned or restricted in other countries due to health or safety concerns, it should not only receive the highest possible score under this criterion but also trigger immediate review and action by FDA. This type of fast-tracking has precedent: Bisphenol A (BPA), for example, was banned in Europe under a precautionary approach, which prompted the U.S. National Toxicology Program (NTP) to prioritize it for testing. The federal government has already acted on international regulatory decisions in the past, so expecting FDA to do the same is both practical and consistent with prior practice. The agency should not delay in taking comparable steps to protect U.S. consumers in line with international standards.

3. *The prioritization methodology includes weighting factors.*

a. *FDA is considering equal weighting among the Public Health criteria and (separately), among the Other Decisional criteria for the Post-market Assessment Prioritization Tool.*
    i. *Should different weights be applied to the Other Decisional Criteria when determining the Total Other Decisional Criteria Score? If so, please specify the weighting scheme that might be considered and why.*

We see the value of the "Building Public Confidence" criterion, particularly in fostering transparency and trust in regulatory decisions. However, we recommend that it be deprioritized and weighted less than "External Stakeholder Activity" and "Other Governmental Decisions," both of which are grounded in research, expert evaluations, and formal regulatory actions. Prioritization should be driven primarily by scientific merit and institutional expertise, not by consumer perception alone.

We are concerned that placing excessive emphasis on public opinion risks turning this tool into an overtly political instrument, vulnerable to influence by misinformation or fleeting trends rather than well-vetted scientific knowledge. Public sentiment, while important, can be reactive and uneven, and over-reliance on it could distort FDA priorities, diverting attention away from chemicals with stronger toxicological evidence and a greater need for regulatory action. Given the agency's finite resources, it is critical that attention remains focused on chemicals posing the greatest demonstrable risks.

4. *The draft toxicity rubric uses traditional toxicity data (*in vivo*, as well as limited* in vitro *such as for genotoxicity), human health outcomes (e.g., adverse event reports), and epidemiological data for determination of the toxicity criterion score within the Public Health criteria. Considering that the prioritization process is not a comprehensive review, please address the following questions.*
    a. *How might FDA incorporate information from new approach methodologies (NAMs) into the toxicity rubric?*
        i. *Are there specific NAMs (e.g. systems biology, engineered tissues, artificial intelligence,* in vitro*, microphysiological systems, or other alternative data or modeling tools) that would be most appropriate for use in the toxicity rubric? If so, please explain which NAM(s) would be most appropriate and why.*
        ii. *Given that a single NAM is not expected to be a one-to-one replacement for a traditional* in vivo *toxicity test, how can the strengths and limitations of each NAM be appropriately considered if it is incorporated into the toxicity rubric?*
    b. *Threshold of Toxicological Concern (TTC) approaches can be used to assess the toxicity of chemicals that lack sufficient safety data and have low dietary exposures. Although the Cramer classification scheme has historically been used in TTC approaches, FDA has recently developed the Expanded Decision Tree (EDT) that assigns chemicals to one of six EDT classes. How might such tools or the information they provide be incorporated into the toxicity rubric?*

While no NAM replaces *in vivo* data entirely, FDA should integrate NAMs like *in vitro* systems, microphysiological models, and *in silico* approaches that include artificial intelligence, which can complement traditional toxicology data, expand coverage of under-studied chemicals, and provide vital mechanistic insights and high-throughput capabilities that traditional models lack. We also support FDA fully leveraging TTC approaches, which help flag potential risks among data-poor chemicals by comparing them to structurally similar substances. Resources like EPA's CompTox Chemicals Dashboard and Generalized Read-Across (GenRA) Tool can predict the toxicity of a chemical by analyzing data from structurally or biologically similar compounds. Using these tools and approaches to flag chemicals (i.e., scoring chemicals High) with similar molecular structures or known toxicophores could help prioritize risk assessments and better utilize existing data.

Conclusion

Overall, this prioritization tool is a step in the right direction, but it cannot operate in isolation or under outdated timelines. If this tool is going to result in meaningful chemical safety decisions, it must integrate modern technologies such as AI/ML resources, align with global standards, and most importantly, move swiftly. ***The public cannot afford a 3.5-year turnaround to learn that a chemical in their food might be unsafe***.

We urge FDA to move toward a system that can score and act on chemicals simultaneously, incorporate advanced data tools, and remain transparent about its inputs and reasoning. A robust prioritization framework should serve as both a screening and decision-making mechanism, rather than just a gateway to further delay.

Thank you for considering our comments.