FOOD LAW and POLICY CLINIC
HARVARD LAW SCHOOL

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Food and Drug Administration
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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Re: Docket No. FDA-2024-N-3609; Comments on the Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food

To Whom it May Concern,

These comments are submitted on behalf of the Harvard Law School Food Law and Policy Clinic (FLPC) in response to the Food and Drug Administration's (FDA) notice on the development of a post-market system for assessing the safety of chemicals in food.

FLPC is an educational program that provides students the opportunity to learn about and engage in food law and policy work for clients and partners. FLPC works with clients and partners at a national and global level to increase access to healthy and nutritious food, support sustainable and equitable food production, and reduce food waste.

FDA's proposal to clarify the post-market safety assessment of food chemicals is an initial step towards much-needed reform in the U.S. food safety oversight system. Chronic disease rates in the U.S. are rising, especially amongst children, 40% of whom suffer from a chronic disease.[1] Many of these conditions have been linked to the use of chemicals in food.[2] Consequently, it is

[1] *See Managing Chronic Health Conditions in Schools*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/healthyschools/chronicconditions.htm#:~:text=Research%20Brief%3A%20Addressing%20the%20Needs,and%20behavior%20or%20learning%20problems (Oct. 20, 2021).
[2] *See generally* Stephanie M. Fanelli et al., *Poorer Diet Quality Observed Among US Adults With a Greater Number of Clinical Chronic Disease Risk Factors*, 11 J. OF PRIMARY CARE & COMMUNITY HEALTH 1 (2020); *Improving Nutrition to Turn the Tide on Diet-Related Chronic Disease*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-voices/improving-nutrition-turn-tide-diet-related-chronic-disease (Mar. 24, 2022); Kellie A. Woodling et

imperative that FDA exercise its regulatory authority over the food market and ensure that Americans have access to food that will allow them to thrive.

FLPC supports FDA's proposal to develop a system to streamline its post-market review of chemicals. FDA's post-market surveillance authority is a crucial tool that is currently being insufficiently used to ensure the safety of the U.S. food system. While FDA conducts pre-market safety assessments for chemicals that enter the market through the food additive petition process,[3] many chemicals are placed on the market without FDA safety assessments because they are determined to be "generally recognized as safe" (GRAS) by the industry entity using them in its products.[4] As a result of the current process, there are many chemicals on the market for which post-market safety assessments are the only means of FDA ensuring their safety. Unfortunately, FDA's current post-market safety assessment system is too limited in light of its important function. While FLPC supports FDA's steps to increase the rigor of this process, we also note that the relatively minor changes proposed by FDA will have limited impact until the agency alters their overarching approach to chemical safety. Accordingly, we have identified several areas of FDA's proposed framework for post-market regulation that could be strengthened to improve the overall safety of the U.S. food system.

As detailed below, FLPC has several recommendations for FDA to build upon its draft enhanced post-market safety assessment to further improve the overall safety of the U.S. food market. Part I discusses the following topics:

- A. FDA should establish a continuous monitoring system for the food chemicals currently on the market.
- B. FDA should maximize its knowledge about and oversight of food chemicals on the market within the framework of the GRAS system.
- C. FDA should incorporate long-term and chronic health effects into its safety analysis for all chemicals in the food supply.

In response to the questions posed by FDA in its August 2024 discussion paper, FLPC makes the following recommendations, discussed in greater detail in Part II below:

- FDA should prioritize public participation and emphasize transparency in all types of post-market safety assessments.
- FDA should implement an advisory committee into the post-market safety assessment process, but only in a market-monitoring role to help regularly identify the chemicals for which assessments are needed. The advisory committee would ensure that post-market safety concerns are appropriately prioritized and are addressed in a timely fashion.

I. FDA should implement more rigorous oversight than proposed in the enhanced post-market safety assessment in order to ensure risk reduction across the food chemical regulation regime.

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al., *Toxicological evaluation of brominated vegetable oil in Sprague Dawley rats*, 165 FOOD AND CHEMICAL TOXICOLOGY 113137 (2022); CALIFORNIA ENV'T PROTECTION AGENCY, POTENTIAL NEUROBEHAVIORAL EFFECTS OF SYNTHETIC FOOD DYES IN CHILDREN (2021).

[3] *See generally* 21 U.S.C. § 348(b).

[4] *See generally* Tom Neltner & Maricel Maffini, *Generally Recognized as Secret: Chemicals Added to Food in the United States*, NATIONAL RESOURCES DEFENSE COUNCIL (Apr. 2014); 21 U.S.C. § 348(b).

In taking steps to address the inadequacy of its current post-market chemical evaluation process, FDA has identified a problem that is crucial for the agency to tackle. However, FDA proposes modifications that are too modest in light of the pressing need for an overhaul of the agency's approach to food chemical safety. Therefore, we propose several additional steps that FDA should consider taking to maximize the safety of the market.

A. FDA should establish a continuous monitoring system for the food chemicals currently on the market.

The proposed enhanced post-market safety assessment framework for chemicals in food is a welcome step towards the overarching goal of establishing a more robust regulatory mechanism for ensuring the safety of chemicals in the food market. However, the efficacy of the proposed process is largely dependent on how it is applied to regularly identify and flag safety concerns for the thousands of chemicals and substances that already exist within the food market. This is briefly touched on in the proposed 1.a) "Food Chemical Signal Monitoring," but we are concerned that without more robust monitoring, too few chemicals of potential concern will be flagged for assessment. Therefore, FLPC recommends that FDA establish a continuous monitoring system that ensures that it comprehensively assesses the safety of *all chemicals* currently on the food market.

FDA's current system of ad hoc post-market safety assessment is inadequate for ensuring that the chemicals in food meet the requisite safety standards.[5] This is true for all chemicals used in food, but it is especially relevant for substances designated as GRAS by industry entities. The GRAS substances category is derived from the statutory definition of a food additive, which specifically excludes substances that are "generally recognized… to be safe under the conditions of [their] intended use."[6] This carveout exempts GRAS substances from the food additive petition process. It is not clear in the statute what process they should undergo instead, but according to FDA's current GRAS rule, such substances are eligible for a voluntary GRAS notification process.[7] The voluntary GRAS notification process provides companies with the option to submit a notification to FDA stating the company's determination that a substance is GRAS, but does not require them to do so.[8] Given its voluntary nature, a company can also choose not to use this process, and thus introduce a substance that it considers GRAS without any involvement or awareness on the part of FDA.[9]

Because of the voluntary nature of GRAS notifications, post-market safety assessment is the primary tool that FDA uses to assess the safety of GRAS chemicals on the market.[10] However,

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[5] *See generally* Jennifer L. Pomeranz, Emily M. Broad Leib, and Dariush Mozaffarian, *Regulation of Added Substances in the Food Supply by the Food and Drug Administration Human Foods Program*, 114 AMERICAN J. OF PUBLIC HEALTH 1061 (2024).
[6] 21 U.S.C. § 321(s).
[7] *See* 21 U.S.C. § 321(s); 21 C.F.R. § 170.205.
[8] *See* 21 C.F.R. § 170.205.
[9] *See* id.
[10] *See Center for Food Safety v. Becerra*, 565 F. Supp. 3d 519, 531, 536 (S.D.N.Y. 2021).

FDA has done so sparingly over the last few decades.[11] More concerning is the fact that FDA does not have a comprehensive list of all GRAS substances on the market, due to the voluntary notification process.[12] Further, even when post-market safety assessments are conducted or specific concerns are brought to FDA via citizen petitions, a significant amount of time passes – frequently multiple years – before FDA removes unsafe chemicals from the market or responds to citizen petitions.[13] For example, despite the fact that tara flour, a manufacturer-designated GRAS ingredient, induced severe and acute illness in hundreds of individuals, it took FDA two years to declare that the ingredient was not GRAS and remove it from the market.[14]

These patterns suggest that the sporadic post-market safety assessment approach that is currently used leaves numerous gaps through which safety issues may go undetected—for GRAS substances as well as food additives. Therefore, FLPC recommends the development of a continuous monitoring system for food chemical safety assessment that ensures consistent evaluation of chemicals on the food market. We have developed several proposed suggestions by which FDA could approach regular identification of concerns within the existing universe of food chemicals, to identify those that should be assessed via the new post-market safety assessment structure:

1. FDA could establish a food chemical evaluation queue modeled after the EPA's TSCA chemical evaluation process.

Under the Toxic Substances Control Act (TSCA),[15] the Environmental Protection Agency (EPA) maintains a forty chemical queue (comprising twenty high-priority and twenty low-priority chemicals) that serve as the agency's immediate priorities for review.[16] The chemicals chosen for each queue primarily come from a Work Plan that contains a list of chemicals that EPA has identified as most concerning with respect to safety.[17]

FDA could adopt a process similar to EPA's TSCA safety evaluations by developing a list of chemicals most in need of review and maintaining a minimum number of chemicals under review at all times. Although TSCA provides a statutory requirement for EPA to engage in this system of prioritization and regular review, FDA could apply a similar structure under their post-market safety review authority. FDA already cites EPA's Multi-Decision Criteria Analysis (MCDA) approach to prioritization as a potential means by which FDA could conduct their own chemical prioritization for review.[18] Given that FDA already recognizes the value of this aspect

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[11] *See* U.S. GOVERNMENT ACCOUNTABILITY OFF., GAO-10-246, FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 20-21 (2010).
[12] Pomeranz et al., *supra* note 5, at 1063. *See* 21 C.F.R. § 170.205.
[13] *See* Pieter A. Cohen & Emily M. Broad Leib, *Ingesting Risk – The FDA and New Food Ingredients*, 391(10) NEW ENGLAND J. OF MED. 875, 875-76 (2024); GAO-10-246, *supra* note 11, at 22-24.
[14] *See* Cohen & Broad Leib, *supra* note 13, at 875-76.
[15] Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003.
[16] *See Prioritization of Existing Chemicals Under TSCA*, U.S. ENV'T. PROT. AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritization-existing-chemicals-under-tsca (Aug. 28, 2024).
[17] *See* i*d.*
[18] *See* U.S. FOOD & DRUG ADMIN., DISCUSSION PAPER DEVELOPMENT OF AN ENHANCED SYSTEMATIC PROCESS FOR THE FDA'S POST-MARKET ASSESSMENT OF CHEMICALS IN FOOD 7 (2024).

of the TSCA framework, it would be a natural extension for FDA to implement another component of the TSCA review process to ensure that the prioritized chemicals are reviewed at an appropriate cadence. Furthermore, this process would largely mirror the process adopted by the EU in which food additives that entered the market prior to 2009 are being re-reviewed for compliance with modern standards.[19]

2. FDA could institute a rolling review process that ensures that all chemicals are reviewed after a consistent number of years.

An alternative model that FDA could use for comprehensively evaluating food chemicals on the market is EPA's pesticide evaluation program, under which each pesticide on the market is reviewed every fifteen years.[20] This framework is an ideal system for safety reassessment because it ensures total evaluation of the existing market according to a predetermined timeline.

FDA could establish a similar model under which the agency would review the safety of every food chemical after a given number of years. Unlike pesticides, not all food chemicals on the market have undergone an initial safety evaluation (specifically GRAS substances, noted above), meaning that FDA could shorten the timeline for evaluation for such substances, or begin with the evaluation of chemicals on the market that have not previously undergone a safety evaluation by FDA. Additionally, a system modeled after EPA's pesticide review process would establish public documentation of the key data that FDA is using to make their decision as well as allow stakeholders from the public to disclose their own information for FDA to use in their assessment.[21]

3. FDA could establish an advisory committee that continuously assesses the food chemical market via periodic meetings and identifies safety review priorities for FDA.

Another method for ensuring comprehensive review of chemicals on the market is an advisory committee dedicated to market monitoring. Specifically, we propose establishing an advisory committee that is responsible for regularly surveying the food chemicals on the market to ensure that FDA is identifying the most important chemicals for safety assessment. An advisory committee could serve a continuous monitoring function by convening on a semi-regular basis to assess developments in the market and ensure that FDA's safety assessment goals are up to date. This could either be annually or semi-annually, or it could be set up similar to the Dietary Guidelines for Americans, where the Dietary Guidelines Committee meets over the course of two years every five years in order to prepare a report that highlights the key changes in nutrition evidence and make recommendations for updates to federal nutrition guidance.[22] In the chemical safety context, a committee could be convened every 3-5 years to meet over the course of several months, examine new evidence on chemical safety including new restrictions imposed in other jurisdictions and the supporting evidence, and propose the key chemicals for FDA to review over the subsequent 3-5 years. While the committee would not be responsible for reviewing the safety

[19] *See* Regulation (EC) 1333/2008, art. 32.
[20] *See Pesticide Reevaluation Registration Review Process*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/pesticide-reevaluation/registration-review-process (Nov. 2, 2023).
[21] *See id.*
[22] *See* 21 U.S.C. § 5341.

of every chemical on the market, they would be able to serve as a dedicated body for tracking trends in the market to ensure that FDA is aware of major developments.

4. FDA should automatically conduct a post-market safety assessment for chemicals that are banned in peer countries.

Under current FDA risk assessment processes, the agency takes into consideration the actions and findings of other regulatory agencies around the world.[23] Safety information generated by peer countries is explicitly mentioned as a potential trigger for post-market safety assessment in the proposed framework.[24] However, FDA should implement a new policy that requires the ban of a chemical by a peer regulatory agency to automatically initiate a post-market safety assessment of that chemical. This will ensure that FDA is efficiently responding to new scientific findings, regardless of where they occur, while still maintaining domestic control over the assessment process. We recommend that the banning of a chemical should trigger an immediate 120-day period for FDA to complete a focused assessment on the chemical in question.

B. FDA should maximize its knowledge about and thus oversight of food chemicals on the market within the framework of the GRAS system.

The importance of a comprehensive system of food chemical safety regulation underscores the need for FDA to monitor the food chemical market as closely as possible, even within the bounds of the GRAS framework. FDA's existing process is already an outlier in that other countries require companies to seek approval prior to placing *any* new food chemical on the market, without any exemption or loophole like that in place here.[25] For example, the European Food Safety Authority requires pre-market approval for all additives to food and does not have any exemption category resembling the U.S. GRAS determination.[26] Furthermore, the EU places all permitted food additives on a list that allows the public to see the complete list of substances permitted in foods, as well as the prescribed parameters for their use.[27]

Even with the U.S.-recognized category of GRAS foods, it is still possible for FDA to compile a list of chemicals that are used in U.S. foods, a necessary step in order for FDA to accurately assess post-market safety concerns. To do so, FDA should increase its oversight of GRAS chemicals to the greatest extent possible. We have several recommendations as to how FDA can do that:

1. FDA should require companies to notify the agency when they place a GRAS substance on the market.

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[23] *See List of Chemicals in the Food Supply Under FDA Review*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review (Oct. 29, 2024).
[24] *See* DISCUSSION PAPER DEVELOPMENT OF AN ENHANCED SYSTEMATIC PROCESS FOR THE FDA'S POST-MARKET ASSESSMENT OF CHEMICALS IN FOOD, *supra* note 18, at 3.
[25] *See* GAO-10-246, *supra* note 11, at 13.
[26] *See id.*; Regulation (EC) 1333/2008, art. 1.
[27] *See* Regulation (EC) 1333/2008, art. 1.

While the FDCA states that GRAS substances are exempt from the additive approval process,[28] this does not mean that FDA cannot require notification of the use of such substances. So long as the notification does not entail a full notice and comment process used for additives, and thus maintains an exemption from that process for GRAS substances as laid out in the statute, merely requiring notification would be allowed under the FDCA.[29] Currently, FDA allows for voluntary premarket notification, but it also allows GRAS substances to be used without any notification to FDA. FDA should establish a gatekeeping mechanism in which companies are required to notify FDA that they are placing a chemical on the market that they have self-determined to be GRAS. Given that FDA is required to consider the safety of food chemicals in light of consumers' cumulative exposure to both the individual chemicals and other chemicals,[30] it is essential for FDA to have an accurate understanding of all chemicals on the food market.[31] Without this information, it is impossible for FDA to undertake the mandatory analysis of whether consumption of a chemical is safe in light of the rest of the diet, and there is evidence that FDA is not sufficiently addressing these considerations at present.[32]

Additionally, as established above, a continuous monitoring system for chemicals is an important component of maximizing the safety of the food market. However, continuous monitoring is only possible if FDA has complete knowledge of the chemicals currently on the market. A mandatory notification from companies to FDA in the event that they place a self-determined GRAS chemical on the market would serve this purpose and be a necessary precursor to establishing a continuous monitoring system.[33] Furthermore, in addition to requiring this notification for future manufacturer-determined GRAS ingredients, FDA should require submission of this information from manufacturers that have previously identified ingredients as GRAS to ensure that FDA has complete knowledge of the marketplace.

2. FDA should monitor and enforce correct use of the GRAS and food additive petition processes.

FDA should implement protocols to ensure that chemicals entering the market do not inappropriately use the GRAS pathway in lieu of the food additive petition process. Since implementation of the GRAS voluntary notification process, the number of food additive petitions has decreased to an annual average of 3.4 between 2000 and 2010.[34] By contrast, FDA responded to an annual average of approximately 28.7 voluntary GRAS notifications during the

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[28] *See* 21 U.S.C. § 321(s).
[29] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54960, 54982 (Aug. 17, 2016) (acknowledging the possibility of FDA having the authority to require notifications of GRAS determinations); Cohen & Broad Leib, *supra* note 13, at 877; Pomeranz et al., *supra* note 5, at 1067 (proposing that FDA could require companies to alert the agency of a new GRAS substance).
[30] *See* 21 C.F.R. § 170.3(i).
[31] *See* Heather M. Alger et al., *Perspectives on How FDA Assesses Exposure to Food Additives When Evaluating Their Safety: Workshop Proceedings*, 12 COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 90, 116 (2013).
[32] *See* 21 C.F.R. § 170.3(i); Alger et al., *supra* note 31, at 116.
[33] *See* Alger et al., *supra* note 31, at 116.
[34] Thomas G. Neltner et al., *Navigating the U.S. Food Additive Regulatory Program,* 10 COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 342, 360-61 (2011).

same time period,[35] which does not include the many ingredients that entered the market without a corresponding notification to FDA (one study estimated this to be 1000 substances between 1990-2010 alone).[36] This pattern suggests that companies may be inappropriately utilizing the GRAS process instead of the food additive petition process, possibly due to confusion over the qualifying substances for each category, or, more likely to reduce the burden of information they share with FDA (via the voluntary notification) or to avoid having to provide information to FDA (if they decide to self-GRAS).[37] The dangers of such an approach are evident in the cautionary tale of tara flour – a novel substance that should have been reviewed via the food additive process where, based on the side effects it ended up causing, it presumably would not have been permitted to enter the market.[38] However, because tara flour entered the market via self-GRAS, these concerns were only identified after nearly 400 consumers became sick and over 130 were hospitalized.[39] Stricter monitoring of the proper use of the GRAS pathway could have prevented such an outcome.

To ensure that the GRAS pathway is only used to the extent intended under the law, FDA should enforce the distinction between food additives and substances that are permitted to go through the GRAS process. For example, FDA could require the submission of a brief justification from each manufacturer as to why they are eligible for the review pathway chosen and review this justification upon receipt of a GRAS notification or food additive petition. FDA should also implement penalties for companies that choose the GRAS pathway when they should clearly have chosen the additive pathway, to further deter companies from incorrectly using the easier GRAS option when inappropriate.

3. FDA should enforce intended use levels for use of GRAS chemicals in food.

Finally, FDA should enforce the maximum permitted levels for GRAS substances on the market. Food additives and GRAS substances can only be considered safe for their "intended use,"[40] making it important for FDA to ensure that GRAS ingredients are not used at levels that exceed the intended use. While manufacturers identify intended use levels when they submit a voluntary GRAS notification, these levels are not clearly identified and published by FDA. Furthermore, in the event that manufacturers make a self-GRAS determination, the intended use level for that determination remains unknown to the public. Accordingly, FDA should document and publish the level at which all substances are determined to be GRAS, including those identified by the manufacturer in a self-GRAS determination. The USDA conducts a similar process wherein they identify and compile quantitative limitations for select substances in USDA-regulated products, including some substances that have entered the market through the GRAS pathway.[41] Furthermore, FDA should continually evaluate existing levels in light of new information,

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[35] *See GRAS Notice Inventory*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory (last visited Jan. 11, 2025).
[36] *See* Neltner et al., *supra* note 34, at 354.
[37] *See* i*d.* at 360-61.
[38] Cohen & Broad Leib, *supra* note 13, at 875-76.
[39] *Id*.
[40] 21 U.S.C. § 321(s).
[41] *See* 9 C.F.R. § 424.21.

similar to the reevaluation process currently being applied in the EU.[42] If FDA is unable to determine the maximum level at which a substance is GRAS, then FDA should consider the chemical not to be GRAS until such information can be discerned. Additionally, FDA should implement protocols to detect when substances are being used at a greater level than their intended use. Doing so will allow FDA to initiate a post-market safety assessment as warranted.

C. FDA should incorporate long-term and chronic health effects into its safety analysis for all chemicals in the food supply.

To protect the health of consumers, FDA should more explicitly consider whether consumption of a chemical will have an overall negative effect on consumer health and wellness. GRAS chemicals, as well as food additives, are considered safe when there is "reasonable certainty in the minds of competent scientists that the substance is not harmful under its conditions of intended use."[43] The strong link between the American diet and the prevalence of chronic diseases in the U.S.—including obesity, type 2 diabetes, cardiovascular disease, certain cancers, and more—is a topic of much current discussion and research.[44] Additionally, there is mounting evidence of strong connections between food ingredients and a variety of other health conditions, including thyroid dysregulation[45] and behavioral and attention issues in children.[46]

FLPC recommends incorporating a clearer analysis of overall health and wellness, including chronic conditions, rather than just acute food safety risks, as part of FDA's safety considerations. Incorporating such factors explicitly into the agency's safety analyses is in line with its existing statutory requirement to consider "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet."[47] Furthermore, this approach is in line with the EU safety assessment process, which requires consideration of the "long-term" safety effects of food, even including effects that may be observed across generations.[48]

II. Response to Questions Posed in FDA's Discussion Paper

FDA's discussion paper included several questions on which the agency seeks feedback.[49] Below are FLPC's recommendations in response to several of these questions.

When and how should FDA engage the public on post-market assessments?

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[42] *See* Regulation (EC) 257/2010.
[43] 21 C.F.R. § 170.3.
[44] *See generally* Fanelli et al., *supra* note 2; *Improving Nutrition to Turn the Tide on Diet-Related Chronic Disease*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-voices/improving-nutrition-turn-tide-diet-related-chronic-disease (Mar. 24, 2022).
[45] *See generally* Woodling et al., *supra* note 2.
[46] *See generally* POTENTIAL NEUROBEHAVIORAL EFFECTS OF SYNTHETIC FOOD DYES IN CHILDREN, *supra* note 2.
[47] *See* 21 U.S.C. § 348(c)(5)(B); 21 C.F.R. § 170.18.
[48] *See* Regulation (EC) 178/2002, art. 14(4)(a).
[49] DISCUSSION PAPER DEVELOPMENT OF AN ENHANCED SYSTEMATIC PROCESS FOR THE FDA'S POST-MARKET ASSESSMENT OF CHEMICALS IN FOOD, *supra* note 18, at 8.

FLPC appreciates FDA's attention to ensuring that consumers and other stakeholders have the opportunity to share their perspectives throughout the post-market safety assessment process. FLPC shares the opinion that engagement with the public throughout the post-market safety assessment process, especially its early stages, is critical. Opportunities for public input and understanding are especially important in light of the fact that current opportunities for public participation are lacking because of the private nature of many GRAS determinations and the long wait times associated with responses to citizen petition submissions seeking FDA review of various additives and GRAS substances.[50]

FLPC supports FDA in its proposal to include formal opportunities for public comment at both the "Scope/Problem Formulation" and "Draft Scientific (Risk and Safety) Assessment" stages of Comprehensive Assessments.[51] FLPC recommends that this opportunity be extended to the public in the context of Focused Assessments as well. A more limited form of public engagement could be appropriate in the context of the more truncated Focused Assessments; however, stakeholders should have an opportunity to voice relevant concerns and information regardless of the scope of the assessment. Stakeholder feedback may also provide data that helps FDA realize that though initiated as a Focused Assessment, the substance really warrants a Comprehensive Assessment.

In addition to ensuring that the public has adequate opportunities to participate in the safety assessment process, FDA should also ensure that it provides complete explanations with respect to its findings of safety and any risk management actions that the agency takes. Providing the public with the supporting information and reasoning underlying FDA's decisions will be important for bolstering public confidence in the safety of food chemicals.

Should the FDA implement an advisory committee review into our post-market assessment process? If yes, at what stage, and what should the committee's role be?

FLPC supports FDA's interest in incorporating an advisory committee into the post-market assessment of food chemical safety. However, we would suggest the use of an advisory committee in a way that seems to differ from what FDA proposes. FLPC does not think that it would be effective to require an advisory committee to review every food chemical during the post-market assessment process. However, we believe that an advisory committee would be an asset if set up in a role that focuses on issue spotting and identifying the chemicals in the food supply that should be prioritized for assessments. Such a committee could thus provide external expertise in a way that reduces FDA's internal workload and budget constraints. Furthermore, establishing an advisory committee for the post-market assessment of food chemical safety would bring the Human Foods Program into closer alignment with the other FDA centers, all of which commonly rely on advisory committees in the course of their safety and efficacy assessments.[52] As discussed in greater detail in Section I.A.3, this would be particularly helpful

[50] GAO-10-246, *supra* note 11, at 22; Maricel V. Maffini et al., *Looking Back to Look Forward: A Review of FDA's Food Additives Safety Assessment and Recommendations for Modernizing its Program*, 12 COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 439, 449 (2013).
[51] *See* DISCUSSION PAPER DEVELOPMENT OF AN ENHANCED SYSTEMATIC PROCESS FOR THE FDA'S POST-MARKET ASSESSMENT OF CHEMICALS IN FOOD, *supra* note 18, at 7-8.
[52] *See* 21 C.F.R. § 14.1.

as a way to address our overarching proposal to ensure that the agency is continuously identifying chemicals of concern.

Conclusion

FLPC applauds FDA's efforts to strengthen the safety assessments that are conducted on chemicals in the U.S. food system. Post-market safety assessments are a vital component of ensuring food chemical safety and have been underutilized in the past. FDA's renewed focus on this topic addresses an existing need for greater structure and urgency in the post-market safety assessment of food chemicals.

However, FLPC believes that there are limitations in the proposed food chemical regulatory scheme that FDA should address before finalizing its post-market food chemical safety review process. In light of the minimal safety assessments previously applied to food chemicals on the market, FDA should establish a continuous monitoring system for food chemicals. Additionally, FDA should maximize its oversight of food chemicals that enter the market through the GRAS pathway by establishing a means by which to monitor all GRAS substances currently on the market and enforcing existing regulations that govern the pathway that food chemicals take to the market. FDA also should actively consider the long-term and chronic health effects of each chemical in the food supply.

Thank you for your consideration of FLPC's comments and recommendations.

Sincerely,

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