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January 21, 2025

Docket Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rocksville, MD 20852

Re: Development of an Enhanced Systematic Process for the Food and Drug Administrations's Post-Market Assessment of Chemicals in Foods; Public Meeting; Request for Comments, Docket No. FDA-2024-N-3609

Dear Deputy Commissioner Jones,

Consumer Reports appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) recent public meeting on the development of an enhanced systematic process for their post-market assessment of chemicals in foods, and the associated discussion paper. We strongly support the FDA's decision to develop an enhanced systematic process for post-market review of chemicals added to food, but think the proposal needs to be significantly strengthened.

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The FDA's system for assessing the safety of chemicals added to foods is clearly broken. Since 2,000 almost 99% of all food chemicals introduced into the U.S. food supply were determined to be safe by the food company that manufactures or uses them rather than go through the FDA's more stringent food additive process.[1] In addition, less than 22% of the almost 4,000 chemicals directly added to food have enough information to estimate a safe level of exposure.[2] Even worse, there is very little post-market assessment of the safety of these food chemicals, which allows harmful chemicals to remain in use long after evidence of their harm emerges.

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[1] https://www.ewg.org/news-insights/news/2022/04/ewg-analysis-almost-all-new-food-chemicals-greenlighted-industry-not-fda#

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC5737876/pdf/pbio.2003578.pdf

For example, although FDA just banned the dye Red No. 3 due to cancer concerns, there are 6 other synthetic food dyes similar to Red No. 3 (e.g., Blue No. 1, Blue No. 2, Green No. 3, Red No. 40, Yellow No. 5, and Yellow No. 6) that still remain on the market, even though there is a lot of human data, animal studies, and mechanistic models which demonstrate that these synthetic food dyes are associated with significant neurobehavioral effects in children, particularly exacerbation of symptoms associated with Attention Deficit/Hyperactivity Disorder (ADHD).[3] A good amount of the data has been acquired in the last 25 years or so. That said, the studies used by the FDA to develop the so-called "safe" levels for most of these synthetic dyes, with the exception of Red No. 3, were done from 35 to 70 years ago.[4] Thus, a strong enhanced systematic process for post-market review of chemicals added to food is clearly needed.

The process FDA proposes for the post-market assessment of food chemicals is flawed since it appears to be reactive rather than proactive. The first step in the process, called Food Chemical Signals Monitoring entails FDA identifying "new information through monitoring of multiple sources."[5] That new information then goes through an assessment process to see if a full risk assessment is needed.

The problem with this approach is that it ignores the large numbers of chemicals that are on the market for which new information vis-a-vis human health impacts has been gathered since those chemicals were allowed on the market. FDA should be doing assessments of the large number of chemicals already on the market and then prioritizing them based on the amount of existing information vis-a-vis toxicity, in addition to watching for emerging information on food chemical safety concerns. Thus, for the prioritization step, FDA should focus on those chemicals linked to the most severe outcomes, such as carcinogens, neurological damage, hormonal disruption, reproductive damage, of special concern to children or linked to irreversible organ toxicity. In addition to toxicity, special attention should be given to those chemicals that are not only toxic, but also are persistent in the environment and/or bioaccumulate in the human body.

Second, once the chemicals have been prioritized for reassessment, for transparency purposes, there should be a risk assessment process as well as a risk management process. The process of reassessment should include both risk assessment and risk management and they should be strictly separated from each other. The office of reassessment should be independent of the office of premarket review, since it's important that those involved in reassessment haven't participated in the premarket approvals, since that might mean they are reviewing their own work. In addition, the experts involved in the reassessment should have expertise with data analysis and integration of evidence from various streams-human studies, animal studies, to mechanistic (e.g., mode-of-action) in vitro studies or molecular pathways.

Third, the process of distinguishing between a focussed assessment or a comprehensive assessment is vague in terms of the exact details to determine about the methods and processes

[3] https://oehha.ca.gov/sites/default/files/media/downloads/risk-assessment/report/healthefftsassess041621.pdf
[4] https://oehha.ca.gov/sites/default/files/media/downloads/risk-assessment/report/healthefftsassess041621.pdf
[5] https://www.fda.gov/media/180942/download?attachment

and criteria for doing one type of assessment versus the other. The FDA should be more specific on the criteria that lead to a focussed vs comprehensive assessment. We believe that the entire process should be more transparent and that there should be stakeholder input and every step of the process, whether for the comprehensive assessment or even the focussed assessment. Ideally, these assessments should be sent out to a panel of independent experts who are unconflicted and that allows for public participation, in addition to having these assessments published publicly.

Fourth, the risk assessment process and the risk management process should be strictly separated. In addition, solely public health concern should be used for the risk assessment, e.g., they should only use data that are relevant to human health and safety and should not take into consideration factors such as cost or feasibility. For risk management, the top priority should be protecting human health, not minimizing impact or cost to industry.

Conclusion

To summarize, the framework for post-market food chemical reassessment needs to be proactive, not reactive, and address both existing and emerging information of food chemical safety concerns, with a focus on existing chemicals for which data are sufficient to take action now. The process should be transparent, with prioritization of chemicals as the first step.

For transparency purposes, the process of risk assessment and risk management should be strictly separated from each other. In addition, risk assessment should only be concerned with protecting public health, not taking into account factors such as impact or cost to industry. All the assessments, whether focussed or comprehensive should be open to stakeholder input and should involve an outside group of independent experts to review the assessments that are done.

Ultimately, the agency needs to emphasise the public health implications of these chemicals, separate from other products under the FDA's jurisdiction. The recent comments by the former commissioner are especially troubling: "It's fascinating to me that Red Dye No. 3 has gotten so much more press than this massive tobacco proposed rule — a trillion dollars a year in savings for 40 years, millions of lives saved — and it's gotten so little press compared to Red Dye No. 3, which, as best I know, there's no definitive evidence that it causes cancer in people." Just because toxic food chemicals may not be as harmful to public health compared to tobacco, it does not mean that these chemicals should remain on the market, and these comments should not be indicative of the agency's approach to this issue.

Yours,

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