

January 21, 2025

Jim Jones  
Deputy Commissioner for Human Foods  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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

**RE:** Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments (Docket FDA-2024-N-3609)

Dear Deputy Commissioner Jones,

The Center for Science in the Public Interest (CSPI) respectfully submits this comment related to the Food and Drug Administration (FDA)'s public meeting held on September 25, 2024, titled "Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food." While CSPI has also authored a longer comment addressing detailed recommendations for FDA's overall post-market reassessment program, we submit this separate comment specifically to urge the FDA to incorporate its work to establish a maximum limit of opiate alkaloid contamination in poppy seeds into its public workplan.

CSPI requested that FDA establish a maximum limit of opiate alkaloid contamination of poppy seeds in a Citizen Petition submitted in February of 2021.<sup>1</sup> In May 2024, more than three years later, we sued the agency in the Federal District Court for the District of Columbia for failing to issue a timely response to the Petition.<sup>2</sup> And in July 2024, CSPI and the FDA jointly moved for a stay of the D.C. court case, in which motion, the agency indicated it was evaluating the Petition and expected to issue its response by February 28, 2025. On January 14, 2025 the agency denied our petition, indicating that information was needed to recommend best practices for poppy seed manufacturers, growers, distributors, and sellers, and that FDA was issuing a request for information (RFI).<sup>3</sup> That request was published in the Federal Register the following day.<sup>4</sup>

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<sup>1</sup> Regulations.gov. *Citizen Petition to establish a maximum limit of opiate alkaloid contamination of poppy seeds and ensure the safety of imported poppy seeds*. Posted by the Food and Drug Administration. February 8, 2021. <https://www.regulations.gov/document/FDA-2021-P-0168-0001>. Accessed January 6, 2025.

<sup>2</sup> Complaint, Center for Science in the Public Interest v FDA and Robert M. Califf. No. 24-1342 (D.D.C. 2024).

<sup>3</sup> Letter from FDA denying CSPI's citizen petition asking for maximum limits on opiate contamination in poppy seeds. Updated January 14, 2025. <https://www.cspinet.org/resource/letter-fda-denying-cspis-citizen-petition-asking-maximum-limits-opiate-contamination-poppy>. Accessed January 21, 2025.

<sup>4</sup> Growing, Harvesting, Processing, and Distribution of Poppy Seeds-Industry Practices Related to Opiate Alkaloids; Request for Information 90 Fed. Reg. 3873 (January 15, 2025).

Opiate alkaloid contamination of poppy seeds is not incorporated into the FDA’s “List of Chemicals in the Food Supply Under FDA Review,” a list currently maintained by the FDA on its website as a means to communicate the agency’s current list of food chemicals under review.<sup>5</sup> It is not obvious why opiates, a chemical contaminant, have been excluded from the workplan. The list clearly includes other chemical contaminants under review, such as the heavy metals being reviewed under the FDA’s Closer to Zero initiative. Opiate alkaloid contamination of poppy seeds is clearly under consideration by the agency, as evidenced by the January 15 request for information. This review would therefore appear to be within the scope of FDA’s food chemical workplan and should be prioritized transparently alongside FDA’s other food chemical review work.

We ask that the FDA update its published list to include opiate alkaloids in poppy seeds. Incorporating a review of the Petition into the FDA’s list will provide transparency and allow the public to understand how the agency is meeting its commitments to provide timely review of food chemical safety risks. We also urge the FDA reconsider its denial of our petition and to set a threshold that protects the public from harm due to this contaminant.

Sincerely,



Sarah Sorscher, JD, MPH  
Director of Regulatory Affairs  
Center for Science in the Public Interest

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<sup>5</sup> FDA. List of Select Chemicals in the Food Supply Under FDA Review. n.d. <https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review> Accessed January 21, 2025.