



February 7, 2022

Susan T. Mayne Ph.D.  
Director, Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
Building CPKI, Room 4B064  
College Park, MD 20740  
*Submitted via email to:* Susan.Mayne@fda.hhs.gov

Re: Citizen Petition from Center for Science in the Public Interest Requesting Regulations and Guidance Establishing a Maximum Permissible Threshold of Opiate Alkaloid Contamination of Poppy Seeds, Submitted February 5, 2021 (FDA-2021-P-0168)

Dear Dr. Mayne,

The Center for Science in the Public Interest (CSPI) submits this letter requesting a meeting to discuss the status of the citizen petition we submitted to the Food and Drug Administration (FDA) on February 5, 2021.<sup>1</sup>

Our petition requested that the agency coordinate with the Drug Enforcement Agency and Customs and Border Protection to establish a safe threshold for opiate contamination in poppy seeds to draw a clear and unambiguous line between seeds that are safe for use in food and those that are dangerously contaminated with narcotics. We also requested that the FDA set import requirements, conduct testing, and issue an import alert to ensure that imported seeds do not exceed the maximum threshold.<sup>2</sup>

CSPI submitted this petition over a year ago on behalf of six families injured by contaminated poppy seeds and medical experts. In the petition, we identified an urgent risk to consumers from poppy seeds that have been contaminated with dangerous levels of opiate alkaloids, including morphine, codeine, and thebaine. As our petition details, opiate alkaloids are addictive, and can cause numerous adverse effects, including nausea, constipation, abdominal pain, sedation, and respiratory depression, as well as overdose leading to death. Moreover, poppy seeds that have been contaminated with opiates are considered controlled substances under the Controlled Substances Act.<sup>3</sup> Our petition cited evidence of at least 20 non-fatal overdoses and 19 deaths attributable to opiate-contaminated poppy seeds in the U.S., most of which have occurred since

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<sup>1</sup> Regulations.gov. Petition to establish a maximum limit of opiate alkaloid contamination of poppy seeds. Posted by the Food and Drug Administration. February 8, 2021. <https://www.regulations.gov/document/FDA-2021-P-0168-0001>. Accessed February 7, 2022.

<sup>2</sup> The petition focused on imports because poppy production is prohibited in the US, meaning all seeds sold in this country are imported. Center for Science in the Public Interest. Petition to establish a maximum limit of opiate alkaloid contamination of poppy seeds. February 4, 2021. [www.cspinet.org/resource/petition-establish-maximum-limit-opiate-alkaloid-contamination-poppy-seeds](http://www.cspinet.org/resource/petition-establish-maximum-limit-opiate-alkaloid-contamination-poppy-seeds). Accessed February 7, 2022.

<sup>3</sup> Drug Enforcement Administration. Unwashed Poppy Seed. Published November 2019. [https://www.deadiversion.usdoj.gov/drug\\_chem\\_info/unwashed\\_poppy\\_seed.pdf](https://www.deadiversion.usdoj.gov/drug_chem_info/unwashed_poppy_seed.pdf). Accessed February 7, 2022.

2015.

Following receipt of the petition, the FDA posted the document on regulations.gov, where members of the public posted 3,294 comments, the vast majority of which were submitted by individual consumers who were concerned that the FDA was allowing poppy seeds contaminated with opiates to enter the U.S. food supply.<sup>4</sup> In addition, on March 3, 2021, the Assembly of the State of Arkansas passed a Referendum (HCR1010) supporting the petition. This referendum was signed by Governor Asa Hutchison, and a copy was provided to FDA staff and U.S. Congressional leadership and has been submitted to the petition docket.<sup>5</sup> And on March 25, 2021, Senators John Boozman, Tom Cotton, and Richard Blumenthal likewise submitted a letter to the FDA expressing support for the petition and urging the agency to take clear, decisive action to address this risk to consumers.<sup>6</sup>

In addition, the Committee on Appropriations of the U.S. House of Representatives directed the FDA to take the actions requested in our petition in its Report on the 2022 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill. Specifically, that report stated “[t]he Committee is concerned with reports of positive drug tests, addiction, overdose, and death related to contaminated imported poppy seeds, and directs the agency to establish a maximum permissible threshold of opiate alkaloid content for poppy seeds and carry out appropriate regulatory or enforcement measures to ensure the safety of poppy seeds.”<sup>7</sup>

The FDA has not provided a final response to our petition. The agency acknowledged receipt of the petition on February 8, 2021, and on July 16, 2021 provided an interim response advising that it had not reached a decision on the petition because of other agency priorities and limited resources.<sup>8</sup>

While we acknowledge that the FDA has many priorities, including actions needed to address the ongoing COVID-19 pandemic, the agency nonetheless has been able to move forward with many initiatives in the year since our petition. For example, in December 2021 the agency issued draft guidance updating standards for sensory (primarily, smell) and other testing of decomposition in fish,<sup>9</sup> which can cause histamine formation leading to temporary illness, but is not associated

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<sup>4</sup> CSPI established a form for individual consumers to submit comments to the docket, which generated 3,288 of these comments. Center for Science in the Public Interest. Tell the FDA to Keep Poppy Seeds Free of Dangerous Opiate Contamination. July 27, 2021. <https://action.cspinet.org/page/81072/action/1?ea.tracking.id=take-action> Accessed February 7, 2022.

<sup>5</sup> State Representative Delia J. Haak also wrote individually to the agency in support of the petition on February 26, 2021, and that letter was also provided to FDA staff and submitted to the petition docket. Regulations.gov. Comment from Delia J Haak. March 9, 2021. <https://www.regulations.gov/comment/FDA-2021-P-0168-0008>. Accessed February 7, 2022.

<sup>6</sup> Regulations.gov. Comment from Senator Cotton, Senator Boozman, and Senator Blumenthal. March 31, 2021. <https://www.regulations.gov/comment/FDA-2021-P-0168-0009>. Accessed February 7, 2022.

<sup>7</sup> Report on the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2022. H.R. Rep. No. 117-82. At 102 (2021).

<sup>8</sup> Regulations.gov. 180 Day Interim Response Letter from FDA CFSAN to Center for Science in the Public Interest. July 19, 2021. <https://www.regulations.gov/document/FDA-2021-P-0168-0146>. Accessed February 7, 2021.

<sup>9</sup> Food and Drug Administration. Sec. 540.525 Scrombrotoxin (Histamine)-forming Fish and Fishery Products – Decomposition and Histamine (CPG 7108.24) Draft Compliance Policy Guide. December 2021. <https://www.fda.gov/media/155085/download>. Accessed February 7, 2022.

with serious adverse health consequences or death.<sup>10</sup> The agency has also, since our petition was submitted, issued guidance on standards of identity for food labeling,<sup>11</sup> food contact substance notifications,<sup>12</sup> and use of recycled plastics in food packaging, among other issues.<sup>13</sup> We suggest that responding to our petition should rise to the same or higher priority as these activities, given that our requested actions address a serious health risk that has contributed to the death of at least 19 Americans, and has garnered broad public interest.

As FDA has deliberated on our petition, jurisdictions outside the U.S. have taken action to protect consumers. In 2021, the European Commission established maximum levels of morphine and codeine in poppy seeds (20 mg/kg) and baked goods (1.50 mg/kg).<sup>14</sup> These standards, which will be in effect beginning July 1, 2022, were set to ensure that European consumers would not exceed the acute reference dose, taking into account consumption patterns for poppy in baked goods.

In the meantime, U.S. consumers remain at risk. Enforcement actions taken to date by the U.S. Department of Justice against individual retailers have proven inadequate to address the sale of contaminated poppy seeds by the retailers. For example, in October of 2021, the Department of Justice filed a civil forfeiture action against the Lone Goose Bakery in the U.S. District Court of the Northern District of Oklahoma, alleging that the company had marketed unwashed seeds containing 290 times the amount of morphine compared to grocery store brands, in violation of drug control laws.<sup>15</sup> This action coincided with a temporary halt to sales on Lone Goose's website, yet reviews on the website left by customers document that sales resumed within a few months of the action. "Their satisfying crunch is back wetting my beak. The goose has returned" says a review from December 2021. As of the date of this letter, poppy seeds can still be purchased on the Lone Goose website for \$29.00 per pound.<sup>16</sup>

The time is overdue for the FDA to establish standards that will protect U.S. consumers from ingesting dangerous levels of opiates through the food supply. Accordingly, we are requesting a meeting with you to review the evidence supporting our requests, and to receive an update on the

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<sup>10</sup> Food and Drug Administration. Scombrototoxin Poisoning and Decomposition. October 30, 2017.

<https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/scombrototoxin-poisoning-and-decomposition>. Accessed February 7, 2022.

<sup>11</sup> Food and Drug Administration. Guidance for Industry: Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity. November 2021. [www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-permits-interstate-shipment-experimental-packs-food-varying-requirements](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-permits-interstate-shipment-experimental-packs-food-varying-requirements). Accessed February 7, 2022.

<sup>12</sup> Food and Drug Administration. Guidance for Industry: Preparation of Food Contact Substance Notifications (Toxicology Recommendations). October 2021. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-substance-notifications-toxicology-recommendations>. Accessed February 7, 2022.

<sup>13</sup> Food and Drug Administration. Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations). July 2021. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>. Accessed February 7, 2022.

<sup>14</sup> Commission Regulation (EU) 2021/2142 amending Regulation (EC) No 1881/2006 as regards maximum levels of opium alkaloids in certain foodstuffs. December 3, 2021. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2142>. Accessed February 7, 2022. The maximum level refers to the sum of morphine and codeine, for which a factor of 0.2 is applied to the level of codeine.

<sup>15</sup> United States v. \$791,646.34 in United States Currency. Civil No. 21-CV-393-GKF-JFJ. (N.D.Okla. October 7, 2021).

<sup>16</sup> Appendix.

status of our petition.

Sincerely,

A handwritten signature in blue ink that reads "Peter Lurie". The signature is written in a cursive style with a horizontal line underneath the name.

Peter Lurie, M.D., M.P.H.  
President, CSPI

Sarah Sorscher, J.D., M.P.H.  
Deputy Director of Regulatory Affairs, CSPI

James Kincheloe, D.V.M., M.P.H.  
Food Safety Campaign Manager, CSPI

Eva Greenthal, M.S., M.P.H.  
Senior Science Policy Associate, CSPI

cc:

Frank Yiannas  
Dr. Conrad Choiniere  
Douglas Stearn

# Appendix

Blue Bird Poppy Seeds for Baking x +

lonegoosebakery.com/product/blue-bird-poppy-seeds/

We're open & shipping through the snow, getting all orders out on time! UPS & USPS might have weather delays on their end. Free Shipping \$50+

## Lone Goose Bakery

Home Shop Recipes Blog Points My Account Cart

Home / Poppy Seeds / Blue Bird Poppy Seeds for Baking SHIP DATE 2/8/21

Sale!



Blue Bird Poppy Seeds for Baking SHIP DATE 2/8/21

★★★★★ (359 customer reviews)

\$29.99 – \$529.99

The seeds have a ship date of Tuesday Feb 8. We have been processing orders on our usual schedule but we want to make sure to allow time for our additional weather-delayed inventory to arrive. This is a temporary issue due to increasing demand and a snowstorm.

These are our world-famous Blue Bird Baking Poppy Seeds. We appreciate your patience with our limited inventory as we work on finalizing our supply chain. We're happy to be back serving you!

Package Size:

Clear

This is 1 Pound of our famous Blue Bird Poppy Seeds for Baking.

Purchase this product now and earn 30 Points!

~~\$32.99~~ **\$29.99**

73 in stock

Earn up to 530 Points.

