



Poppy Seed White Paper

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Background

Poppy seeds used as food come from the plant species *Papaver somniferum* L., which is native to parts of Europe and Asia and currently cultivated around the globe. The same plant species is cultivated to make opium products and is listed as a Schedule II drugⁱ under the Controlled Substances Actⁱⁱ and therefore cannot be legally cultivated in the United States. The statute specifically defines opium poppy as the plant of the species *Papaver somniferum* L., and further specifies that the poppy straw and concentrate of poppy straw from the opium poppy are considered controlled narcotics,ⁱⁱⁱ but fully exempts the poppy seeds. As such, poppy seeds must be imported in the United States due to the ban on cultivation.

The latex or “milk” within the poppy straw contains naturally occurring opium alkaloids, including morphine. Mature poppy seeds do not contain the latex,^{iv} but can become contaminated with residual opium alkaloids as a result of certain growing and harvesting practices. Poppy seeds typically undergo preliminary cleaning and processing prior to import into the U.S. that reduces residual levels.^v Additional cleaning and processing, such as heat treatment,^{vi} further diminishes these residues in finished products sold to consumers.^{vii} Any remnants on food grade poppy seeds are typically present at very low levels.^{viii} Poppy seeds used as food in the United States are generally recognized as safe (GRAS) for their intended use for consumption as such.^{ix} Poppy seeds are GRAS only when used as a spice or seasoning under the statute. U.S. law requires that manufacturers ensure their products are safe. As addressed below, poppy seeds containing unsafe levels of morphine or used in applications other than as a spice or seasoning are not covered under the regulations and could be considered adulterated under current law.

“Unwashed Poppy Seeds”

In 2016, there was a reported case of a fatal morphine overdose resulting from the consumption of tea brewed from poppy seeds marketed as “unwashed poppy seeds.” As a consequence, there was an initiative to establish a legal framework to address morphine content in poppy seeds and products that contain poppy seeds. Additionally, a study was recently commissioned^x to evaluate the levels of morphine in tea brewed from products marketed as “unwashed poppy seeds.” This study found that of the 22 “unwashed poppy seed” products tested, a number of these products contained morphine levels above the lethal dose.

Additionally, some “unwashed poppy seed” products on the market have carried claims touting positive health benefits, such as “relieves pain” and “helps you sleep.” The U.S. Food and Drug Administration (FDA) has issued warning letters to companies for making unauthorized drug claims and indicated that the “product is not generally recognized as safe and effective”^{xi} for the uses for which it is marketed.

Current Laws & Regulations

- **FSMA**

Under current law, all food manufacturers must comply with the Food Safety Modernization Act (FSMA), which requires manufacturers to have preventive controls in place for hazards that can occur in the product. As such, poppy seeds must be processed to ensure that they are safe for consumption prior to being sold to or consumed by the final consumer.

- Definition of Adulteration

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the current Section 402 provides that a food is adulterated if it bears or contains any:

poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Under current law,^{xii} it is a prohibited act to introduce into interstate commerce any food that is adulterated or to adulterate any food. It is conceivable that poppy seeds with an extremely high level of opium alkaloid are adulterated and therefore it would be a prohibited act to introduce them into interstate commerce. The import, sale or introduction into interstate commerce of adulterated food in the U.S. is illegal and punishable by seizure, civil fines and potentially criminal penalties. The FDA has exclusive authority to enforce these statutory and regulatory provisions. Therefore, the issue of whether a food product is adulterated is one that must be brought by the FDA, as opposed to private litigation.

Potential Risk of Litigation

The FDA has exclusive authority to enforce the statutory and regulatory provisions related to the FFDCA. Should there be instances where a product causes actual harm, in addition to enforcement action by FDA, there is also potential for civil lawsuits and/or criminal actions brought in state court. Private litigation can only be brought if a product causes actual harm or death and, in that scenario, litigation would be brought under state law. Unlike a state statute such as California's Prop 65 where the enforcement mechanism is through private, bounty hunter lawsuits and the court system, there is not private enforcement via litigation for the FFDCA.

CSPI Petition

In February 2021, the Center for Science in the Public Interest (CSPI) submitted a citizen petition^{xiii} on poppy seed enforcement to the FDA. The petition urges the FDA to take steps regarding the potential presence of opiate alkaloids in poppy seeds. Requested actions include establishing a maximum level for opiate alkaloid content in poppy seeds and asking the FDA to issue an import alert based on that maximum level to ensure the safety of imported poppy seeds. FDA must respond and may either approve, deny, dismiss, or provide a tentative response to the petition. While the FDA is required to respond to a citizen petition within 180 days, it can take much longer, even years, and most citizen petitions are denied.

International Proposed Regulation

In July 2021, [Annex 6](#), a preliminary draft regulation to European Commission (EC) 1881/2006,^{xiv} included proposed levels for opioid alkaloids. The proposed maximum level was 20 ppm in poppy seeds as sold to the final consumer. There is also a proposed level of 1.5ppm for bakery products containing poppy seeds. The draft proposal provided an effective date of July 2022. Member states provided comments by August 22, 2021.

Previously Proposed Legislation

In April 2019, Senator Tom Cotton (R-AR) introduced a bill^{xv} to stop the sale of poppy seeds contaminated with extremely high levels of opium alkaloids, including high levels of morphine, that are sold directly to retail consumers. An identical bill was introduced in the House of Representatives.

The proposed legislation would have amended Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331) and make the following a prohibited act:

“(fff) Selling, or offering to sell, directly to consumers a food that is or contains poppy seeds, including concentrates, metabolites, constituents, or extracts of poppy seeds, that contain levels of morphine, codeine, or other alkaloid compounds that may render the food injurious to health.”

The bills died at the end of the 116th Congress, and no Committee hearings were held. The bill has not been reintroduced in the 117th Congress.

During the 116th Congress, Senator Cotton’s office reached out to ASTA to engage the manufacturers of food grade poppy seeds. The Senator’s office indicated that it had no interest in impacting the legitimate trade of poppy seed for food use. The Senator worked with ASTA to respond to the industry’s concerns about potential unintended consequences for the food trade. For example, ASTA worked to ensure the legislation did not create a standard for “washed” versus “unwashed” poppy seeds, as washing is not typical in the poppy seed process. Additionally, ASTA worked to ensure that the legislation applied only to poppy seeds sold directly to consumers to not interfere with the poppy seed trade. ASTA did not anticipate that the proposed legislation as introduced would disrupt the legitimate trade of food grade poppy seeds.

ⁱ The DEA places substances on a specific controlled substance schedule based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. A Schedule II substance is a substance that has a high potential for abuse which may lead to severe psychological or physical dependence. Examples of Schedule II narcotics include oxycodone, fentanyl, morphine, opium, codeine, and hydrocodone. <https://www.deadiversion.usdoj.gov/schedules/>. https://www.dea.gov/sites/default/files/drug_of_abuse.pdf. 21 USC § 841 provides penalties for offenses related to Schedule II drugs (<https://www.deadiversion.usdoj.gov/21cfr/21usc/841.htm>).

ⁱⁱ . 21 USC § 802(20). <https://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>

ⁱⁱⁱ 21 USC § 802(17). Poppy straw is considered part of the narcotic drug.

^{iv} EFSA Paper Section 1.3.5 page 15. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5243>

^v EFSA Paper page 57, <https://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>

^{vi} EFSA paper page 63, Section 3.2.3. Food Processing. Combination of poppy seed pretreatment and food preparation (baking) has been shown to result in an overall reduction of 80–100% in the final food product.

^{vii} Prof. Dr. Alejandro Cifuentes, CSIC Evaluation of Alkaloids Content in Raw Poppy Seeds and Processed Foods Containing Poppy Seeds, Section 2.2, October 9, 2013.

^{viii} Deborah Powers,¹ M.S.; Stephen Erickson, M.D.; and Madeleine J. Swortwood,¹ Ph.D. Quantification of Morphine, Codeine, and Thebaine in Home-Brewed Poppy Seed Tea by LC-MS/MS. *J Forensic Sci*, 2017. Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1111/1556-4029.13664>

^{ix} 21 CFR § 182.10

^x Deborah Powers,¹ M.S.; Stephen Erickson, M.D.; and Madeleine J. Swortwood,¹ Ph.D. Quantification of Morphine, Codeine, and Thebaine in Home Brewed Poppy Seed Tea by LC-MS/MS. *J Forensic Sci*, 2017. Available at:

<https://onlinelibrary.wiley.com/doi/abs/10.1111/1556-4029.13664>

^{xi} <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwpoppyseedwashcom-553349-07122018>

^{xii} 21 USC § 331, [http://uscode.house.gov/view.xhtml?req=\(title:21%20section:331%20edition:prelim\)](http://uscode.house.gov/view.xhtml?req=(title:21%20section:331%20edition:prelim))

^{xiii} https://www.cspinet.org/sites/default/files/attachment/2.5.2021_Petition_to_Establish_Safe_Opiate_Limits_for_Poppy_Seeds.pdf

^{xiv} European Regulation (EC) 1881/2006, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1881>

^{xv} Senator Tom Cotton, S. 1016, the Stephen Hacula Poppy Seed Safety Act. <https://www.congress.gov/bill/116th-congress/senate-bill/1016?q=%7B%22search%22%3A%5B%22s+1016%22%5D%7D&s=1&r=1>