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Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2021-P-0168: Growing, Harvesting, Processing, and Distribution of Poppy Seeds – Industry Practices Related to Opiate Alkaloids; Request for Information (January 15, 2025)**

To Whom It May Concern,

The American Spice Trade Association (ASTA) appreciates the opportunity to provide comments on FDA's Request for Information (RFI) titled "Growing, Harvesting, Processing, and Distribution of Poppy Seeds- Industry Practices Related to Opiate Alkaloids".<sup>1</sup> ASTA has worked collaboratively with FDA on prior inquiries regarding poppy seed processing and is committed to continued partnership on this matter. As such, ASTA has coordinated with its members and global counterparts to respond to this RFI.

ASTA was founded in 1907 and represents the interests of more than 200 members, including companies that grow, dehydrate, and process spices. ASTA members include U.S. based agents, brokers and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA members manufacture and market the majority of spices sold in the U.S. for industrial, food service, and consumer use. ASTA membership also includes companies that import, process, and trade poppy seeds. The highest priority for ASTA and our members is ensuring the supply of pure, safe spice to American consumers.

Below, we repeat the RFI questions and then provide our responses.

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<sup>1</sup> 90 Fed. Reg. 3873 (Jan. 15, 2025)

**Question 1.** Please tell us about the growing, harvesting, and post-harvest processes used to produce poppy plant crops and seeds and what types of equipment are used for these processes. What, if any, are the different processes used for different geographic areas where the plant(s) are grown and why are the different processes used? We are particularly interested in information about good agricultural practices, scoring or nicking pods, harvesting procedures, cleaning and separation of plant parts, opiate alkaloid testing method and frequency, thermal treatments (e.g., to degrade opiate alkaloids), packaging, cleaning of equipment, frequency of cleaning, and storage.

**ASTA Response:**

Cultivation & Growing Practices

Poppy plants are primarily commercially cultivated for pharmaceutical purposes. The poppy plant (*Papaver somniferum*) produces both latex (which contains opiate alkaloids) and seeds within the pod structure. The latex, which contains opiate alkaloids such as morphine and codeine, permeates all parts of the plant other than the seeds. Poppy seeds within the pods contain negligible concentrations of opiate alkaloids. However, residues of opiate alkaloids often deposit on poppy seeds during harvesting (or from pests or other damage) due to adhesion of opiate alkaloid-laden dust from the dried latex.

While some poppy seeds imported into the U.S. are derived from poppy plants grown exclusively for food use, most poppy seeds used in the U.S. food supply are sourced from poppy that has been produced for the pharmaceutical sector. The pharmaceutical sector cultivates varieties of poppy to target desired ratios of specific alkaloids, such as morphine and codeine. The seeds, which do not contain opiate alkaloids naturally while in the plant (but, as explained above, are inadvertently exposed to opiate alkaloid-containing dust during growing/harvesting), are a byproduct of pharmaceutical poppy production. Because exclusive licenses may be required to produce pharmaceutical-grade poppy crops, these supply chains are typically more regulated than conventional agricultural products. The following eighteen countries are authorized by the United Nations to produce poppy for pharmaceutical use: Austria, Australia, China, France, Germany, Great Britain, Hungary, India, Japan, Macedonia, Netherlands, New Zealand, Poland, Romania, Slovakia, Spain, Turkey, and Ukraine. The Netherlands and Spain are the two largest exporters of poppy seeds to the U.S., and exported approximately 2,200 metric tons (MT) and 1,800 MT last year, respectively<sup>2</sup>. Minor volumes of poppy seeds are also imported to the U.S. from Australia, Turkey, Hungary, India, and the United Kingdom.

A minor volume of poppy seeds grown exclusively for food use are sourced from countries where only “low-morphine” varieties of *P. somniferum* are authorized for cultivation (e.g., Germany, the Czech Republic). Certain countries (e.g., Hungary, Slovakia) cultivate both culinary and pharmaceutical varieties of poppy. While the majority of poppy seeds used in food in the U.S. are a byproduct of pharmaceutical production and are sold to the industrial bakery sector, a minor amount of poppy seeds produced exclusively for food use are used in the U.S. and are typically used in products sold directly to consumers.

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<sup>2</sup> U.S. Department of Agriculture, Foreign Agriculture Service. (May 2025) Global Agricultural Trade System Online: GATS. <https://apps.fas.usda.gov/gats/default.aspx?publish=1>

Growers adhere to strict Good Agricultural Practices (GAPs) to promote plant health, reduce the risk of contamination with latex dust, and maintain quality. These practices include, but are not limited to, the adequate control of pests and diseases, prevention of bad harvesting conditions caused by lodging of plants, and minimizing environmental stress factors. GAPs also address post-harvest activities such as proper cleaning, ventilated storage, and pretreatment processes aimed at reducing opiate alkaloid concentrations in poppy seeds.

### Harvesting Procedures and Equipment

The term “poppy straw” refers to the whole of the dried poppy plant. The straw contains both the cut, dried plant stalks and seed-bearing capsules. The capsules (minus the seeds) and straw are used by the pharmaceutical sector for subsequent extraction of opiate alkaloids.

Harvesting occurs once the poppy capsule is fully dry, which allows the capsule/pod to open naturally without crushing. Crushing of the pods may release latex and result in opiate-alkaloid contamination of the seeds. Harvesting involves cutting the capsule along with the upper portion of the stem (~3 inches) using combines adapted with harvester bars. The resulting seed-straw mixture is collected and stored in ventilated containers in preparation for cleaning and separation.

### Post-Harvest Processing

#### *Pre-Cleaning*

The initial separation of seeds from capsule fragments and the chaff/straw is performed using winnowing and threshing machines. Common equipment models include:

- Petkus U90
- Cimbria Delta 118
- Petkus M 12 3,5

These machines remove over 90% of the straw content from the seed mixture.

#### *Cleaning*

Although poppy seeds contain negligible levels of opiate alkaloids internally, their high oil content allows alkaloid-laden dust to adhere to the surface during harvesting and processing. Multiple physical cleaning steps are used to reduce surface contamination, including threshing to remove straw fragments, the use of destoners and density tables to separate lightweight debris, the use of aspirators to remove dust, and the use of vibrating sieves and air columns to dislodge any remaining particles.

#### *Equipment Cleaning*

Regular equipment cleaning is essential to minimize residual contamination. Cleaning protocols vary by facility and company, but typically include the frequent emptying of pipelines and hoppers.

### Sampling & Testing

Due to the uneven distribution of opiate alkaloids across batches, opiate alkaloid levels can vary significantly by shipment, pallet, or in individual bags. Testing may be performed using high-performance liquid chromatography with diode-array detection (HPLC-DAD). Each company establishes its own sampling and testing protocols with varying frequencies.

### Thermal Treatments

Some U.S. market customers require steam treatment of poppy seeds to reduce microbiological loads. While the primary objective of steam treatment is food safety, studies have shown that it may also result in up to a 30% reduction in opiate alkaloid residues.<sup>3</sup>

Additionally, most poppy seeds are subject to further processing – such as baking, cooking, or bottling – prior to consumption. Studies show that the process of baking reduces opiate alkaloid content by 80-90% at high temperatures (220 °C).<sup>4</sup> In addition to the secondary reductions obtained by heat treatments (e.g., steam treatment or baking) it has been reported that grinding can significantly reduce morphine content on poppy seeds by approximately 25%.<sup>5</sup> As such, levels of opiate alkaloid content in finished products often are significantly reduced by processing treatments.

**Question 2. Do buyers of poppy plants request specific varieties or cultivars based on the amount of opiate alkaloid produced by the variety or cultivar? If so, what are the specific varieties or cultivars and, if known, what are the preferred uses for these varieties or cultivars, and why are those varieties or cultivars preferred?**

**ASTA Response:** The majority of poppy seeds used in the food industry are not grown from cultivars bred specifically for food use. Instead, most are a byproduct of pharmaceutical-grade poppy cultivation, where the primary objective is the extraction of opiate alkaloids for medical applications. Seed collection occurs as a secondary process following the harvest of the capsules for alkaloid extraction.

While some spice companies do source seeds from poppy plants bred specifically for food use, production of food-specific varieties is limited and current supply cannot meet U.S. demand. As a result, much of the poppy seed supply chain is influenced by the pharmaceutical sector's priorities, and the seed varieties available to food manufacturers depend on the alkaloid needs and agricultural strategies of that industry, rather than on food industry specifications. However, to the extent that spice companies do have a choice, selection is generally based on quality and sensory attributes important for culinary applications, such as color, flavor profile, and performance/consistency in bakery products.

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<sup>3</sup> General J, Unbehend G, Lindhauer MG, Kniel B and Moser M, 2007. Untersuchungen zur Reduzierung von Morphin in Mohnsamen und Mohngebäcken mit praktikablen technologischen Massnahmen. Getreidetechnologie, 61, 36-42. (as cited in EFSA, 2011)

<sup>4</sup> Lachenmeier DW, Sproll C and Musshoff F, 2010. Poppy seed foods and opiate drug testing--where are we today? Therapeutic Drug Monitoring, 32, 11-18

<sup>5</sup> Sproll C, Perz RC, Buschmann R, Lachenmeier DW (2007) Guidelines for reduction of morphine in poppy seed intended for food purposes. European Food Research Technology, 226:307–310

**Question 3.** What types of equipment (e.g., agricultural threshers, combines, cultivators, other equipment) are used for harvesting poppy plants? FDA is aware that machine harvesting can result in opiate alkaloids being deposited on poppy seeds (Ref. 9). Please elaborate on style, model, settings, etc.

**ASTA Response:** Poppy plants are typically harvested using combine harvesters that have been adapted for poppy-specific needs. These combines are equipped with modified cutting heads or harvester bars designed to remove only the upper portion of the plant—approximately the top three inches—which includes the seed capsule and a small section of the stem. This selective cutting approach helps preserve seed quality and facilitates efficient collection while leaving most of the stalk behind.

Machine harvesting can result in contact between the seeds and opiate alkaloid-containing plant surfaces. To address this, the spice industry employs multi-stage cleaning systems to reduce opiate alkaloid content. These include threshers, gravity tables, fans, stone removers, magnets, and optical sorters. Examples of commonly used cleaning equipment include:

- Petkus KD 120, KD 400, U90 (gravity table)
- HEID GA-310 (gravity table)
- Superciclofan Cimbria CF-615 and CF-930 (dust separation ventilator)
- Cimbria Delta series (seed processing cleaners)
- Sortex optical sorters (optical sorting)

**Question 4.** What practices are used to monitor, control, reduce, or otherwise affect poppy seed opiate alkaloid content, such as opiate alkaloid testing or poppy seed heat treatments (Refs. 10-12)? We are particularly interested in information on the types of practices to reduce opiate alkaloids and frequency of use of the practices, as well as any evidence of their impact on the opiate alkaloid content of poppy seeds and the quality of the seeds.

**ASTA Response:** Several practices are employed across the supply chain to monitor, control, and reduce opiate alkaloid content in poppy seeds. These practices include both mechanical cleaning processes and thermal treatments, as well as periodic analytical testing to assess opiate alkaloid levels.

The primary method for reducing opiate alkaloid residues on poppy seeds is dry mechanical cleaning, which removes plant-derived dust and debris that may contain opiate alkaloid residues. As previously noted, common equipment and techniques include the use of threshers to separate seeds from capsule and stem fragments, gravity tables and destoners to sort seeds and remove foreign particles based on weight and density, air aspiration systems and fans to extract dust and lightweight plant debris, vibrating sieves and air columns to further clean the seed surface, and optical sorters to identify and remove damaged seeds. These dry-cleaning steps are applied before packaging and further processing to ensure seed cleanliness.

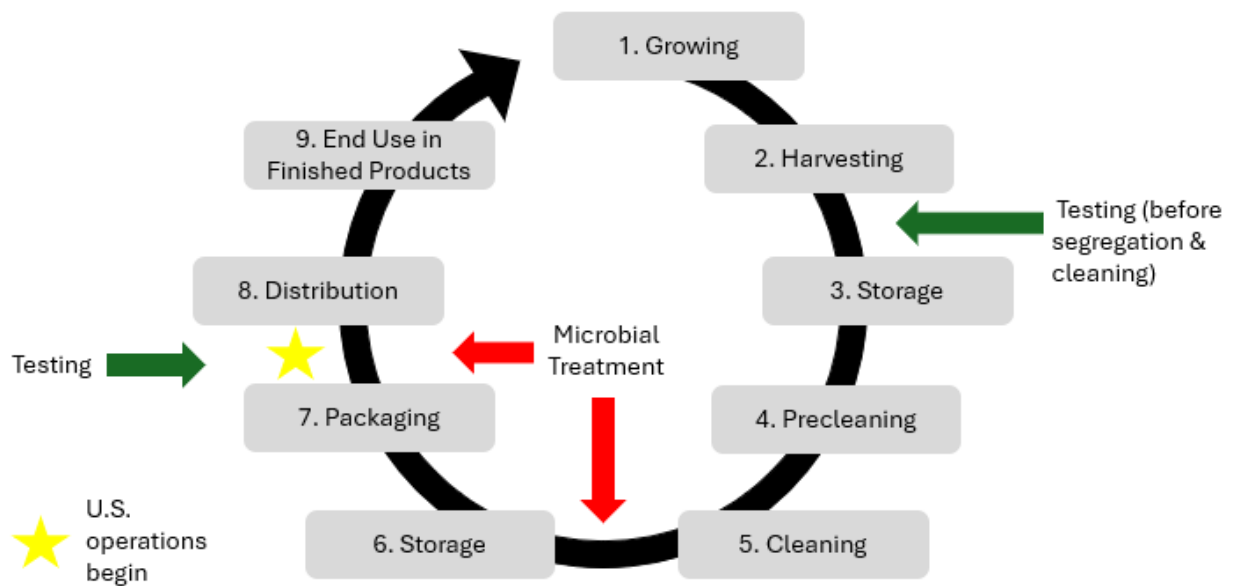
Additionally, as discussed above, further processing of poppy seeds may result in reductions in opiate alkaloid content as a secondary benefit. Moreover, poppy seeds are rarely consumed raw. Poppy seeds typically undergo cooking or baking during food preparation, which can contribute to further reductions in alkaloid content.

Opiate alkaloid content is periodically monitored through analytical testing by using HPLC-DAD. However, it is notable that opiate alkaloid levels can vary significantly due to the heterogeneous distribution of opiate alkaloid-containing dust. Even within a single lot, sample-to-sample variability is common. Opiate alkaloid levels may also differ depending on where in the supply chain testing occurs. For example, higher levels of opiate alkaloids may be detected at import as seeds may not yet have undergone final cleaning or sterilization. Comparatively, poppy seeds tested at retail typically reflect additional post-import processing, which may result in lower levels of opiate alkaloids. This variability complicates the establishment of universal thresholds or industry specifications.

**Question 5. What are the various intermediaries and processes that are part of the supply chain for poppy seeds? Please include information about what intermediaries (such as brokers, exporters, importers, consolidators, manufacturers, and retailers) and processes (such as opiate alkaloid testing, testing frequency, packing, sale, and transportation) might be involved at various stages throughout the poppy seed supply chain.**

**ASTA Response:** The supply chain for poppy seeds involves a network of intermediaries and processors that differ depending on whether the seeds are a byproduct of pharmaceutical poppy cultivation or grown exclusively for food use.

An example of a typical poppy seed supply chain and key processes is provided in Figure 1. It is important to note that not all processes are applied for all importers' supply chains (e.g., testing is discretionary, microbial treatment may depend on end use) or at the same stage. Additionally, please note that there may be variability amongst supply chain operations in the order and steps that are applied.



**Figure 1.** Overview of Poppy Seed Supply Chain & Processes

Exporters and consolidators may include companies located in the producing countries that collect and clean poppy seeds, consolidate lots from various farms, and prepare them for international shipment. At this stage, these operations typically perform mechanical cleaning and conduct initial quality checks. These operations may also perform opiate alkaloid testing before export.

International brokers often act as intermediaries between exporters and importers. They help match the poppy seed supply with buyer specifications, arrange logistics, and facilitate negotiations.

Importers in the U.S. are responsible for ensuring that the incoming poppy seeds comply with food safety regulations and determine whether additional microbial reduction treatments are required.

Processors and manufacturers perform additional post-import processing as appropriate, such as steam treatment, final cleaning, and/or repacking into consumer-ready retail quantities or bulk packs for industrial bakeries or foodservice customers.

Retailers sell the final product to consumers or commercial food manufacturers. Products may be packaged as whole poppy seeds, processed or ground seeds, or incorporated into finished bakery products.

Opiate alkaloid testing can occur at multiple points and testing frequency varies by company and region. However, testing is most commonly performed immediately after harvest (before segregation of the seeds and stem and prior to cleaning), post-cleaning, post-packaging, and pre-distribution.

**Question 6. What activities are performed in the distribution chains of poppy seeds? For example, do distributors or wholesalers engage in opioid alkaloid testing and heat treatments of poppy seeds? If so, what types of testing, treatments, or other activities are performed and how frequently are such activities performed?**

**ASTA Response:** As previously outlined, producers and exporters in poppy-producing regions may conduct analytical testing of poppy seeds to measure opiate alkaloid content. These results may be shared with importers or distributors in the U.S. as part of standard quality documentation. U.S.-based importers and distributors may conduct additional testing. However, this testing typically focuses more heavily on food safety specifications, such as microbiological safety, physical contaminants, or quality specifications (e.g., seed color, size).

As previously discussed, poppy seeds undergo microbial reduction treatments to comply with food safety requirements. These treatments are primarily intended to reduce the natural microbiological load of the poppy seeds and are not designed specifically for opiate alkaloid reduction, although reductions may occur as a secondary benefit. These treatments are typically applied prior to further distribution to food manufacturers or retail packaging.

**Question 7. Describe the role of any brokers or other intermediary distributors that sell poppy seeds between pharmaceutical companies (or poppy plants grown for pharmaceutical use) and food manufacturers. Do brokers or other intermediary distributors request poppy seeds from specific cultivars of poppy plants? If so, what are these specific cultivars?**

**ASTA Response:** Both brokers and distributors facilitate the movement of poppy seeds from origin countries to end users in the food industry. These operations perform distinct but complementary roles. Brokers primarily represent poppy seed sellers (e.g., producers from origin countries) and help negotiate and arrange contracts with U.S. buyers (such as importers or food manufacturers). In contrast, distributors purchase and import poppy seeds directly. Distributors also may oversee testing of poppy seeds for food safety parameters and may coordinate additional processing steps (e.g., steam sterilization, grinding, bottling).

Specific cultivars are not typically requested by brokers or distributors, as the majority of poppy seeds used by the food sector are derived as a byproduct of pharmaceutical poppy cultivation. However, quality specifications may be established for organoleptic and functional characteristics.

**Question 8. Do brokers or other intermediary distributors typically sell poppy seeds direct to retailers or individual consumers? What additional precautions or steps are taken when selling directly to retailers or consumers?**

**ASTA Response:** In the U.S., poppy seeds can be used as a food ingredient or for the production of edible seed oil. The vast majority (approximately 90%) of poppy seeds are sold by the spice industry to



industrial bakeries for use as ingredients in baked goods and other processed foods. A minor percentage of poppy seeds are sold at retail directly to consumers for home baking applications.

While brokers do not sell directly to retailers or consumers, they may facilitate transactions between producers and retailers. Distributors may sell directly to retailers. In all cases, poppy seeds generally undergo additional processing, such as sterilization or baking, prior to consumption.

**Question 9. What manufacturing processes are used to manufacture poppy seed food products and what processes are applied to reduce poppy seeds' opiate alkaloid content? Information about any processes, such as initial inspection, cleaning or separation of plant parts, mixing, crushing, blending, treatments such as heating or washing, drying, cleaning of equipment, cleaning frequency, packaging, testing, testing type, and transportation, used to process poppy seeds and manufacture poppy seed products would be useful.**

**ASTA Response:** As discussed in previous responses, a variety of manufacturing processes are employed to ensure product safety and quality, including physical cleaning steps to remove alkaloid-containing dust and debris, as well as subsequent treatment steps that have the secondary benefit of reducing opiate alkaloid content.

**Question 10. When using contract growers or otherwise procuring seeds, what specific varieties, cultivars, characteristics (e.g., color, aroma, opiate alkaloid levels), or other specifications are typically required for food use?**

**ASTA Response:** When sourcing poppy seeds for food use, spice companies typically do not require specific varieties or cultivars, as seed availability is largely influenced by pharmaceutical cultivation priorities. However, to the extent that spice companies source "food-grade" poppy seed, selection is generally based on quality and sensory attributes important for culinary applications, such as color, flavor profile, and performance/consistency in bakery products.

**Question 11. If you are a manufacturer of poppy seeds or poppy seed products, what types of customers (e.g., manufacturers of other products, retailers, individual customers) do you sell to? What additional precautions or steps, if any, are taken when selling to various customers?**

**ASTA Response:** Manufacturers and suppliers of poppy seeds primarily sell to industrial food manufacturers, such as commercial bakeries. These customers incorporate poppy seeds as an ingredient in baked goods. This segment represents the vast majority of poppy seed usage in the U.S. food supply chain.

**Question 12. If you are a manufacturer of poppy seeds or poppy seed products, what types of sellers (e.g., manufacturers of other products, growers, other sources) do you buy poppy seeds from? What additional precautions or steps, if any, are taken when buying from various sellers?**

**ASTA Response:** Manufacturers of poppy seeds primarily procure seeds from origin producers, including growers or processors located in countries authorized to cultivate poppy plants and who often operate with pharmaceutical poppy production systems. Due to regulatory controls on poppy cultivation, these producers are subject to strict governmental oversight. Buyers will typically seek poppy seeds that align with their own internal food safety, quality and organoleptic/performance specifications.

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ASTA thanks FDA for the opportunity to comment on its RFI on poppy seed industry practices. Please do not hesitate to contact us if you have any questions.

Sincerely,



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