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Photo courtesy of PNW Farmers Cooperative.

The Safety and Regulation of Chickpeas, Lentils, and Field Peas in Farming and Post-Harvest Operations

ABSTRACT

Pulses are food legumes and include the seeds of dry field peas, lentils, and chickpeas. This family of agricultural commodities plays an important role in human nutrition worldwide and has an extensive track record of safety. Familiar foods in North America made from these three commodities include hummus, split pea soup, dahl, and canned garbanzos. Raw, dry packed chickpeas, lentils, and field peas are never intended as a ready-to-eat food and must be further processed to be edible. Pulses that have been harvested, stored, cleaned, and bulk packed rarely introduce chemical or physical hazards into the food supply chain. They are further thermally processed to minimize biological hazards. Although growing, storage, cleaning, and packing of pulses is more akin to primary agriculture than to food processing, controls such as pest control, good manufacturing practices, audits, screens, magnets, gravity tables, and dry equipment cleaning all serve to ensure product safety. Several of the regulations adopted under Congress' Food Safety Modernization Act, including updated registration requirements, the Produce Safety rule, and preventive controls for both human and animal food, may apply to the agronomy, cleaning, and packing of pulses. Exemptions within these rules and withheld U.S. Food and Drug Administration enforcement reduce some industry compliance requirements.

INTRODUCTION

Pulses are important crops to the Pacific Northwest and Plains states. They are part of the food legume family, as are oilseeds, and include the seeds of dry field peas *(Fig. 1)*, chickpeas (garbanzos) *(Fig. 2)*, and lentils *(Fig. 3)*. Together, they have been important to human nutrition since ancient times. Recently, pulses have assumed a greater distinction and distribution in the North American diet through products such as hummus dip, pea protein isolate, and meat protein substitutes.

New U.S. Food and Drug Administration (FDA) food safety regulations have brought additional scrutiny to raw agricultural commodities that receive minimal or no microbial kill steps. For example, many recent outbreaks attributed to *Escherichia coli* have been associated with the consumption of romaine

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Figure 1. Dry field peas.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 2. Chickpeas.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 3. Lentils.

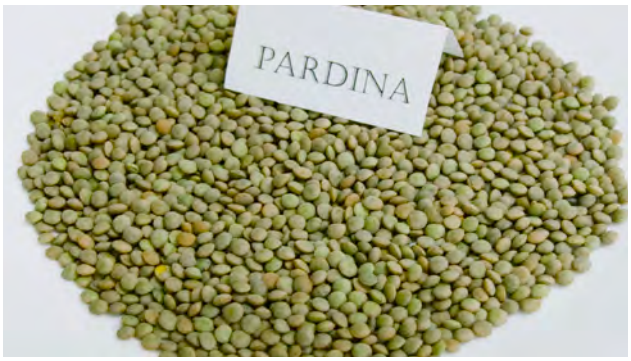

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 4. Dry field pea plants.

Photo courtesy of USA Dry Pea and Lentil Council.

lettuce. This article provides a review the safety of three pulses —chickpeas, lentils, and dry field peas—that are marketed as raw agricultural products and destined for further processing. Potential food safety hazards during growing, harvesting, storage, and cleaning are discussed, along with industry best practices to prevent food contamination. In addition, the article characterizes the regulatory status of these pulse types in the United States through a review of the new Food Safety Modernization Act (FSMA) rules governing the growing, storage, cleaning, packing or packaging, and distribution of these commodities. Discussion of the FSMA regulations is intended for educational purposes only and is not provided or represented as legal advice. Specific questions regarding regulatory compliance should be directed to professional licensed legal counsel in food law and to the FDA's Technical Assistance Network (TAN).

Legumes are part of the botanical family Papilionaceae and include dry peas, lentils, chickpeas, dry beans, soybeans, fava beans, peanuts, vetches, lupines, and alfalfa *(2)*. The Food and Agriculture Organization of the United Nations uses the term "legume" to refer to all leguminous plants. Their seeds are categorized by oil content: pulses such as dry field peas, lentils, and chickpeas are legumes having low fat content; leguminous oil seeds (e.g., soybeans and peanuts) have high fat content. Legumes have butterfly-shaped flowers that produce pods with seeds.

All pulses are legumes and are defined by the Food and Agriculture Organization of the United Nations as "crops harvested solely for dry grain of leguminous plants, excluding crops harvested green, such as green beans and green peas, which are considered vegetables" *(6)*. Legumes and pulses are the second leading group of plant food staples after cereal grains and are recognized as good-quality vegetable protein. Pulses are high in dietary fiber, resistant starch, protein, vitamins, minerals, and other beneficial nutrients such as phenolic acid, an antioxidant. The mean protein value for lentils is 25%, for chickpeas is 21%, and for dry peas is 24% *(7)*. Legumes contain antinutritional factors, and most of these nutrient inhibitors are heat labile and decrease significantly with further processing by food service or by consumer preparation. A description of three key pulse commodities is as follows:

1) Dry field pea or "dry pea" is an important food crop and grain legume derived from the common pea, *Pisum sativum* subsp. *arvense* (L.) Asch (also referred to as *P. arvense*), a herbaceous annual in the *Fabaceae* family *(Fig. 4)*. The crop matures and dries in the field and is a commodity crop that is a distinctly different cultivar from the succulent or garden pea. The succulent pea is marketed as a fresh or canned vegetable, and some varieties have an edible pod such as snow peas and sugar peas. The common pea belongs to a different genus than

Figure 5. Chickpea plants.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 6. Harvesting pulses.

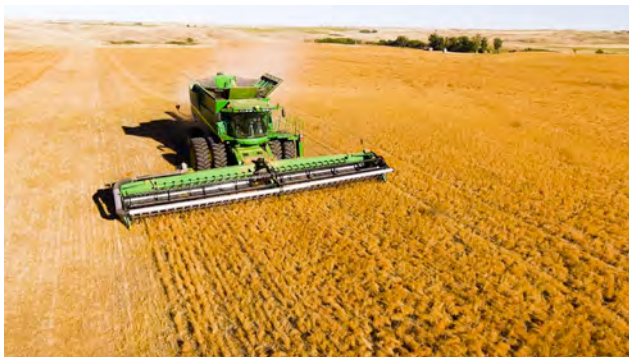

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 7. On-farm pulse storage.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 8. Country pulse elevator.

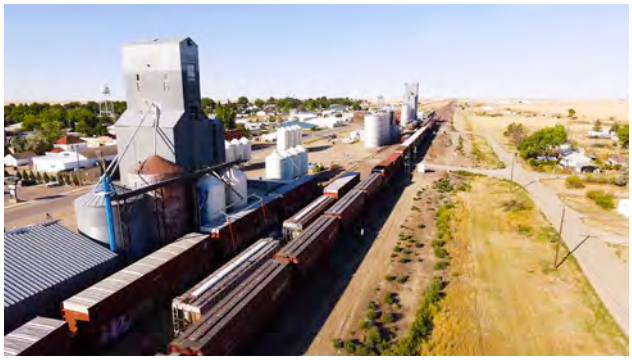

Photo courtesy of USA Dry Pea and Lentil Council.

sweet pea (*Lathyrus odoratus*). Although edible, sweet peas have seeds that contain toxic lectin compounds that must be heat inactivated. The pods of dry field peas are ca. 75 mm long and contain four to nine green, yellow, or cream-colored seeds. Once planted, peas require 100 days to mature dry seed. Dry peas are harvested from pods that are inedible in contrast to succulent peas. Dry peas and succulent peas are not grown together for commercial purposes and are not comingled during further processing. Succulent pea seeds become wrinkled when dry, but dry field peas seeds have a smooth appearance.

2) Lentils (*Lens culinaris*) are a feathery-looking legume with lens-shaped seeds that grow two per pod. The seeds range from red to yellow to green to brown, and even black. There are both large (Chilean type) and small (Persian) seed varieties, ranging from 2 to 9 mm in diameter. Lentils are a rich source of dietary fiber.
3) The chickpea, another grain legume, is a self-pollinated pulse crop *(Fig. 5)* that gets its name from the semblance of the seed to a baby chicken head. The two main chickpea varieties (both *Cicer arietinum*) are Desi and the Kabuli. Desi has smaller, more angular seeds than Kabuli, with thick coats that vary from light tan to solid black. Kabuli, known as garbanzo beans in the United States, have 7- to 10-mm-diameter seeds, with coats ranging from white to tan. The seeds reach maturity in 120 days, when seeds begin to change color inside the upper-most pods and when the leaves turn yellow or brown. The lowest pod height is typically 107 cm (4 in.) above the ground *(10)*. The worldwide mean annual production of chickpeas from 2013 to 2017 was recorded at 11.67 million tons *(11)*.

These three pulse types are allowed to mature and dry in the field before harvest. Drying pulses in the pod ensures the pod separates from seeds during combining (harvesting) operations *(Fig. 6)*, and this enables crop storage with no mechanical drying.

After harvest, chickpeas, lentils, and field peas are stored in elevators or silos at the grower farm *(Fig. 7)* or at a "country"-located facility *(Fig. 8)*. They are then shipped to a cleaning facility *(Fig. 9)*, where seeds are run through equipment to remove field debris, foreign materials, extraneous vegetable materials, and cosmetic defects. Industry vernacular for this cleaning process is "milling" or "processing," although it does not involve any heating, cooking, washing, or grinding steps. This cleaning process also typically creates no additional risks for introducing biological hazards into the seeds due to its dry nature, the regular cleaning and sanitation of these facilities, and further thermal processing by end users. On completion of

Figure 9. Pulse cleaning facility.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 10. Tote packing of pulses.

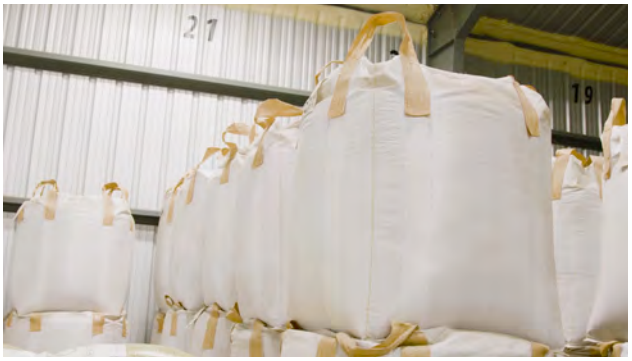

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 11. Split dry field peas.

Photo courtesy of USA Dry Pea and Lentil Council.

Figure 12. Field peas inspection.

Photo courtesy of USA Dry Pea and Lentil Council.

cleaning, dry pulses are typically packed into food-grade bulk nylon totes *(Fig. 10)* or 50# or 100# polypropylene-lined paper or burlap bags that are intended for industrial (food processor) customers. Some facilities also may package product into smaller food service-size or retail-size packaging. Dry pulses can be stored for many years under proper conditions of temperature, humidity, and pest control.

There are few significant biological, chemical, and physical hazards in the agronomy, storage, and cleaning of chickpeas, lentils, and dry peas. Potential chemical hazards may involve mycotoxins, pesticide residues, lectins, and antinutritional factors. Some individuals have food allergies to pulse proteins *(8)*. The FDA specifies some spore-forming and vegetative pathogens as potential biological hazards in raw dried chickpeas and lentils. Physical hazards may include pests, metal, and other foreign materials. Farms, storages, and cleaning facilities using best practices leverage food safety prerequisite programs, critical control points, and preventive controls to minimize or eliminate these hazards.

Agronomy and postharvest operations for the three pulses under discussion are regulated through several FSMA regulations. Although chickpeas and lentils are exempt from the FDA's Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("Produce Safety") rule, dry field peas were not exempted until 2019 when the FDA indicated they would suspend compliance requirements through "enforcement discretion" *(32)*. Farms fitting within the primary production and secondary activities farms' definitions are exempt from FDA registration requirements. The human and animal food preventive control rules contain exemptions for these farms, along with enforcement discretion for secondary farms that pack and hold pulses. Facilities such as storages and cleaning operations that are not farms must not only register with FDA but also comply with requirements within one or both of the two preventive control rules.

PULSE AGRONOMY

In the United States, pulses are cool-season crops grown primarily in the Northern Plains (Montana, North Dakota, and South Dakota) and the Palouse (Idaho, Washington, and Oregon) regions. They are planted in rotation with cereals, creating higher cereal yields by disrupting pests and conserving soil moisture *(2)*. As legumes, pulses produce their own nitrogen by symbiotic growth with a soil bacterium. The most serious disease for chickpeas is *Ascochyta* blight, which can be treated with systemic fungicides *(10)*.

Pulse crops must dry on the vine before harvest by a single pass of a combine; 12% moisture is the optimum level for harvest to prevent spoilage and mold problems. According to

the "Pulse Advisor," lentils can be combined (harvested) at 16 to 18% moisture; chickpeas can be harvested at 18% moisture, and peas at 18 to 20% *(3)*. Premature harvest of high-moisture pulses is avoided because the product may mold, ferment, or split during storage. Chickpeas and green lentils must be stored at less than 14% moisture and peas at less than 16% to prevent molding during product storage. Final maximum moisture levels to meet U.S. Department of Agriculture (USDA) grading standards for U.S. #3 grade are 15% for dry peas, 14% for lentils, and 18% for chickpeas *(17)*.

POSTHARVEST HANDLING

Pulses can be stored after harvest for up to 2 years under optimum conditions and in some cases for 3 to 4 years. Much of the crop may be stored on the farm or delivered to country elevators at harvest time, before it is cleaned, packed, and distributed. If high moisture is a problem, chickpeas and lentils can be stored in aerated hopper-bottom bins *(2)*.

Without dry, cool conditions during storage (i.e., <16% moisture and <15°C [59°F] for dry peas), pulses may be susceptible to spoilage by mold and insect infestation. Pulses are rarely infested when stored under dry, cool conditions *(3)*, but stored grain insects of concern include the dry bean weevils (bruchids): vetch weevil (*Bruchus brachialis* Fahraeus), pea weevil (*Bruchus pisorum* L.), broadbean weevil (*Bruchus rufimanus* Boheman), and bean weevil (*Acanthoscelides obtecetus* (Say)) *(3)*. Bean weevils also can attack beans and peas when they are in the field *(18)* and can continue to breed in dry seeds if stored in a warm place. The lepidopteran Indian meal moth (*Plodia interpunctella* (Hübner)) also can attack dried peas and beans, leaving webbing and frass from larvae feeding on product that is split or has cracked seed coats. Bruchids are controlled by sanitation and inventory control in the elevator facility *(15)*. Additional controls for stored product insects include placing diatomaceous earth in the bottom of storage bins. This material acts as an insecticide by absorption of insect cuticle lipids and fatty acids, resulting in desiccation and death.

FURTHER PROCESSING AND USE OF PULSES

Dry peas are traditionally used in soups, casseroles, stir fry dishes, salads, and pot pies, always after the dry hard seeds are rehydrated *(2)*. Canned dry peas are soaked for 10 to 15 h, blanched at 88°C to 93°C (190 to 199°F) for 4 to 6 min, and brined and filled into cans in preparation for commercial sterilization.

Peas also can be further processed through a cleaning, seed coat-heating, and splitting process into split peas *(Fig. 11)*, a popular soup ingredient in North America and Europe. In Asian countries, whole dry peas may be roasted or fried and consumed as a snack. This process involves rehydrating dry product for 8 to 10 h at room temperature before frying in oil.

A more recent use of dry peas is fractionation into pea protein and pea starch. These ingredients are made through either dry or wet fractionation processes that take advantage of the difference in physical properties of starch- and protein-containing particles *(2)*. Pea protein is used as a protein booster in such foods as nutritional bars, nondairy creamers and yogurts, and meat substitutes.

Chickpeas may be further processed through extensive cooking, canning, or milling into flour. A popular dip made from cooked garbanzos in the Middle East and North America is hummus. Like dry peas, chickpeas may be roasted to create a snack food. Pulses can be either wet or dry milled into flour products. Chickpea flour (sometimes known as gram flour) also is used as an alternative to wheat flour in gluten-free baked goods and for other cooked products such as falafel and farinata. The normal intended use of pulse flour calls for further cooking or baking before consumption.

In the Americas and Europe, lentils are typically prepared in soups. They may be further commercially processed through cooking, freezing, and canning. A lentil stew made with spices and water known as dhal is consumed regularly in India and South Asia.

Regardless of the final use of pulses, they must be cooked before consumption to assume an edible, palatable state. The only exception would be sprouting pulses for which there is not a thermal processing step and they thus poses a higher risk for biological hazards, such as *Escherichia coli, Salmonella,* and *Giardia.* Sprout production falls under the Produce Safety rule *(24)*, 21 CFR 112, and is addressed specifically in the FSMA guidance "Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry Draft Guidance, 2017" *(29)*.

POTENTIAL FOOD SAFETY HAZARDS OF PULSES

During growing and storage, beans and chickpeas may be exposed to potential biological, chemical, and physical food safety hazards. Under the right conditions, many types of fungi and bacteria can grow on pulses, including *Aspergillus, Cladosporium, Fusarium, Penicillium, Rhizopus, Rhizoctonia,* and *Macrophomia (4, 15)*. *Fusarium* and *Aspergillus* are the most probable mycotoxin-producing fungi in beans. Mycotoxin presence is correlated with seed discoloration *(14)*. Examples of storage fungi include *Aspergillus halophilicus* and *Aspergillus glaucus*, and growth occurs during storage of beans for 6 months or longer at a high moisture content. *A. halophilicus* has not been found to produce compounds toxic to humans and animals *(4)*, whereas *A. glaucus* and *Aspergillus candidus* have the potential to produce toxic compounds when beans are used as animal feed. *Aspergillus parasiticus* has been found to produce aflatoxins in navy, kidney, and pinto beans at 20% moisture content and at 21, 28, and 35°C. Ochratoxin and aflatoxin can be produced by *Aspergillus ochraceus* and *Aspergillus flavus*. Several species of *Penicillium* may be

associated with beans and also can produce mycotoxins such as penicillic acid and ochratoxin *(4, 12)*. *Rhizoctonia solani* can cause production of stress metabolites in beans known as phytoalexins *(4)*. For lentils, *Aspergillus* is the most prevalent genus of fungi, followed by *Rhizopus.* Aflatoxin is not produced under normal dry storage conditions *(15)*.

Mold growth will occur when beans contain greater than 18% moisture, leading to storage instability *(15)*. Chickpeas in the USDA #1, #2, and #3 grade categories and containing 18% moisture are graded as "high moisture" *(17)*. Optimal seed moisture levels for safe storage of pulses are 15% for peas and 14% for chickpeas and lentils *(1, 2)*. Mold growth can be prevented during storage with aeration and also by drying with warm air, especially for product that was harvested at high moisture.

In terms of pesticide hazards, the FDA import alerts were reviewed for pulses. Alert #99-08, "Detention without Physical Examination of Processed Human and Animal Foods for Pesticides," lists three cases of detention. This alert involved chickpeas and red whole lentils imported from Australia in 1991, 1992, and 2020. It included pulses with pesticide residues of haloxyfop, chlorpyrifos methyl, and chlorpyrifos *(33)*.

Another well-known hazard associated with legumes is the toxicity of phytoagglutinins or lectins *(16)*. These hemagglutinins are proteins that have the ability to agglutinate the red blood cells and bind to the epithelial cells of the intestinal tract, which can impair nutrient absorption. An edible legume and pulse that contains lectin is lentils.

Peas also have antinutritional factors, including trypsin inhibitors, phytic acid, and oligosaccharides. Trypsin (protease) inhibitors are low-molecular-weight proteins that bind to and inactivate the digestive enzyme trypsin. Phytic acid lowers bioavailability of minerals, and oligosaccharides cause flatulence. Trypsin inhibitors are inactivated by cooking or heat processing *(2)*. Lectins in legumes can be inactivated by heat during cooking or by controlled heating during food processing, such as cooking beans at 100°C (212°F) for 20 min *(16)*.

Chickpeas, lentils, and field peas contain storage proteins that may cause allergic reactions in susceptible individuals *(8)*. Nonpriority (emerging) legume allergies have been associated with severe allergic reactions.

Two databases were reviewed to ascertain the role of pulses in foodborne illness outbreaks: National Outbreak Reporting System (NORS) and Foodborne Illness Outbreak Database.

The NORS database, compiled by the Centers for Disease Control and Prevention, was queried for outbreaks attributed to chickpeas, lentils, and peas from 1998 to 2016 *(5)*. During this period, there were three outbreaks related to chickpeas and one for lentils, with a total of 72 illnesses and no deaths. Two of these chickpea outbreaks in 2007 and 2013 involved illness from *Salmonella enterica* from falafel or garbanzos served at restaurants. The other incident involved catered food with garbanzos, and *Clostridium perfringens* was the suspected pathogen. The other outbreak from lentils sickened 37 individuals from food prepared and served by a caterer; the causative agent was unknown.

The Foodborne Illness Outbreak Database is sponsored by Marler Clark *(9)*. The only reference to an outbreak caused by pulses between 1984 and 2017 was in July 2007 and involved *Salmonella infantis* linked to the consumption of garbanzo beans at a California restaurant.

Notably, the outbreaks documented in both of these databases involved garbanzos or lentils prepared through food service businesses (catering or restaurants), where postcooking contamination from poor food handling practices likely led to the growth of vegetative pathogens, viruses, or outgrowth of spore-forming bacteria. Lentils and chickpeas must be well cooked before serving, which acts as a microbial kill step for vegetative pathogens. There was no indication in any of the reported outbreaks that chickpeas or lentils were served in a raw, uncooked state.

The FDA's "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry," Appendix 1, contains "information on the potential biological, chemical, and physical hazards that are food-related and process related" *(30)*. Tables provided in Appendix 1 are published by the FDA for use by food processors who are compiling Food Safety plans as required by 21 CFR 117. These tables are referenced while conducting a hazard analysis of the ingredients or raw materials that will be processed into final products. For example, a hummus processor who is evaluating hazards from chickpeas would use data from the tables to determine whether preventive controls need to be established in the Food Safety plan. The tables are used to evaluate potential biological and chemical hazards associated with ingredients and raw materials used in food processing and potential hazards with these same items that may occur when they are undergoing processing. The tables do not specify whether potential hazards listed for pulses originate from growing, harvesting, transport, storage, cleaning, or packing activities.

Table 1J from this FDA Guidance Appendix *(30)* lists the following biological hazards from raw whole dried chickpeas, lentils, and other dry beans (dry field peas are not listed): *Bacillus cereus, Clostridium botulinum, Clostridium perfringens, pathogenic E. coli,* and *Salmonella* spp. The only potential chemical hazards listed in *Appendix 1* in *Table 2J* for the same pulses is "mycotoxins/natural toxins."

Finally, the process-related hazards listed for chickpeas and lentils in *Table 3J* are "bacterial growth and/or toxin formation due to lack of time/temperature control," "recontamination with environmental pathogens," and "metal." These are hazards that may occur when raw, dry, shelf-stable pulses are processed by cooking, retorting, milling, and other process steps into finished products. They are not potential hazards associated with cleaned, dry (low

TABLE 1. FSMA Requirement for Pulse Growing on Regulated Farms Under the Produce Safety Rule, 21 CFR 112

Crop Type	Rarely Consumed Raw Exemption 21 CFR 112.2	Worker Training 21 CFR 112 SUBPART C	Health and Hygiene 21 CFR 112 Subpart D	Agricultural Water 21 CFR 112 Subpart E	Biological Soil Amendments 21 CFR 112 Subpart F	Domesticated and Wild Animals 21 CFR 112 Subpart I	Growing, Harvesting, Packing, and Holding Activities 21 CFR 112 Subpart K	Equipment, Tools, and Buildings 21 CFR 112 Subpart L	Suspended Enforcement 2019 Produce Safety Rule Enforcement Policy-Guidance for Industry
Dry Field Peas		•	•	•	•	•	•	•	•
Chickpeas	•								
Lentils	•								

TABLE 2. FSMA Requirements for Pulse Storage

Storage Type	FDA Registration Section 415, FD&C Act[3]	Produce Safety Rule 21 CFR 112	Preventive Controls for Human Food Rule (PCHF) 21 CFR 117			Preventive Controls for Food for Animals Rule (PCAF) 21 CFR 507		Suspended Enforcement[4] Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs-Guidance for Industry January 2018
			Subpart B GMP's	Subpart C Preventive Controls	Subpart G Supply-Chain Program	Subpart B GMP's	Subpart C Preventive Controls	
On Farm Storage[1]		•	•					•
Off Farm Storage[2]	•	•	•	•	•		•	
Off Farm Storage: Co-located with human food processing facility	•		•	•	•	—	—	
Off Farm Storage: Co-located with animal food processing facility	•		—	—	—	•	•	

[1]FDA-defined primary production and secondary activities farms (21 CFR Part 1.227). Farm or Farm mixed-type facilities holding dry pulses must implement GMP's from applicable requirements in 21 CFR 112 or from 21 CFR 117, Subpart B. See 21 CFR 117.5 Exemptions in (k)(2).
[2]Off-farm storage facilities for RACs that are produce must implement GMPs from applicable requirements in 21 CFR 112 or in 21 CFR 117 Subpart B (21 CFR 117.8). No exemptions from preventive controls for solely engaged "vegetable" RACs storage facilities (21 CFR 117.5 (j)).
[3]Federal Food, Drug, and Cosmetic Act.
[4]Enforcement discretion of human food preventive controls and animal food GMP's and preventive controls for facilities that would qualify as secondary activities farms except for the ownership of the facility or except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity.

water activity [a_w] value), raw packaged pulses, or those destined for further processing into products such as soup.

FOOD HAZARD CONTROLS IN PULSE AGRONOMY

Because raw dry pulses are not consumed as ready-to-eat foods and are always cooked or otherwise thermally treated during further processing or consumer preparation, biological hazards during growing are of lesser concern to dry pulse cleaning and packing operations. Pulse crops also grow above ground, and unlike grains such as wheat, which has a husk, the edible seeds of dry peas, chickpeas, and lentils are fully enclosed in protective pods.

For control of chemical hazards, mycotoxins may be tested postharvest during storage and cleaning operations. Adequate field drying is key to mycotoxin prevention, because it prevents mold growth during later storage. Grower good agricultural practices include controlled application of pesticides and other agricultural chemicals. Application of these products is recorded to confirm use complied with the specified product label application rate.

TABLE 3. FSMA Requirements for Pulse Cleaning Facilities

Facility Type	FDA Registration Section 415, FD&C Act[2]	Produce Safety Rule 21 CFR 112	Preventive Controls for Human Food Rule (PCHF) 21 CFR 117			Preventive Controls for Food for Animals Rule (PCAF) 21 CFR 507		Suspended Enforcement[3] Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs-Guidance for Industry January 2018
			Subpart B GMP's	Subpart C Preventive Controls	Subpart G Supply-Chain Program	Subpart B GMP's	Subpart C Preventive Controls	
On Farm[1] Cleaning and Packing (Dry Field Peas Only)		•	•					See also 2019 Produce Safety Rule Enforcement Policy: Enforcement Discretion for Certain Pulses
Off Farm Cleaning and Packing	•	•	•	•	•	•	•	•

[1]FDA-defined primary production and secondary activities farms (21 CFR Part 1.227).

[2]Federal Food, Drug, and Cosmetic Act.

[3]Enforcement discretion for facilities that would qualify as secondary activities farms except for the ownership of the facility or except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity. Exemption applies only to preventive controls for human food. Pulses are categorized as "produce RACs" and are not exempted from human food GMPs. Preventive controls plus GMP exemption only applies to animal foods. "Facilities" in the Policy Regarding Guidance are considered to be only facilities required to register under the FD&C Act.

Physical hazards, including stones, field trash, extraneous vegetative matter, and metal, may be present in raw pulses. However, combining (harvesting) equipment removes much of these materials during harvest. Screening equipment, typically used just before packing, also may be used to remove such materials.

FOOD HAZARD CONTROLS IN STORAGE FACILITIES

Storage of pulses is accomplished through grain elevators. Equipment such as dump pit drag chains, augers, grain transfer legs, and bins must be maintained in a dry state to prevent mold and bacterial growth. Some storage facilities also may use aeration to further dry incoming crops. Aeration bins are commonly used for lentil drying in Canada *(1)*.

Storage facilities should have adequate sanitation and pest exclusion procedures to protect stored product. An integrated pest control program for rodents will typically include external bait stations and internal mechanical traps to prevent activity from rats and mice at elevators and surrounding areas. Facilities are swept and vacuumed to control foreign materials, dust, decomposed pulses, and product buildup that could result in insect activity. Food facility pesticides approved by the U.S. Environmental Protection Agency (EPA) are used to control insect infestations in the elevator, such as diatomaceous earth. In the event infestations occur, silos may be fumigated with phosphine gas at approved labeled rates. Cyfluthrin is a pyrethroid insecticide that also may be applied to empty grain bins as a control against insect activity *(13)*.

Pulse elevators using best practices also undergo routine maintenance to further protect product. Equipment should receive preventive maintenance, and any damage should be repaired regularly.

During the transfer of pulses to storage facilities, product is sampled and inspected by trained personnel from the USDA Federal Grain Inspection Service *(Fig. 12)*. A USDA grading system, based on published standards for pulses, is used to inspect both raw product from growers and also product after it has been stored, cleaned, and packed. Once product is sampled and inspected, USDA issues grade certificates. These USDA grade inspections evaluate some food safety product attributes, including presence of foreign materials (e.g., stones, glass, metal, dirt, weed seeds) and insect infestation. For example, a US #1 grade for chickpeas mandates not more than 0.5% foreign material and not greater than 0.2% stones *(17)*.

FOOD HAZARD CONTROLS USED DURING CLEANING, PACKING, OR PACKAGING

After storage of raw pulses, they are cleaned and packed for shipment to food processors. The cleaning process serves to remove product defects, chips, seed split pieces, hulls, and foreign materials that entered the product flow from harvest through storage. In addition, product is sorted by size and color to meet quality standards and USDA specifications. Graded out residues, along with seed coats, are important cleaning by-products that may be sold as animal or pet food ingredients.

Equipment used to remove foreign materials in pulses includes aspirators, screen cleaners, gravity tables, destoners, and optical sorters. High-velocity air may be used to remove field trash that includes stems, leaves, pods, seed coats, and other plant material that is lighter than beans *(15)*. Screening takes out oversized and undersized materials, such as small or large seeds, splits, stones, and mud balls. Optical sorters can be used as a final cleaning step to remove discolored beans and other grains. Extraneous or "tramp" metal is controlled through the use of magnets, and in some cases, metal detectors are used during packing or packaging.

One company interviewed by this author uses a gravity-fed metal detector calibrated to reject spherical ferrous metal pieces greater than 3.5 mm in diameter. The metal detector is regularly monitored by passing a ferrous metal test ball through the geometric center of the search head aperture. Both magnets and metal detectors are monitored regularly to ensure they are fully operational, and metal finds from this equipment are investigated on a timely basis.

Packing and packaging materials use FDA-approved food contact materials to further protect product from contamination. Most facilities use lot codes on packaging or containers to facilitate traceability.

The cleaning and packing process is conducted under dry conditions to prevent microbial growth and includes regular dry cleaning of equipment with compressed air, vacuums, brushes, and brooms. Use of compressed air, however, is discouraged because it has the potential to spread contamination and cause employee eye injuries. Employee hygiene and good manufacturing practices (GMPs) further prevent introduction of biological hazards. Pulse cleaning facilities that have adopted industry best practices typically make extensive use of pest control equipment, including external bait stations or mechanical traps, internal mechanical traps, insect light traps, pheromone monitoring traps, and bird deterrent devices.

Potential chemical hazards include chemicals used for maintenance, lubrication, cleaning, and janitorial activities. Operations following best practices from Global Food Safety Initiative (GFSI) audit schemes and/or regulatory requirements store toxic chemicals in controlled access areas. Food-grade lubricants should be used for equipment bearings and motor gearboxes in food contact zones.

Cleaning and packing facilities do not normally handle food that contains any of the nine food allergens that require special label declarations by the FDA, or they use special cleaning practices if equipment is not dedicated to nonallergen commodities. Wheat that may be incidentally introduced from growing, transport, and storage operations is fully removed during the many screening and sorting processes used during pulse cleaning operations.

Many cleaning facilities choose to implement and comply with GFSI food safety audit schemes (standards) due to quality objectives and customer requirements. These stringent standards typically exceed regulatory food safety requirements, such as those prescribed in 21 CFR 117, the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (PCHF) rule *(20)*. The majority of pulse and bean cleaning facilities in Idaho choose to certify under one of the GFSI food manufacturing audit schemes. They undergo annual inspection by third-party auditors employed by independent certification bodies to maintain certification status. Certification mandates corrective actions if there are nonconformances to the audit scheme requirements. The audit schemes require extensive implementation of prerequisite food safety programs and hazard analysis (and) critical control point or Food Safety plans.

REGULATION OF PULSE SAFETY

Overview

Pulse agronomy, storage, cleaning, packing, and packaging primarily fall under state and federal food safety inspection. The USDA Federal Grain Inspection Service regulates safety of pulses through a grading and product certificate system that evaluates levels of physical contaminants in cleaned raw materials sold into markets. The FDA regulates pulse growing on "covered farms" through the Produce Safety rule (21 CFR 112) *(24)*. Specifically, Part 112 requires good agricultural practices for dried field peas, which FDA currently has categorized as a "vegetable" (21 CFR 112.1(b)(1)). Conversely, growing chickpeas and lentils is exempt from this rule because they are categorized as "produce rarely consumed raw" (21 CFR 112.2(a)(1)) *(Table 1)*.

"Off farm" storage (not falling under the FDA primary production or secondary activities farm definitions given in 21 CFR 1.227) and cleaning operations fall under the requirements for facility registration (FSMA section 102; 21 CFR 1.225), which triggers requirements under the PCHF- (21 CFR 117) and/or the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals or "PCAF" (21 CFR 507) rules *(22)*. Human food, pet food, or animal feed manufacturers, either domestic or foreign, that manufacture, process, pack, or hold food to be consumed in the United States must register their facilities with the FDA initially and then every 2 years thereafter *(19)*.

Pulse growing

The FDA currently defines produce in the Produce Safety rule as any fruit or vegetable and includes mushrooms, sprouts, peanuts, tree nuts, and herbs. Produce does not include food grains, "meaning the small, hard fruits or seeds of arable crops, or crops bearing the fruits or seeds, that are primarily grown and processed for use as a meal, flour, baked goods, cereals, and oils rather than for direct consumption as small hard fruits or seeds" (this includes cereal grains, pseudo cereals [amaranth, buckwheat, quinoa, and millet], oilseeds [soybeans and sunflower seeds], and other plants used in the same manner). The FDA provides example food grains as barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds. Oilseeds include cotton seed, flax seed, rapeseed, soybean, and sunflower seed.

The Produce Safety rule was proposed by the FDA primarily to prevent or control the introduction of biological hazards during the growing, harvesting, and storage of fresh, ready-to-eat fruits and vegetables. The rule's preamble states that "Many legumes fall within our definition of produce, but also meet the criteria for produce that is rarely consumed raw and are

therefore not subject to this rule under 112.2 (a)(1)." The FDA also states the following:

> "We consider beans to fit within the definition of produce. Beans are typically sold in both a fresh and a dried form and the drying creates a distinct commodity. The fresh beans are produce RACs [raw agricultural commodities] and are subject to this rule except where an exemption applies. Some types of fresh beans are not subject to this rule because they fit the criteria for produce that is rarely consumed raw, and are therefore exempt under 112.2 (a)(1) ...We understand that many beans receive commercial processing that adequately reduces the presence of microorganisms of public health significance, such that in many cases, beans that are not exempt from this rule as rarely consumed raw may be eligible for the exemption in 112.2 (b). In addition, dried beans are distinct commodities from fresh beans and are therefore processed foods. Processed foods are not subject to this rule, such that once beans subject to this rule are dried/dehydrated, they are no longer subject to this rule. We also consider that lentils fit within the definition of produce ... However, lentils are rarely consumed raw and are therefore not subject to this rule under 112.2 (a)(1)."

In the preamble to the PCAF rule *(22)* FDA states that "We classify peanuts and beans (such as kidney beans, lima beans, and pinto beans) within the category of "fruits and vegetables;" we classify soybeans as grain (see the discussion of grains at 78 FR 64736 at 64764 and 79 FR 58476 at 5848, and fruits and vegetables at 78 FR 3646 at 3690 and proposed §§ 112.1 and 112.2 in the Produce Safety rule)." The FDA states in the "Policy regarding certain entities subject to the current GMP and preventive controls, produce safety, and/or foreign supplier verifications programs: Guidance for industry" *(31)* (4.a.; p.13) that although they classify dried beans as "produce RACs" in 1998 (FR54532@54542; 9 October 1998), dried beans were characterized by both FDA and EPA in a group of commodities that included legumes and grains that remain RACs even though they were dried (FR54532@54542).

The Produce Safety rule has exemptions for produce that is "rarely consumed raw" (RCR); in 21 CFR 112.2(a)(1), the FDA lists black beans, great northern beans, kidney and lima beans, navy and pinto beans, chickpeas, and lentils. Dry field peas are not included in this rarely consumed raw list, despite being inedible in their dry state. Raw agricultural commodities that are covered under the rule include broad beans, cowpea beans, peas, peas-pigeon, and snow peas (21 CFR112.1(b)(1)). The "covered produce" under the rule is therefore subject to all the good agriculture practices components mandated in the regulation, such as "Worker Training and Health and Hygiene," "Agricultural Water," "Domesticated and Wild Animals," "Biological Soil Amendments," "Growing, Harvesting, Packing, and Holding Activities; and "Equipment Tools and Building." The FDA does not differentiate between a dry field pea and a succulent pea and therefore has included dry peas as a produce raw agricultural commodity that falls under the produce safety regulation requirements *(Table 1)*.

Dry field peas, whether whole or split, in contrast to succulent peas, are not consumed raw; they are typically further processed into foods such as soup through cooking, retorting, and other forms of thermal processing. As defined by the FDA, large farms (>US$500,000 revenue per year) that grow covered produce such as dry field peas were required to comply with this rule by 26 January 2018 (except for the rule's customer assurance provisions).

In March 2019, the FDA issued a guidance for industry, "Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds; Guidance for industry *(32)*. In section C of this guidance, the FDA indicated an understanding that succulent peas and dry peas "are recognized as distinct commodities" and that dry field peas are a pulse crop. Consequently, the FDA decided to "exercise enforcement-discretion for entities growing, harvesting, packing or holding pulse crops that are not currently classified as rarely consumed raw, while we explore this topic further and consider pursuing rulemaking to address the unique circumstances of these commodities." Enforcement discretion as explained in the introduction to this guidance means that FDA will not enforce the requirements of the Produce Safety rule as they apply to entities growing, harvesting, packing, and holding certain commodities, which includes dry field peas.

Pulse storage and handling

Storage and holding of pulses on farms defined by the FDA as "primary production" or "secondary activities" farms are exempt from food facility registration (21 CFR Part 1, Subpart H) *(Table 2)*. Registration is required for off-farm food holding and processing facilities under section 415 of the Federal Food, Drug and Cosmetic Act. Primary production farms may pack or package or hold RACs. A secondary activities farm is one that is not located where crops are grown and harvested (e.g., the primary production farm) and that is devoted to harvesting, packing, and/or holding of RACs, provided that the primary production farm owns or jointly owns a majority interest in the secondary activities farm (21 CFR 1.227) *(25)*. Because primary production and secondary activities farms are exempted from FDA registration, they are generally not subject to the PCHF and PCAF rules *(25)*. Farms may be regulated under the Produce Safety rule, however, if they work with covered produce.

The FDA defines holding as storage of food and includes activities performed incidental to storage of food, such as activities performed for the safe or effective storage, including fumigating food, and drying or dehydrating raw agricultural commodities. However, "holding" does not include drying or dehydrating that creates a distinct commodity, such as drying or dehydrating alfalfa or drying grapes to produce raisins. Holding also includes activities performed as a practical

necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. The farm definition therefore allows holding, packing, packaging, and labeling of RACs, but not processed foods.

Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. In the guidance document, "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry" *(25)*, FDA provides further clarification as to what type activities can be considered part of 'holding' and 'packing'." Holding can include "activities performed incidental to storage of a food," and includes fumigation during storage, aeration for safe and effective storage, coating grains with diatomaceous earth to control insects during storage, cooling, heat treatment for purposes of pest control, and turning for safe or effective storage, such as turning grain to manage temperature and moisture, and to monitor condition and quality. It can also include "activities performed as a practical necessity for the distribution of a food." These activities are limited to "only those activities that are truly necessary, as a practical matter, to any holding and distribution of the food in question, rather than value-adding activities." These allowed activities include placing grain in a silo, blending RACs such as grain to meet a customer's quality specification, loading food into a vehicle, sampling food for grading or quality control purposes, screening grain with scalpers and shakers to remove rocks and other extraneous material, sorting-culling-grading, and weighing or conveying. Alternately, the FDA does not consider "sifting" to be a holding activity. Sifting, as in sifting of flour to make baked goods, is categorized by the FDA as a manufacturing or processing activity. A facility that "manufactures" must register with the FDA and loses the farm exemption.

Nonfarm facilities for storage and holding of pulses (elevators or silos not located on primary production or secondary activities farms) that do not fall within the FDA "farm" definition are not exempt from facility registration under section 415 *(Table 2)*. The FDA definitions do not fully clarify the categories of primary production farms and secondary activities farms. They do not completely explain which types of farm businesses and ownership qualify for primary production and secondary activities farm status. The farm definition includes both entities that are primary production farms and secondary activities farms that are cooperatives *(21)* and notes that a farm must be under one management, defined as persons or person controlling and directing the affairs of a business or institution (see response 23 in the PCHF final rule's preamble, FR55926) *(20)*. After specifying farm definitions in the final PCHF rule, the FDA further addressed farm definitions in the "Extension and Clarification of Compliance Dates" rule *(26)*. It is still not fully resolved as to what business structures and ownership arrangements (corporations, partnerships, cooperatives or other business enterprises) constitute a farm under the rules.

Under the PCAF and PCHF rules, establishments (nonfarm facilities) that are "solely engaged" in the holding and/or transportation of one or more RACs are exempt from human food GMPs requirements (21 CFR 117.5(k)(1)(iii)) or animal food GMPs requirements (21 CFR 507.5(h)(1)). The GMPs exemption applies to FDA-defined RACs and not dried pulses that have been categorized as "processed food." If the exemption no longer applies, Subpart B of PCHF or PCAF rules must be implemented, including documented Qualified Individual training in food hygiene and food safety (21 CFR 117.4(d) or 21 CFR 507.4(d)) and compliance to all applicable GMP rules *(Table 2)*.

Human food GMP exemptions also do not apply to nonfarm facilities that are not solely engaged in storage and that also pack, package, and store pulses (21 CFR 117.8). These facilities must either comply with the GMPs in 21 CFR Subpart B, or implement applicable GMPs in the Produce Safety rule. In addition, farms or farm mixed-type facilities that dry or dehydrate RACs that are produce (i.e., pulses) must comply with GMPs in either 21 CFR 117 Subpart B or applicable GMP requirements for packing and holding specified in 21 CFR 112 (21 CFR 117.5(k)(2)) *(Table 2)*.

There are also exemptions that apply to human food preventive control and supply-chain requirements (21 CFR 117.5(j)) or animal food preventive control and supply-chain program requirements (21CFR 507.5(g)) for facilities solely engaged in storage of RACs other than fruits or vegetables that are intended for further distribution or processing *(28)*. The allowable exemptions to the rules imposing preventive controls and supply-chain requirements apply only apply to facilities solely engaged in storage of nonproduce RACs intended for further distribution or processing. These nonproduce RACs include items such as wheat, corn, and soybean ("grains"). The FDA classifies pulses as produce in the Produce Safety rule. Dried beans (i.e., garbanzo beans) are also called out as "processed food." The PCHF rule also defines dried legumes as processed food (21 CFR 117.5(g)(2)(i)).

Nonfarm pulse storage elevators are therefore not exempt from preventive control requirements because they are not solely engaged in storing nonfruit and vegetable RACs (21 CFR 117.5(j))*(23)*. These facilities would be required to employ or contract a trained or experienced preventive controls qualified individual (21 CFR 117.180 or 21 CFR 507.53) *(Table 2)*. This person, while creating a required written food safety plan, would conduct hazard analyses for these facilities, and maintain the written plan on-site. If food hazards are identified during the hazard analysis that require preventive controls (due to severity and likelihood), there must be ongoing documented monitoring, corrective action, and verification, along with a written recall plan. The food

safety plan must be reanalyzed at least once every 3 years, and the facility must comply with record keeping requirements in PCHF Subpart F. The pulse storage facility would also be subject to FSMA inspections. If the same elevator was used for grains, rather than pulses, these preventive controls requirements would be exempted.

The FDA was contacted via their TAN by the author to gain clarification on the question (FDA TAN #00104672) whether pulse storage elevators enjoy the same exemptions as elevators that store food grains, such as wheat *(27)*. The FDA TAN response was that dry beans are not RACs; rather, they are a processed food according to 21 CFR 112 and 80 Federal Register, 74354 at 74385. Furthermore, "although the dry beans that you store/hold cannot be consumed without further processing, they are a vegetable and therefore are not subject to the exemption in 21 CFR 117.5(j). Dry beans are not a raw agricultural commodity (RAC), but rather have been transformed into a distinct commodity by drying and are therefore a processed food (see Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety rule) (21 CFR part 112; 80 Fed. Reg. 74354 at 74385))." Storage elevators are therefore not eligible for the exemption in 21 CFR 117.5(j). Under this rationale, these facilities would be subject to both the GMPs (Subpart B) and Preventive Controls (Subpart C) requirements of the PCHF rule. Interestingly, in a later guidance document, the FDA acknowledges inconsistencies between its definitions of dry beans as a processed food, and the EPA's categorization of beans as RACs, "even though they may have undergone some drying" *(31)*.

Pulse cleaning and packing

On-farm cleaning facilities are also exempt from FDA registration, because the holding and packing or packaging operations in the cleaning of pulses are allowed farm activities. They are not considered "processing" activities by the FDA *(Table 3)*.

Packaging is defined by the FDA to mean "placing food into a container that directly contacts the food and that the consumer [a consumer is not a business by FDA definition] receives *(25)*." Packing, however, is when food is placed into containers that are not consumer containers. Although the FDA considers packaging RACs to be a manufacturing activity, the farm definition rulemaking allows this activity to take place within the "farm" definition *(25)*. This status holds true as long as there is no further "manufacturing/processing" performed on the RAC. Therefore, farms may package or pack RACs, and because of the registration exemption, do not have to implement PCAF or PCHF regulations.

In addition, the FDA has stated that activities performed for the safe or effective packing of food, such as sorting, culling, grading, and weighing/conveying all can be considered part of "packing" under the rule. Other activities categorized as part of packing include blending different lots; cooling; mixing RACs in a packing container; hulling; shelling; sifting for safe or effective packing (such as sifting grains to remove plant debris); and washing RACs to remove dirt, where pesticides can be used in the wash water. If the on-farm packing or packaging facility also performs at least one activity that falls outside the "farm" definition, the food facility registration requirement also may be triggered, requiring compliance with the PCHF and/or PCAF regulations. An example of this activity includes manufacturing or processing certain types of foods (see *Table 6*, Examples of manufacturing/processing activities, in Classification of activities as harvesting, packing, holding, or manufacturing/processing for farms and facilities: guidance for industry) such as milling chickpea or wheat flour *(25)*.

Facilities that store, clean, package, and pack RACs that are not considered part of primary production or secondary activities farms must register with the FDA because they do not qualify for the farm registration exemption and therefore fall under the processing or manufacturing definition; they are subject to the PCHF or PCAF rules *(Table 3)*. Extensive feedback was received by the FDA during rulemaking from the food industry regarding this requirement for RACs, and a guidance document was issued in January 2018, "Policy Regarding Certain Entities Subject to Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry"*(31)*. The guidance also addresses facilities that store "produce RACs," which under the current definitions includes all pulses.

Specifically, relative to pulse storage, cleaning, packing, and packaging operations, the guidance states that the FDA will exercise enforcement discretion for two types of facilities *(Table 2)*. Below is a summary of the enforcement policy with regard to human food *(31)*:

1) Facilities that would qualify as secondary activities farms except for the ownership of the facility; these fall under either the PCHF or the PCAF rule. The FDA has provided examples of such facilities, those engaged in farm-related activities on produce RACs (produce packinghouses and warehouses), and facilities engaged in farm-related activities on non-produce RACs (grain elevators).
2) Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed foods that consists only of RACs that have been dried/dehydrated to create a distinct commodity and therefore fall under either the PCHF or the PCAF rule.

The FDA, in the preamble to the final rule of the Produce Safety regulation *(24)*, has stated "that dried beans are a processed food (i.e., a distinct commodity)." This stance regarding dried beans is also echoed in the "Policy Regarding Guidance." Food processing activities do not meet FDA farm definitions. However, due to feedback received by the FDA through the TAN from industry regarding dried beans and their categorization as "produce RACs," the FDA is

reconsidering their status. They will not be enforcing the PCHF preventive controls requirements for facilities that pack, package, label, and/or hold processed food that consists only of dried or dehydrated RACs that have become a distinct commodity *(Table 3)*, until further rulemaking regarding farm activities is completed *(31)*.

In addition, the FDA will not enforce the human food GMP requirements for the same type of facilities that are packing, labeling, and/or holding nonproduce RACs; this notably would not include pulses. The same rules apply to facilities handling animal foods that consist only of dried or dehydrated RACs that are subject to the PCAF rule, except that enforcement discretion will be applied for both preventive controls and CGMP requirements for these dried or dehydrated nonproduce and produce RACs.

DISCUSSION

Food safety track record of pulses

As a raw agricultural commodity, pulses in the United States have an extensive history of product safety. Dry, packed, or packaged field peas, chickpeas, and lentils are food commodities more closely aligned with farm production activities than with processed, ready-to-eat foods. Their normal expected or intended use is further processing or preparation by an end user or consumer. As such, they present no significant biological, chemical, or physical hazards in their dry commodity state.

During further processing of pulses into products such as hummus or sprouts, health-threatening hazards may be introduced. These potential hazards include microbial pathogens and physical contaminants. Likely sources include the facility environment, employees, and food processing equipment. Processors use prerequisite food safety programs, hazard analysis (and) critical control point critical control points, and preventive controls to manage such hazards. Further processing of pulses falls under FDA and state regulations, especially the pertinent rules of FSMA.

This article presents potential food safety hazards to pulses during farming, storage, cleaning, and packing of raw product. Biological hazards evaluated include vegetative pathogens, spore-forming pathogens, viruses, and parasites. For chemical hazards, the risk of mycotoxins, natural toxins such as lectins and phytic acid, heavy metals, and pesticides was reviewed. Physical hazards such as rocks, metal, glass, plastic, and extraneous vegetable matter were considered. For all of these potential hazards, there have been no foodborne illness outbreaks reported by the Centers for Disease Control and Prevention that can be attributed to raw, dry, packed, or packaged pulses.

During the cultivation of pulses, there is controlled and regulated application of agricultural chemicals. Raw manure is not used during planting and growing of these products, and farm harvesting equipment is routinely cleaned. Dry field peas, chickpeas, and lentils are naturally dried in the field before harvest and not through the use of processing equipment.

Facilities implementing best food safety practices incorporate controls during storage to prevent product contamination. These controls include pest control; proper ventilation; and moisture control, sanitation, and preventive maintenance.

Finally, during cleaning and packing of raw pulses, many food safety controls are applied to eliminate physical and chemical hazards. These controls may include preventive maintenance, extensive metal and foreign material control or removal equipment, GMPs, and dry cleaning practices. During cleaning, incidental grains that may create allergen hazards (i.e., wheat) are removed by vibratory screens, gravity tables, and other equipment. A health risk from biological hazards has a very low likelihood of occurring, as cleaning facilities are operated under dry conditions. Many of the cleaning facilities voluntarily participate in GFSI certification through recognized audit schemes. Although these operations are more related to farming and product storage than to food processing, most comply with FDA and state regulations and third-party audits to ensure a safe product is provided to the end customer or consumer.

FSMA regulatory challenges

The FDA regulates pulses through the Produce Safety rule, the PCHF and PCAF rules, and facility registration requirements and exemptions (1.227 of section 415 of the Federal Food, Drug, and Cosmetic Act). Other FSMA regulations may apply, such as the Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense) rule (21 CFR 121) and the Sanitary Transportation of Human and Animal Food (Sanitary Transport) rule (21 CFR 1), depending on types of facilities, products, and means of transportation. These rules come into play during farming, on-farm storage, on-farm cleaning of pulses, off-farm storage, off-farm cleaning of pulses, and transport of final product.

Classifying dry field peas as "vegetables" initiates the full requirements of the Produce Safety rule for growers of this commodity. Dried field peas are a crop that is handled in similar manner to wheat, which is not classified as a vegetable. There would be many challenges to implementing the rule for field peas. For example, there would be a significant economic impact to inspect all crop land before harvest for wild animal excreta (see 21 CFR 112.83(b)(1)), over thousands of acres of dry pea farming ground in the Palouse region. The FDA's announcement of enforcement discretion in a March 2019 guidance document *(32)* for growing dry peas addresses these challenges, although further rulemaking to address the status of dry field peas in the Produce Safety rule has yet to occur.

All storage and processing facilities that are not part of farms must register with the FDA. Registrations triggers many requirements under the PCHF and the PCAF rules. The FDA has not clearly defined all allowable business structures for primary production and secondary activities farms, and this has an adverse impact on the pulse industry by requiring regulatory compliance for businesses which may be otherwise

exempted due to farm status. These facilities may incur significant costs complying with these rules by additional training of "qualified individuals" (QIs) and preventive controls qualified individuals, developing food safety plans, implementing GMPs and preventive controls, record keeping, and managing food safety plans. In 2018, the FDA indicated in the "Policy Regarding" guidance that it is pursuing future rulemaking related to farm activities and solutions to address the issues of ownership of secondary activities farms *(31)*.

Storage facilities for pulses solely engaged in storage and/or transportation that are not associated with farms must currently implement Subparts A, B, C, D, E, F, and G of the PCHF rule. Subpart C at a minimum requires evaluation for food contaminants and a written hazard analysis. Preventive controls would need to be implemented if called out in the hazard analysis. Storage facilities solely engaged in holding and/or transportation of RACs are exempt from GMP requirements (21 CFR 117.5 (k)(1)(iii)). However, because the FDA categorizes pulses as processed food, rather than as RACs, pulses in these same storage facilities would not be exempted from GMP requirements.

The same conditions and exemptions apply for solely engaged storage of animal food (21 CFR 507.5(g) and 21 CFR 507.5(h)(1)). Depending on types of storages and findings during facility hazard analyses, these regulatory requirements can be costly and time consuming for elevator businesses in key pulse growing regions. The case for these regulatory requirements is questionable, given the innocuous nature of the commodity and low food safety risk of elevators to stored lentils, chickpeas, and dry field peas.

Improvements to pulse regulation

New FSMA rules seek to improve the safety of our food supply from farm to fork. However, components of the produce safety, PCHF, and PCAF rules present challenges for the pulse agribusiness community that are not necessarily related to the improvement of public health. Modifying these FDA regulations through further notice and comment rulemaking would streamline industry compliance and remove uncertainty.

Like chickpeas and lentils, dry field peas should be exempted from the produce safety rule requirements. Dry peas have been miscategorized in the same group as succulent peas, which are vegetables and can be consumed raw. Consuming raw dry field peas without prior cooking is a next to impossible scenario! The FDA is now temporarily suspending enforcement of produce safety rule requirements for dry field peas *(32)*. However, a better strategy would be for the FDA to reclassify all dry pulses as "food grains," rather than "produce," "bean produce," "dried legumes," "vegetables," or "processed foods." Pulse agriculture is more akin to growing food grains than it is to vegetable cultivation, in terms of growing, harvesting, storage, and further handling. Raw dry chickpeas, lentils, and dry peas are not a "processed" food that are dried off-farm to create a commodity.

The FDA considers drying or dehydrating of RACs such as "grains" in the growing area on a farm as a "harvesting activity" and therefore not manufacturing or processing under the 2016 "Classification of Activities" Guidance for Industry (see p. 30, *Table 7*) *(25)*. Pulses should receive this same status. Secondary activities farms that store and clean pulses are not creating dried or dehydrated RACs; pulse RACs are grown and harvested on primary production farms. There is precedent with both the FDA and EPA prior policy (63FR 54532 at 54542, 9 October 1998) for categorizing beans as commodities in the same way the agency treats hay, nuts, rice, beans, corn, other grasses, legumes, and grain that "remain RACs even though they may have undergone some drying" *(31)*. In this same document, the FDA and EPA agreed that if drying is for the purpose of facilitating storage or transportation of the commodity, it would not be considered processing food. Interestingly, "activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant" is also listed in this policy *(Table 2)* as an activity that does not change the status of a RAC.

The definitions of primary production and secondary activities farms would benefit from further clarification as to which business and ownership structures are allowed. Certain pulse cleaning facilities in the United States could be categorized as secondary activities farms and thus be exempt not only from registration but also from PCHF and PCAF rule requirements.

FDA-registered nonfarm pulse storage (elevator) facilities that are solely engaged in storage and distribution are not exempted from GMPs and preventive controls compliance. Like grain elevators, pulse storages pose little food safety risk to human and animal consumers.

A 2018 enforcement discretion policy temporarily waives enforcement of preventive controls at storages regulated under PCHF and PCAF rules. This applies only to facilities that could be secondary activities farms except for ownership classification, or facilities that could be "secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity" *(31)*. Although enforcement discretion provides temporary relief, updating PCHF and PCAF regulations by new rulemaking to provide full exemptions to GMPs and preventive controls requirements would be a more rational and straightforward regulatory approach.

Many nonfarm FDA-registered pulse storage facilities are not solely engaged in storage or distribution. Rather, they are colocated or integrated with a food processing operation. Examples would include a facility that processes dry chickpeas into hummus or an elevator containing pulses on the same geographic premises as a feed mill. These facilities do not currently receive the same GMP exemptions as "solely engaged" grain elevators and exemptions from preventive controls applicable to grain storage. Having this type of double standard for solely engaged versus nonsolely engaged storage

facilities for pulses creates an unnecessary burden on industry for an extremely low food safety risk.

Secondary activities farms can hold, pack, and package RACs and maintain the farm definition and registration exemption. Pulse cleaning facilities not located on a farm also should qualify for the same exemptions as a RAC holding and cleaning facility that is located on a secondary farm.

For nonfarm FDA-registered pulse cleaning facilities, the FDA has indicated it will exercise enforcement discretion if the facility would otherwise qualify as a secondary farm that holds, packs, packages, or labels RACs that have been dried or dehydrated to create a distinct commodity (a "processed" food). In addition, the FDA has indicated it will exercise enforcement discretion if the facility would otherwise qualify as a secondary farm except for the ownership of the facility *(31)*.

Temporary waiver of enforcement could be replaced by updated rules that fully exempt nonfarm pulse cleaning facilities from GMPs and preventive controls requirements due to the farm-like nature of activities conducted. There is technically no difference between a pulse cleaning operation located on a farm and that of an operation located on a different nonfarm plot of land, besides ownership of the commodity being cleaned and the business structure of the facility owner. The type of food and activities performed on the crop after harvest, rather than ownership and location of farms and facilities, better prescribe the extent of needed food safety regulations.

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