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Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry

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**U.S. Department of Health and Human Services
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Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting Guidance for Industry¹

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I. Introduction

This guidance document is intended to inform the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) of FDA’s serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly-cooked sprouts and to provide our recommendations to firms throughout the production chain of seed for sprouting. Throughout this guidance document, we refer to everything that can be sprouted, including beans, as “seeds.”

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II. Background

In the United States, between 1996 and 2020, FDA has observed 52 reported outbreaks of foodborne illness associated with contaminated sprouts. Together, it is estimated that these outbreaks resulted in more than 2,700 cases of illness (Refs. 1-6). Seeds and sprouts can become contaminated with pathogens at any point along the supply chain, such as the seed farm, seed conditioner, seed supplier, transportation, sprout operation, sprout distributor, retailer, or consumer. However, contaminated seed has historically been identified as the likely source of most sprout-related outbreaks and continues to be the most common source of sprout contamination (Refs. 7-10). For example, between November 2015 and May 2016, contaminated seed was associated with a multistate outbreak of *Salmonella* (multiple serotypes)

¹ This guidance has been prepared by the Division of Produce Safety in the Office of Food Safety at the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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infections linked to alfalfa sprouts, which sickened at least 26 people in 12 states (Ref. 11). The outbreak investigation traced the underlying cause of the outbreak to a single contaminated seed lot, which had been sprouted by several different sprout operations throughout the United States (Ref. 11). After positive test results for multiple serotypes of *Salmonella* were obtained from this seed lot and from sprouts grown from this seed lot, the entire seed lot was recalled (Ref. 11). In addition, based on the epidemiological information and traceback data from FDA’s analysis of 14 sprout outbreaks that occurred in the United States between 2012 and 2020, FDA found that contaminated seed was the likely cause of most sprout-related outbreaks during this timeframe (Ref. 10).

In the *Federal Register* of November 27, 2015 (80 FR 74353), we issued a final rule entitled “Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption” (the Produce Safety Rule). Subpart M of the Produce Safety Rule includes standards specific to sprout operations. This subpart includes provisions to prevent the introduction of known or reasonably foreseeable hazards into or onto seed that will be used for sprouting, once seeds have been received at the sprout operation. In addition, for those sprout operations subject to the Produce Safety Rule, we announced the availability of a draft guidance for the sprout industry on January 23, 2017, entitled “Compliance With and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations” (82 FR 7751). However, we consider seeds for sprouting to be outside the definition of “covered produce” in the Produce Safety Rule, and activities such as growing, conditioning, and distributing seeds for sprouting to be outside the scope of “covered activities” in the Produce Safety Rule. In addition, we recognize that the end use of seed may sometimes be unknown by the farmers who grow the seed and by the conditioners and distributors who handle the seed. Therefore, we did not prescribe specific provisions in the Produce Safety Rule to prevent the introduction of known or reasonably foreseeable hazards into or onto seed during growing, harvesting, conditioning, or holding of seed for sprouting.

We note that, although seeds for sprouting are not covered produce under the Produce Safety Rule, these seeds are “food” as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and are subject to regulation under the FD&C Act.^{2,3,4} Therefore, if a grower, holder, conditioner, packer, or distributor reasonably believes that its seeds will be used for sprouting, we recommend that the grower, holder, conditioner, packer, or distributor take steps that are reasonably necessary to prevent those seeds from becoming adulterated. We also recommend that firms throughout the supply chain – from seed production and distribution through sprouting – review their current operations related to seeds for sprouting to determine whether such steps are in place. We recommend firms throughout the supply chain follow the recommendations in this guidance, regardless of whether the seed for sprouting will be eventually treated to reduce microorganisms of public health significance. Seed treatments may reduce, but not eliminate, pathogens on seed for sprouting; therefore, reduction of incoming microbial load through

² CPG Sec. 555.750 Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, Etc. (<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074562.htm>).

³ 21 CFR Part 112.

⁴ Section 201(f) of the FD&C Act defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

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implementation of good agricultural practices (GAPs) in seed production is a key step in ensuring safety of seeds and sprouts.

III. Recommendations and Considerations

If You Grow, Condition, Pack, Hold, or Distribute Seeds for Sprouting:

We recommend that everyone in the sprout seed supply chain become as informed as reasonably possible about the food safety practices, processes, and procedures followed by the firm(s) from which you source your seed; where your seed will go after it leaves your firm; and whether your seed is reasonably likely to be used to produce sprouts for human consumption. Some firms may perform multiple operations, such as growing, conditioning, packaging, and distributing seeds, while other firms may perform a single type of operation.

The practices and conditions appropriate for producing seed for sprouting most likely will necessitate a higher level of food safety precautions compared to practices and conditions for producing seed that will be used for other purposes. In sprout-related outbreaks where seeds have been implicated as the source of contamination, the following have been identified as possible sources of contamination of the seed: rodent and bird activity within the seed conditioning operation; use of chicken manure to fertilize fields where seed was grown; transport in unclean vehicles; and use of irrigation water impacted by drainage from neighboring fields where manure was applied as a soil amendment. Sampling of soil sediment and water undertaken by FDA in 2020 identified isolates of *Salmonella* in the agricultural environment, which were determined to be genetically related by Whole Genome Sequencing to clinical isolates from 2016 and 2018 illness outbreaks associated with consumption of sprouts (Ref. 12). The observed genetic association between pathogens found in the growing environment, and clinical cases from earlier outbreaks in which sprouts were implicated as a vehicle, highlight the importance of taking food safety precautions during the growing and production of seed for sprouting before the seed reaches the sprout grower.

Specifically, we recommend that you:

- Take steps to educate and train personnel, with a specific emphasis on personnel who handle seeds for sprouting or food contact surfaces of equipment and tools used for seeds for sprouting, or those engaged in the direct supervision such personnel, on the principles of food hygiene, food safety, and personal health and hygiene, and how these principles apply to their job duties. Food contact surfaces are those surfaces that contact human food (e.g., seeds for sprouting) and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations.
- Provide adequate, readily accessible, clean, and well-maintained and -supplied toilet and hand-washing facilities to personnel who handle seeds for sprouting or food contact surfaces of equipment and tools used for seeds for sprouting, or are engaged in the direct supervision thereof, and ensure that wastes from those facilities do not serve as a source

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of contamination of the seeds for sprouting, food contact surfaces, or water sources and distribution systems used for seed for sprouting.

- Encourage good hygiene practices, including: adequate personal cleanliness (through handwashing before starting work, when returning to work after breaks, immediately after using the toilet, and after handling trash, manure, or animals); personal behavior (including avoiding spitting, chewing, eating, and sneezing or coughing over unprotected seed); and communication (including providing notification to their supervisor if an employee has a health condition that presents a public health risk in the context of their normal work duties) among personnel who handle seeds for sprouting or food contact surfaces of equipment and tools used for seeds for sprouting, or are engaged in the direct supervision thereof.
- Assess your operation for opportunities for seed for sprouting to become contaminated by other seeds or grains that are not for sprouting or human consumption and take steps that protect seed for sprouting from becoming contaminated by these other products. For example, you could store seed for sprouting separately from seed for other uses. If your operation uses the same equipment to process seed for sprouting and other commodities, consider ordering your operations from “cleanest” to “dirtiest” (i.e., if you use shared equipment, use it on seed for sprouting before using it on seed for other uses).
- Ensure that food contact surfaces are cleanable, as appropriate to the manner in which the equipment will be used and the method of cleaning. In many instances, dry cleaning (e.g., brushing, scraping, blowing with compressed air, suction with vacuum system to remove residual debris) may be preferable to wet cleaning (e.g., use of water and cleaning solutions, along with mechanical debris removal) to avoid the introduction of moisture into an otherwise low-moisture environment, which can facilitate pathogen growth and impact seed integrity. However, there may be times when wet cleaning is preferable and feasible, for example when the equipment is frequently exposed to moisture naturally (e.g., it is left out in fields or in unenclosed buildings exposed to the elements).
- Clean food contact surfaces as frequently as reasonably necessary to protect against contamination of seed for sprouting. For example, if you intend to process seed for sprouting after processing other types of seed on the same equipment, you should clean the food contact surfaces of that equipment before use on seed for sprouting.
- Evaluate your operation to determine which food contact surfaces can be sanitized, assess what options are available under the conditions of your operation for sanitizing such food contact surfaces, and determine under what circumstances sanitizing is necessary for these food contact surfaces (e.g., before their use to contact lots of seed for sprouting, or after events when they may have become contaminated, such as contact with flood waters or uncomposted manure).
- Ensure that seed is transported in a manner that minimizes the likelihood of contamination with pathogens. For example, choose transportation vehicles and equipment that are suitable for their intended use and cleanable, as appropriate to the manner in which the equipment will be used and the method of cleaning (e.g., dry cleaning); and take measures to segregate or use packaging to protect seeds for sprouting from contamination (e.g., contamination by other foods, seeds for uses other than

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sprouting for human consumption, or other non-food items in the same load or previous loads).

- Take appropriate follow-up actions if you know or have reason to believe the seed you have produced may be contaminated with a pathogen. These actions may include, for example, informing sprout growers who purchased seed from the suspected lot(s) regarding the contamination; destroying or diverting remaining seeds from the lot(s) of concern to non-food uses; and investigating and addressing the potential source(s) of contamination, as necessary.

Some seed producers may opt to test their seed for pathogens before distribution. While testing lots of seed for sprouting for pathogens can help identify contaminated lots, we note that there are limitations to what the test results can tell you (for example, because contamination may be at low levels or unevenly distributed throughout the seed lot). Laboratory analyses have frequently been unable to detect pathogens from lots of seeds that have been conclusively implicated as the vehicle in foodborne illness outbreaks because of low levels and lack of uniformity of pathogens (Ref. 13). Therefore, testing seed is not a substitute for implementing GAPs and should not replace efforts to prevent seed from becoming contaminated during production. In addition, we recognize that while a positive test can indicate seeds are contaminated, a negative test result is not a guarantee of the absence of pathogens in the lot of seeds. You should not re-test lots of seed that have tested positive for a pathogen to demonstrate that the seed lot is not contaminated. A positive test result is not negated by a subsequent negative test result.

If You Grow Seed for Sprouting:

We recommend that seeds for sprout production be grown using GAPs or in conformance with international standards such as the Codex Alimentarius International Code of Hygienic Practice for Fresh Fruits and Vegetables,⁵ including Annex II (Sprout Production), which addresses primary production of seeds for sprouting. For example, we recommend the following:

- You should determine at the time of planting whether a particular crop is intended for sprouting, so that you can follow the recommendations in this guidance while it is growing.
- If you use biological soil amendments of animal origin (e.g., manure) in seed for sprouting growing fields, you should only use them in such a way that they do not contaminate the seed for sprouting, areas used for growing or handling seed for sprouting, food contact surfaces, or water sources and distribution systems used for seed for sprouting. For example, you should treat any such soil amendments using a scientifically valid chemical, physical, biological, or combination process, such as static or turned composting, to ensure they do not contain pathogens of public health significance (e.g., *Salmonella* or *E. coli* O157:H7).

⁵ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BRCP%2B53-2003%252FCXC_053e.pdf

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- You should assess the areas used for growing seed for sprouting for evidence of potential contamination of seed from domesticated or wild animals as needed during the growing season, based on the type of seed you use, your growing practices and conditions, and your past observations and experience (e.g., observation of animals, animal excreta, crop destruction). If significant evidence of potential contamination is found (e.g., animal excreta on or near the crop, crop damage, or destruction by animals) you should evaluate whether or not the seed should be harvested. If any seed should not be harvested because it is reasonably likely to be contaminated (e.g., it is visibly contaminated with animal excreta), we recommend that you take measures to help you later identify, and not harvest, the affected seed. For example, you might mark the affected area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the excreta such that it is not visible later during harvest.
- You should assess the areas used for growing seed for sprouting for adjacent land use considerations, such as the presence of nearby animal production facilities (e.g., concentrated feed operations, poultry farms, dairy farms) and related factors (e.g., slope of land, runoff controls, spreading manure) that could lead to contamination of the seed or irrigation water with untreated manure, and you should take steps to prevent such contamination.
- You should ensure that water used for crop protection sprays or irrigation of areas where you grow seed for sprouting, in which there is contact with the seed, is safe and of adequate sanitary quality for its intended use. For example, if you learn that your irrigation water has tested positive for a pathogen of public health significance, you should treat your water to eliminate the pathogen or change your water source.

If You Pack or Hold Seed for Sprouting:

We recommend that you pack and hold seed under sanitary conditions, including taking steps to control pests. For example, we recommend:

- Seed should be stored in closed or covered containers, in a clean, dry area dedicated to seed storage. We recommend that containers be positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests and to facilitate regular monitoring for pest problems.
- You should use packaging for seeds that minimizes the potential for contamination.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has

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verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change overtime.

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