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

Draft Guidance

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For questions regarding this draft document contact the Office of Food Safety in the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance document is intended to make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware 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."

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

In the United States, between 1996 and August 2018, FDA has 50 reported outbreaks of foodborne illness associated with contaminated sprouts. Together, these outbreaks resulted in more than an estimated 2,600 cases of illness (Refs. 1-5). Between January and August 2018, there were two reported outbreaks associated with sprouts in the United States, resulting in more than an estimated 100 illnesses (Ref. 5).² Studies indicate that contaminated seed is the likely source of most sprout-related outbreaks (Ref. 6). For example, in late 2015 and early 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.

² Data represent outbreak information from January 2017 and August 2018; 2018 data are preliminary, as CDC data have not yet been released.

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linked to alfalfa sprouts.³ This outbreak sickened at least 26 people in 12 states between November 2015 and May 2016.⁴ 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.⁵ 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.⁶

On November 27, 2015, we published in the *Federal Register* (80 FR 74353) 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. Subpart M of the Produce Safety Rule 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 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.

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.^{7,8,9} Therefore, if a grower, holder, conditioner, or distributor reasonably believes that its seeds are expected to be used for sprouting, we recommend that the grower, holder, conditioner, or distributor take steps that are reasonably necessary to prevent those seeds from becoming adulterated. We also recommend

³ <http://www.cdc.gov/salmonella/muenchen-02-16/> and <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm487329.htm>

⁴ <http://www.cdc.gov/salmonella/muenchen-02-16/> and <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm487329.htm>

⁵ <http://www.cdc.gov/salmonella/muenchen-02-16/> and <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm487329.htm>

⁶ <http://www.cdc.gov/salmonella/muenchen-02-16/> and <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm487329.htm>

⁷ CPG Sec. 555.750 Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, Etc. (<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074562.htm>)

⁸ 21 CFR Part 112

⁹ 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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that firms throughout the supply chain – from seed production and distribution through sprouting – review their current operations related to seeds for sprouting.

III. Recommendations and Considerations

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

FDA recommends that everyone in the sprout seed supply chain make an effort to 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 likely will require a higher level of consideration and food safety precautions compared to practices 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: evidence of rodents and birds within the seed conditioning operation; use of chicken manure to fertilize fields where seed was grown; transport of alfalfa seed in unclean vehicles; and fields where seed was grown being irrigated with water draining from neighboring fields where manure was applied as a soil amendment.

Specifically, we recommend that you:

- Take steps to educate and train personnel who have food safety responsibilities on the principles of food hygiene, food safety, and personal health and hygiene;
- Provide adequate, clean, and well-maintained toilet and hand-washing facilities to personnel;
- Encourage good hygiene practices among personnel;
- Store seed for sprouting separately from seed for other uses;
- Ensure that food contact surfaces are cleanable. Food contact surfaces are those surfaces that contact human food (including 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;
- Clean food contact surfaces regularly and sanitize them as appropriate. For example, clean and sanitize food contact surfaces before their use to contact lots of seed for sprouting, and between individual lots of seed for sprouting to minimize potential cross-contamination between lots; and
- 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; and take measures to segregate, isolate, or use packaging to protect seeds for sprout production from contamination by other foods or non-food items in the same load or previous loads.

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If You Grow Seed for Sprouting:

We recommend that seeds for sprout production be grown using good agricultural practices (GAPs) or in conformance with international standards such as the Codex Alimentarius International Code of Hygienic Practice for Fresh Fruits and Vegetables,¹⁰ including Annex II (Sprout Production), which addresses primary production of seeds for sprouting. For example, we recommend the following:

- If you use biological soil amendments of animal origin (e.g., manure) in seed growing fields, you should only use them in such a way that they do not contaminate the seed for sprouting. For example, we recommend that you treat any such soil amendments to ensure they do not contain pathogens of public health concern.
- You should assess the relevant areas used for growing seed for evidence of potential contamination of seed as needed during the growing season (based on your seed, your practices and conditions, and your observations and experience). If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), we recommend that you evaluate whether or not the seed should be harvested. If any seed should not be harvested because it is reasonably likely to be contaminated (for example, if it is visibly contaminated with animal excreta), we recommend that you take measures to assist you later during harvest so you can 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 evidence so it is not visible later during harvest.
- You should ensure that water used for irrigation of areas where you grow seed for sprouting 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 (e.g., *Salmonella* or *E. coli* O157:H7), we recommend that you consider treating your water to eliminate the pathogen or changing 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.

- 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 appropriate packaging for seeds to minimize potential for contamination.

¹⁰ 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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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.

1. D’Lima, C., et al. “Memorandum to the File – Produce Related Outbreaks and illnesses, December 2011.” Food and Drug Administration.*
2. Merriweather, S., et al. “Memorandum to the File – 2011-2014 Produce Related Outbreaks and Illnesses, May 2015.” Food and Drug Administration.*
3. Gubernot, D., et al. “Memorandum of Record: 2015-2016 Sprout and Sprout-Derived Product Related Outbreak Data, July 28, 2016.” Food and Drug Administration.*
4. Fatica, Marianne K., et al. “Memorandum of Record: July-December 2016 Sprout Related Outbreak Data, February 16, 2017.” Food and Drug Administration.*
5. Fatica, Marianne K., et al. “Memorandum of Record: January 2017-August 2018 Sprout Related Outbreak Data, September 12, 2018.” Food and Drug Administration.*
6. National Advisory Committee on Microbial Criteria for Foods (NACMCF), “Microbiological Safety Evaluations and Recommendations on Sprouted Seeds,” *International Journal of Food Microbiology* 52(1999):123-153.