

## MEMORANDUM

**From:** Joseph A. Levitt  
Mary B. Lancaster

**Date:** July 2, 2019

**Re: FDA Issues Draft Guidance on Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting**

FDA recently released a Draft Guidance for Industry entitled, “Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting” (“Draft Guidance”). <sup>1/</sup> The Draft Guidance addresses the growing, harvesting, conditioning, and holding of seed for sprouting.

The Draft Guidance notes that FDA has reported 50 outbreaks of foodborne illness associated with sprouts in the last 22 years, resulting in approximately 2,600 illnesses. The agency suggests “contaminated seed is the likely source of most sprout-related outbreaks.” <sup>2/</sup> Although seeds for sprouting are not covered by the Produce Safety Rule, <sup>3/</sup> FDA clarifies that seeds are nonetheless considered “food” under the Federal Food, Drug, and Cosmetic Act (FFDCA), which makes growers, holders, conditioners, and distributors responsible for taking steps reasonably necessary to prevent adulteration.

### Recommendations for Operations that Grow, Condition, Pack, Hold, or Distribute Seeds for Sprouting

FDA acknowledges that “the end use of seed may sometimes be unknown by the farmers who grow the seed and the conditioners and distributors who handle the seed.” <sup>4/</sup> Nonetheless, FDA encourages all industry participants to “make an effort to become as informed as reasonably possible” about the firms from which they source seed and to whom they sell seed, and, generally, whether their seed is reasonably likely to be used to produce sprouts for human consumption. <sup>5/</sup> In particular, the agency recommends:

- Food hygiene and food safety education and training for seed-handling personnel;

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<sup>1/</sup> Draft Guidance for Industry: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting (June 2019), <https://www.fda.gov/media/127972/download>; 84 Fed. Reg. 29867-29869 (June 25, 2019).

<sup>2/</sup> Draft Guidance at 3.

<sup>3/</sup> Final Rule, “Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption” (“Produce Safety Rule”), 80 Fed. Reg. 74353 (Nov. 27, 2015).

<sup>4/</sup> Draft Guidance at 3.

<sup>5/</sup> Draft Guidance at 5.

- Adequate, clean, and well-maintained toilet and hand-washing facilities;
- Separate storage for sprouting seeds;
- Cleanable contact surfaces;
- Cleaning and sanitation practices that minimize the potential for cross-contamination between lots; and
- Transportation practices that minimize the likelihood of contamination with pathogens. For example, segregating seed for sprout production from other foods or non-food items in the same or previous loads.

### **Recommendations for Operations that Grow Seed for Sprouting**

For operations growing seed for sprouting, FDA recommends that either good agricultural practices (GAP) or Codex Alimentarius International Code of Hygienic Practice for Fresh Fruits and Vegetables, including Annex II (Sprout Production), be followed. In particular, FDA recommends the following practices:

- If soil amendments such as manure are used in seed growing fields, treat soil amendments to eliminate pathogens of public health concern.
- Assess the crop throughout the growing season for evidence of potential contamination such as animal excreta or crop destruction. Any affected portion of the crop should be marked to ensure it is not harvested with the rest of the crop.
- Use safe irrigation water, which may require treating potentially contaminated water to eliminate potential pathogens, or changing water sources.

### **Recommendations for Operations that Pack or Hold Seed for Sprouting**

FDA recommends seeds be stored off the floor and away from the wall in clean, dry areas dedicated to seed storage. The agency recommends closed or covered containers or other appropriate packaging be used to minimize the potential for contamination.

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We will continue to monitor FDA policy and guidance related to seed handling and sprout production. Please contact us with any questions regarding this or other matters.