As covered on this blog, FDA announced a draft guidance on June 25, 2019 for the seed sprouting industry that provides recommended steps to prevent adulteration for firms involved in the growing, conditioning, and distribution of seed for sprouting. Possible sources of contamination of seeds implicated in foodborne disease outbreaks include 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.

On May 13, 2022, FDA issued a final guidance titled “Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry.” While the Produce Safety Rule (PSR) implemented under the FDA Food Safety
Modernization Act (FSMA) includes provisions to prevent the introduction of known or reasonably foreseeable hazards once seeds have been received at the sprout operation, FDA considers seeds for sprouting to be outside the definition of “covered produce” in the PSR. Reduction of the incoming microbial load, however, is considered a key step in ensuring the safety of seeds and sprouts. Thus, FDA recommends that seeds for sprout production be grown using good agricultural practices (GAPs) in seed production or in conformance with international standards such as the Codex Alimentarius International Code of Hygienic Practice for Fresh Fruits and Vegetables. In response to comments, FDA’s final guidance for preventing the introduction of known or reasonably foreseeable hazards into or onto seed during growing, harvesting, conditioning, or holding of seed for sprouting includes changes as follows:

- The addition of examples relevant to storing seed, cleaning equipment, and following up after the discovery of contamination;
- More information about when to use wet cleaning and sanitizing versus dry cleaning of food contact surfaces;
- Clarification that testing seed is not a substitute for implementing GAPs and that a positive test result is not negated by a subsequent negative test result;
- Research from FDA’s analysis of 14 sprout outbreaks that occurred in the US between 2012 and 2020, which showed that contaminated seed was the likely cause of most sprout-related outbreaks; and
- Updated recommendations related to proximity of seed growing operations to a domestic animal raising farm.

- The final guidance recommends 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 they source their seed, where the seed will go after it leaves their firm, and whether their seed is reasonably likely to be used to produce sprouts for human consumption.

- Keller and Heckman attorneys and scientists are experienced with advising on FSMA, the PSR and sprout seed, and related regulatory issues, and would be happy to answer any questions.

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