

ALERTS

Food, Drug & Device Law Alert - FDA Issues Final Produce Safety Rule

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The Food and Drug Administration (FDA) has released its final rule on produce safety, which is one of seven designed to implement the Food Safety Modernization Act. According to the executive summary of the 800+ page rule, the final rule establishes science-based minimum standards for the safe growing, harvesting, packing and holding of produce on farms.

The rule focuses on five major routes of contamination and also discusses sprouts:

- Worker Training and Health and Hygiene
 - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (§§ 112.21, 112.22, and 112.23);
 - Require documentation of required training and corrective actions (§ 112.30); and
 - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (§§ 112.31, 112.32, and 112.33).
- Agricultural Water
 - Require that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Agricultural water is defined in part as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces (§ 112.3(c));
 - Establish requirements for inspection, maintenance, and certain other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (§§ 112.42 and 112.48);
 - If a farm chooses to treat agricultural water to meet relevant requirements for its intended use, establish requirements related to methods of treatment and monitoring such treatment (§ 112.43);
 - Establish specific requirements for the microbial quality of

RELATED PEOPLE



Lynn C. Tyler, M.S.

Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com



Robert R. Stead

Partner
Grand Rapids, Southeast
Michigan

P 616-742-3995
F 616-742-3999
robert.stead@btlaw.com



William W. Wales

Retired Partner
Indianapolis

P 317-231-7493
F 317-231-7433
william.wales@btlaw.com

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agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies, under certain specified conditions, and treated water), and requiring certain actions to be taken when such water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality requirements (§§ 112.44, 112.45, 112.46, and 112.47); and provide for the use of alternative requirements for certain provisions under certain conditions (§§ 112.12 and 112.49); and

- Require certain records, including documentation of inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions (§ 112.50).

- Biological Soil Amendments

- Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (§§ 112.51 and 112.52);
- Prohibit the use of human waste for growing covered produce except in compliance with U.S. Environmental Protection Agency (EPA) regulations for such uses or equivalent regulatory requirements (§ 112.53);
- Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards (§§ 112.54 and 112.55), including examples of such processes;
- Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (§ 112.56); and
- Require certain records, including documentation from suppliers of treated biological soil amendments of animal origin, documentation that process controls were achieved, and corrective actions (§ 112.60).

- Domesticated and Wild Animals

- If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, require measures to assess as needed relevant areas during growing and, if significant evidence of potential contamination is found, take measures reasonably necessary to assist later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§§ 112.83 and 112.112).

- Equipment, Tools, and Buildings

- Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (§§ 112.121-134); and
- Require certain records related to the date and method of cleaning or sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities, and corrective actions (§ 112.140).

- Sprouts

- Establish scope of applicability of sprout provisions (§ 112.141);
- Establish measures that must be taken related to seeds or beans for sprouting (§ 112.142);
- Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (§ 112.143);
- Require testing the growing environment for *Listeria* species (*Listeria* spp.) or *Listeria monocytogenes* (*L. monocytogenes*) and testing each production batch of spent sprout irrigation water or sprouts for *Escherichia coli* (*E. coli*) O157:H7, *Salmonella* species (*Salmonella* spp.) and, under certain conditions, other pathogen(s), and taking appropriate follow-up actions (§§ 112.144-112.148); and
- Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, certain test methods used, and corrective actions (§ 112.150).

A copy of the final rule can be found [here](#).

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys:

For more information, contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; William Wales at (317) 231-7493 or william.wales@btlaw.com; Bob Stead at (616) 742-3995 or robert.stead@btlaw.com; or Alicia Raines at 317-231-7398 or alicia.raines@btlaw.com.

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