

# FDA FACT SHEET

## Produce Safety Rule (21 CFR 112) Adjacent and Nearby Land Use and its Impact on Produce Safety

Several recent produce outbreak [investigations](#) have demonstrated that conditions and practices on adjacent and nearby land can play a critical role in contributing to produce contamination. Microbial hazards, such as *Salmonella* or *E.coli* O157:H7, can originate from areas outside the farm - areas often referred to as adjacent and nearby land. "Adjacent" land refers to land sharing a common border with the farm. "Nearby" land includes land that does not adjoin the farm, but has the potential to affect the farm based on the land's location.

This fact sheet is intended to help produce farms understand how conditions and practices on adjacent or nearby land can impact produce safety, and how the Produce Safety Rule requirements can address identified hazards.

### Question 1. Why is it important to evaluate potential hazards associated with conditions and practices on adjacent or nearby lands?

Conditions and practices on adjacent and nearby land can impact the safety of all types of produce, whether grown domestically or internationally. Pathogens can be transferred from sources on adjacent or nearby lands to produce farms in several ways, including through the movement of animals, equipment and tools, water, wind, or people.

Several recent produce outbreak [investigations](#) have identified conditions and practices on adjacent or nearby lands as a potential contributing factor. These outbreaks include:

- *Salmonella* Newport in red onions in 2020 [1];
- *Salmonella* Enteritidis linked to peaches in 2020 [2]; and
- Six Shiga-Toxin Producing *E. coli* (STEC) outbreaks associated with leafy greens, including four outbreaks between 2018 – 2020 [3].
- *Salmonella* Typhimurium outbreak involving cantaloupe grown during 2022 [4].

### Q.2 What are potential sources of common pathogens that cause foodborne illness?

Understanding the potential sources of pathogens that cause foodborne illness (i.e., the pathogen's natural habitat or where it prefers to live) is important to help you identify potential hazards to your covered produce, including those that may be associated with adjacent and nearby land use, practices, and conditions. Some commonly occurring foodborne pathogens and their sources are outlined in Table 1; another helpful source of information is FDA's webpage for [Foodborne Pathogens](#).

**Table 1. Selected foodborne pathogens and their potential sources.**

Selected Foodborne Pathogens	Potential Sources Include:
<i>Salmonella</i> spp.	Domesticated and wild animals and their feces; humans and their feces <sup>[5]</sup>
Shiga-Toxin Producing <i>Escherichia coli</i> (STEC)	Domesticated and wild animals, particularly ruminant animals (e.g., cattle, sheep, goats and deer), and their feces <sup>[6]</sup>
<i>Listeria monocytogenes</i>	Soil, decaying vegetation, water, and domesticated and wild animals and their feces <sup>[7]</sup>
<i>Cyclospora cayetanensis</i>	Humans and their feces <sup>[8]</sup>

**Question 3. What conditions and practices on adjacent or nearby lands can contribute to potential contamination of my produce?**

Conditions or practices associated with adjacent or nearby lands, including those that may not be under your farms control, may serve as a source of known or reasonably foreseeable hazards that can introduce contamination to the produce you grow or handle. Many factors can impact conditions on the farm, including the types of potential hazards on adjacent and nearby land, the types of activities on adjacent and nearby land, and environmental factors.

Factors to consider when evaluating potential sources or routes of contamination from adjacent and nearby land include:

- Presence of domesticated animals, animal housing, animal waste, and related practices;
- Presence of wild animals, or presence of animal attractants or habitats;
- Practices related to storage or applications of soil amendments, manure or biosolids;
- Presence of waste or trash storage areas;
- Presence or evidence of recreational activities (e.g., camping, boating, swimming);
- Proximity to urban areas, housing or recreational areas (e.g., houses, apartment buildings, businesses, RV sites, golf courses, and parks);
- Proximity to toilet facilities, sewage or septic systems, or wastewater treatment facilities;
- Agricultural water sources or systems, and related practices;
- Susceptibility of produce growing and handling areas and water systems to runoff, waste water drainage or other drainage;
- Worker practices and traffic patterns;
- Equipment and transport vehicle handling and traffic patterns;
- Presence of untreated or improperly treated human waste;
- Land features (e.g., topography, vegetation) and land use;
- Weather events;
- Historical observations and other information.

**Question 4. How does the Produce Safety Rule apply to preventing contamination of covered produce from hazards associated with adjacent and nearby lands?**

Several requirements of the Produce Safety Rule apply to preventing contamination of covered produce with hazards associated with adjacent and nearby lands. Covered farms must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards (21 CFR 112.11). This includes known or reasonably foreseeable hazards introduced from conditions and practices on adjacent and nearby land.

As applicable, requirements include, but are not limited to:

- domesticated and wild animals (see applicable requirements of Subpart I);
- growing, packing, harvesting and holding activities (see applicable requirements of Subpart K);
- agricultural water [9]; and
- equipment and tools, including food packing materials, buildings, and sanitation (see applicable requirements of Subpart L).

More information on these requirements can be found in the Produce Safety Rule and related chapters of the draft guidance, specifically:

- [Draft Guidance Chapter 5: Domesticated and Wild Animals \(Subpart I\)](#)
  - [At a Glance: Key Points in Chapter 5; Descripción General: Capítulo 5](#)
- [Draft Guidance Chapter 6: Growing, Harvesting, Packing, and Holding Activities \(Subpart K\)](#)
  - [At a Glance: Key Points in Chapter 6; Descripción General: Capítulo 6](#)
- [Draft Guidance Chapter 7: Equipment, Tools, Buildings, and Sanitation \(subpart L\)](#)
  - [At a Glance: Key Points in Chapter 7; Descripción General: Capítulo 7](#)

For more information:

• **FSMA Final Rule on Produce Safety.**

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>

• **Produce Safety Network:**

<https://www.fda.gov/food/food-safety-modernization-act-fsma/produce-safety-network>

[ProduceSafetyNetwork@fda.hhs.gov](mailto:ProduceSafetyNetwork@fda.hhs.gov)

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- [1] - [Factors Potentially Contributing to the Contamination of Red Onions Implicated in the Summer 2020 Outbreak of Salmonella Newport](#)
- [2] - [Factors Potentially Contributing to the Contamination of Peaches Implicated in the Summer 2020 Outbreak of Salmonella Enteritidis](#)
- [3] - [Outbreak Investigation Reports](#)
- [4] - [FDA Issues Report Highlighting Salmonella Outbreak in Cantaloupe During Summer of 2022](#)
- [5] - Jay, J.M. et al. 2005. "Chapter 26. Foodborne Gastroenteritis Caused by Salmonella and Shigella in Modern Food Microbiology", 619-636, New York, New York. Springer.
- [6] - Meng, J. et. al. 2007. "Chapter 12. Enterohemorrhagic Escherichia coli in Food Microbiology", 249-269, Washington, DC. ASM Press.
- [7] - Jay, J.M. et al. 2005. "Chapter 25. Foodborne Listeriosis in Modern Food Microbiology", 591-617, New York, New York. Springer.
- [8] - Ortega, Y.R. 2007. "Chapter 31. Protozoan Parasites in Food Microbiology", 663-681, Washington, DC. ASM Press.
- [9] - Subpart E of the Produce Safety Rule also applies to preventing contamination of covered produce from potential hazards associated with adjacent and nearby lands. In December 2021, we published a [proposed rule](#) which would revise subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Regulation to change the pre-harvest agricultural water requirements for covered produce (other than sprouts). The proposal includes expedited mitigation measures that would be required for specific types of hazards related to certain activities associated with adjacent and nearby lands.