



The Produce Safety Rule as it Applies to the Food Chain

21 CFR PART 112

Introduction

The Produce Safety Rule:

- Part of the FDA's Food Safety Modernization Act (FSMA)
- Established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption



Scope of Coverage of the Rule

Covers:

- Domestic and imported produce
- Produce for human consumption
- Raw agriculture products typically consumed raw



What is not within the scope of the Produce Safety Rule (PSR)

- Chemical and physical hazards
- Produce quality factors (grades, sizes)
- Manufacturing
- Warehouses/distribution centers not managed by the farm
- Retail (farmers markets, produce auctions, grocery, etc.)
- Plant sales (nurseries)
- Pesticide use and/or drift
- Transportation after it leaves the farm



Produce Defined

Generally, means any fruit or vegetable and includes mushrooms, sprouts, peanuts, tree nuts, and herbs.

- ❖ Fruit: the harvestable or harvested part of a plant developed from a flower
- ❖ Vegetable: the harvestable or harvested part of any herbaceous plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs.



Commodities that are Not Produce:



- Grains and oil seeds (e.g. dent corn, wheat, oats, rice, soybean)
- Saps (e.g. maple syrup)
- Algae (e.g. seaweed)



Key Requirements of the PSR

- Personnel Qualifications and Training
- Health and Hygiene
- Agricultural Water
- Biological Soil Amendments of Animal Origin (BSAAO)
- Domesticated and Wild Animals
- Growing, Harvesting, Packing, and Holding Activities
- Equipment, Tools, Buildings and Sanitation
- Sprouts
- Records



Farm Exemptions



SPECIFIED PRODUCE
RARELY CONSUMED
RAW



FARMS WITH AN AVERAGE
ANNUAL PRODUCE SALES OF
≤ \$25,000 PER YEAR/3 YEARS



PRODUCE FOR
PERSONAL OR ON-FARM
CONSUMPTION



PRODUCE THAT IS
COMMERCIALY PROCESSED



Qualified Exemption

- Less food sold to wholesale buyers than to qualified end users.
 - Direct-to-consumer
 - Direct to retail or restaurant within the state, Indian reservation, or 275 miles from the farm
- The value of all food from a farm sold during the preceding 3-year period must be less than \$500,000



Qualified Exemption (cont.)

Modified Requirements

Must have the farm name and address listed:

- If labeled: Prominently and conspicuously on the food packaging label
- If not labeled: Prominently and conspicuously display, at the point of purchase on a label, poster, sign, placard, or documents delivered with the produce



Farms Exempt from the Produce Safety Rule

- These farms still have a responsibility to provide safe produce
- Cannot be adulterated according to FD&C Act



Produce as a Manufactured Food



Manufacturing Program Considerations

USING A “KILL STEP”

- Examples: canning, pasteurized juice, baking, distilling, brewing
- Exempt from the Produce Safety Rule
- May be inspected under 21 CFR Part 113, 114, 117, or 120

NOT USING A “KILL STEP”

- Examples: freezing, slicing, dicing, fruit cups, veggie trays, pre-made salads
- Must meet Produce Safety Rule standards (if not exempt or qualified exempt)
- 21 CFR Part 117 inspection



Mixed-type facilities

A farm that also conducts activities outside of the farm definition.



Requires the establishment to register as a food facility under section 415 of the FD&C Act.



Will be subject to 2 different inspections:

Produce Safety Rule
(Part 112)

GMP/Preventive Controls
(Part 117)



Produce at Retail





Retail Program Considerations

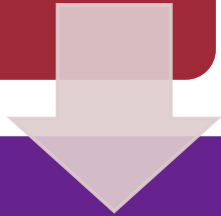
- Food code definition of an “approved” food source
 - “Food shall be obtained from sources that comply with law”
- Not all produce farms are subject to the produce safety rule due to exemptions
- All produce farms do have responsibility to produce food that complies with FD&C Act
 - Food cannot be adulterated



AFDO Guidance for Interpretation of
Approved Source as it relates to Retail
Food Establishments and the Produce
Safety Rule



Does the produce appear to be adulterated?



Has there been a foodborne illness related to the specific commodity?



Has there been a recall with the specific commodity?

Critical thinking for produce in an establishment or facility:



Produce Resources for Retail

Iowa Checklist for Retail Purchasing of Local Fresh Produce -
<https://store.extension.iastate.edu/product/12938>

Buying Local – Approved Food Sources for Food Establishments – Michigan Department of Agriculture & Rural Development
<https://www.michigan.gov/mdard/food-dairy/regulators/evaluation/buying-local-approved-foodsources-for-food-establishments>

Verifying On-Farm Food Safety - <https://theicn.org/resources/179/produce-safety/105766/verifying-on-farm-foodsafety-fact-sheet.pdf>

Ensuring Traceability of Fresh Produce
<https://theicn.org/resources/652/produce-safety-best-practices-factsheets/107985/traceability.pdf>



State Differences

Talk to your state produce safety partner to learn state specific requirements (e.g. registration requirements)

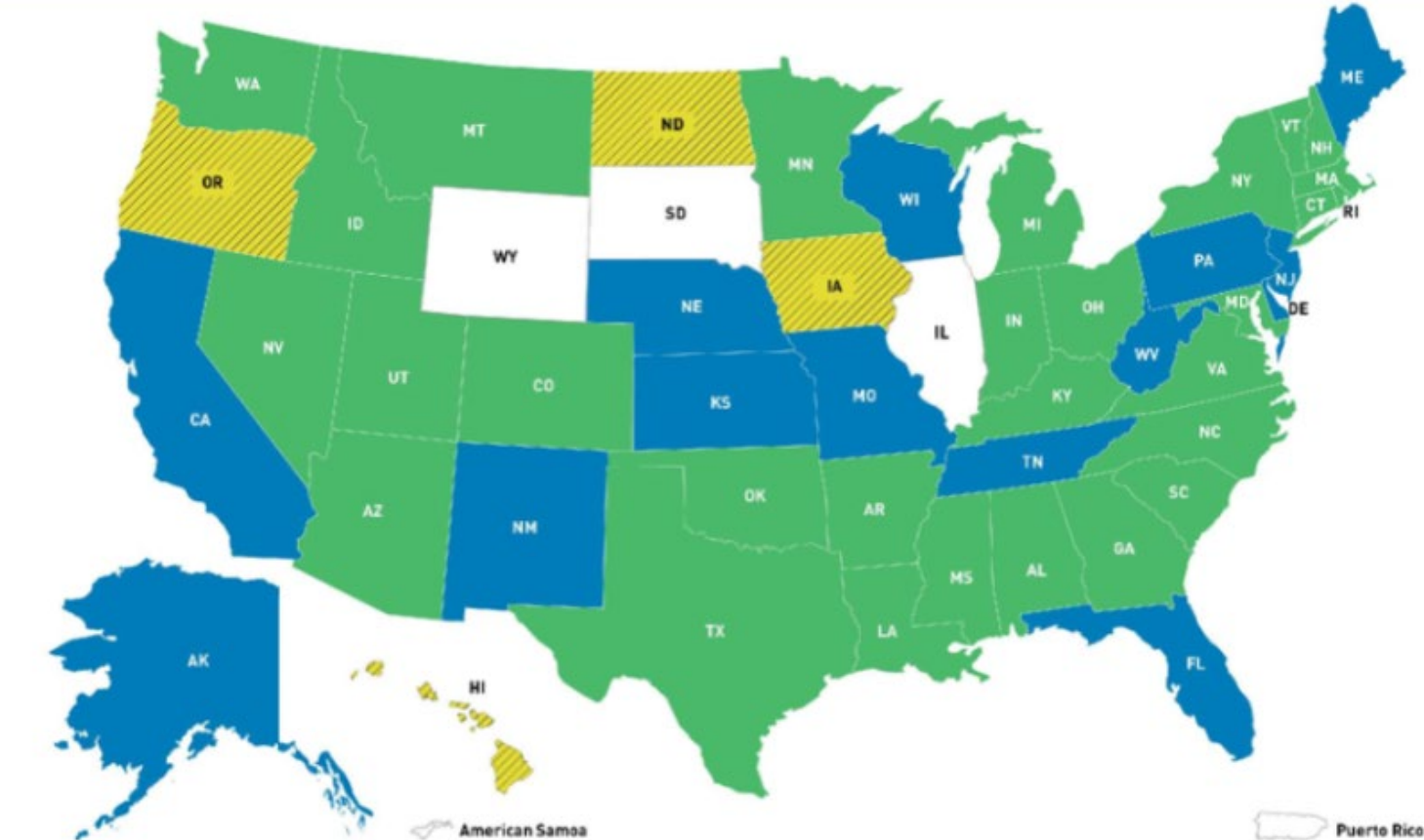






A few states do not have a produce safety program and will have to reach out to your FDA State Liaison



Your state may have other non-PSR rules related to produce:

Pesticide laws	Plant and seed laws	Manufacturing and retail inspections	Cottage food laws
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-  **Path A** grantees are non-regulatory programs; FDA will conduct produce safety inspections in these states
-  **Path B** grantees will conduct produce safety inspections under FDA’s authority
-  **Path C** grantees will conduct produce safety inspections under their own authority
-  White states and territories are not participating in the Produce Safety CAP; FDA will conduct produce safety inspections in these states and territories.

State Produce Regulatory Programs





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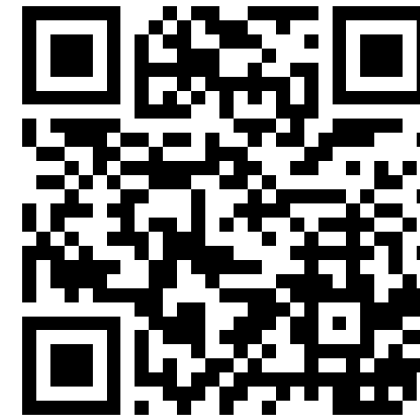
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Who to contact?

- Use the AFDO DSLO list to contact your state produce regulatory program





Questions?