

Fresh Unprocessed Fruits and Vegetables

The sale of fresh unprocessed fruits and vegetables can be a relatively accessible way for newcomers to get involved in farm-to-table markets. In Ohio, regulatory burdens for the production and sale of fresh unprocessed fruits and vegetables is very minimal. A fruit or vegetable is “unprocessed” when it is not processed beyond merely rough trimming and rinsing.¹ To sell produce that has been processed (including washing) or on a larger scale, producers will need to determine what additional regulatory or licensing requirements may apply in order to sell their fruits and vegetables.

FSMA Regulations

The sale of fruit and vegetables is predominantly regulated by FDA through the Food Safety Modernization Act² with the ODA Division of Food Safety being the responsible agency for enforcement in Ohio. FSMA rules establish science-based minimum standards that covered farms and processors must adhere to ensure the safe growing and handling of fruits and vegetables produced for human consumption. The key requirements under FSMA address health and safety concerns with agricultural water quality, biological soil amendments, sprouts,³ domestic and wild animals, worker training and health, and equipment and buildings. FSMA rules/standards and guidance may be accessed on ODA’s website at ofb.ag/foodsafety.

Here are just some of the topics producers can expect to find in the FSMA:

- Agricultural water that would be reasonably likely to transfer harmful microbes to produce through either direct or indirect contact cannot have any detectable amount of generic E. coli. Examples include water used for handwashing, to clean food-contact surfaces, or that would come in contact with produce during or after harvest (i.e. ice). If water is found to be above the general E.coli thresholds, corrective action must be taken as soon as practicable but no later than the following year.⁴



- FSMA rules require that untreated biological soil amendments of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with produce after application. Any compost used in produce production must meet the microbial standards that set limits on detectable amounts of bacteria.⁵
- Farmers are required to take all measures reasonably necessary to identify and not harvest produce that has been contaminated by wild or domestic animals. This requires, at minimum, visual examination of the growing areas and additional assessments during growing seasons if there is significant evidence of potential contamination by animals. Measures should be taken when there is significant evidence of the contamination to assist later during harvest (i.e. placing flags around the affected area).⁶
- Workers should take all necessary measures to prevent contamination of produce and food-contact surfaces by sick individuals. Proper hygienic practices and available toilet and handwashing facilities for all visitors to the farm is imperative. Employees who come in contact with food-contact surfaces need to be properly and regularly trained in the importance of health and hygiene.⁷

1 ORC 3717.01(R)

2 21 CFR 112, OAC 901:3-12-01

3 21 CFR 112.141 through 112.151

4 21 CFR 112.41 through 112.50. Water used to grow produce may have a geometric mean of 126 or less CFU of generic E. coli per 100mL of water with a statistical threshold of 410 CFU or less generic E. coli in 100mL of water.

5 21 CFR 112.51 through 112.60

6 21 CFR 112.81 through 112.140

7 21 CFR 112.21 through 112.33

- Facilities must take measures to prevent contamination of produce through measures such as appropriate storage facilities, and proper maintenance and cleaning of all equipment and tools.⁸ The Produce Safety Rule requires that at least one responsible party from every farm covered by the rule be trained under the FDA curriculum. Training is offered by ODA at no cost to in-state producers throughout the state.

For more information about the federal standards for growing, harvesting, and holding produce for human consumption please see: ofb.ag/fsmafinalrule and ODA's website ofb.ag/divisionfoodsafety.

FSMA Exemptions

Certain small farms or producers are not covered by FSMA standards for produce safety and will be exempt from inspection for FSMA compliance. These exemptions include:

- Farms that have an average annual income of \$25,000 or less over the previous three-year period;⁹
- Farms that only produce fruits and vegetables for personal or on-farm consumption;¹⁰ and
- Produce that has been identified as rarely consumed raw.¹¹

This includes:

- Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

Other farms may be eligible for qualified exemptions and modified FSMA requirements if they meet one of the following criteria:

- The on average income from food sales is less than \$500,000 and the majority of food is being sold to "qualified end-users" (the consumer of the food or a restaurant or retail food establishment located in the same state or not more than 275 miles from the farm);¹² or
- The produce is intended for commercial processing that adequately reduces pathogens.¹³

Farms with qualified exemptions will still need to meet modified requirements, including disclosing the name of the farm the produce was grown at the point of purchase and other record-keeping requirements.¹⁴



Exempt producers of fruit and vegetables may request a voluntary inspection under the FSMA Produce Safety Rule.¹⁵ Farms that request voluntary inspection must register annually with ODA between March 1 and February 28/29. Once a farm has voluntarily registered with ODA it may not withdraw its registration unless specifically permitted by ODA. Farms that choose to undergo voluntary inspection will receive documentation from ODA showing they have been inspected under the federal standards. Prior to requesting voluntary registration and inspection, farmers are able to receive a free consultation visit from ODA to help determine the specific requirements for their farm.

Pesticides

US EPA is the responsible agency for determining the appropriate use and tolerance levels of pesticides used in food production. Food with residue of any pesticide chemical beyond the tolerance or maximum levels set by EPA will be deemed unsafe for human consumption.¹⁶ Tolerances and exemptions for pesticide chemical residues can be found within the Code of Federal Regulations.¹⁷

Similar to federal regulations, Ohio law deems food to be unsafe and adulterated when any poisonous or deleterious substance is added during its production, except where such substance is required or cannot be avoided.¹⁸ ODA is the responsible state agency for the regulation of pesticides and pesticide application in Ohio. Prior to the application of any pesticide or fertilizer, individuals should first contact the Pesticide & Fertilizer Section within ODA to ensure it is aware of any potential requirements, such as applicator licensing.

8 21 CFR 112.121 through 112.140

9 21 CFR 112.4(a)

10 21 CFR 112.2(a)(2)

11 21 CFR 112.2(a)(1)

12 21 CFR 112.3(c)

13 21 CFR 112.2(b)

14 21 CFR 112.2, 112.6, 112.7

15 ORC 3717.221, OAC 901:3-12-06

16 21 USC 346a

17 See 40 CFR 180. For information about how to search for tolerance levels, visit <https://www.epa.gov/pesticide-tolerances>.

18 ORC 3715.62, 3715.59

State Law

Ohio has, for the most part, adopted the federal standards for growing, harvesting, packing and holding produce for human consumption found in Title 21 of the Code of Federal Regulations.¹⁹ The Ohio Department of Agriculture Division of Food Safety is responsible for overseeing produce safety enforcement. ODA has divided those who grow produce into four categories:

- Farms excluded from the FSMA rule.
- Farms that are eligible for a qualified exemption.
- Farms that are covered by the rule.
- Farms that request voluntary inspection under the rule.

Farms that request voluntary inspection receive a free inspection and documentation to show they are inspected under the FSMA Produce Safety Rule. This can be a good way for small producers to show they are following produce safety standards that reduce the risk of microbial contamination during the growing, harvesting, packing, and holding of their product.

Ohio’s uniform safety code specifically states that raw fruits and vegetables are to be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form. However, whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.²⁰ Keep in mind, in order to sell fruits or vegetables without first needing to obtain a retail food establishment license, the produce must be unprocessed. This means that unless a farm has obtained proper licensing for food processing, the seller may only roughly trim and/or rinse their product before offering it for sale.

Package and Label

All statements made about fruit and vegetables, either written or verbal, must be true and honest with reference to quantity, grade, price, variety, minimum size, or the state of origin when offered for sale.²¹

Fruit or vegetables sold in containers used to hold or enclose a quantity of items need to be marked in a plain and legible manner with the following information:

- The full name and address of the farm.
- The contents of the package by net weight at the time of sale, numerical count, or dry measure.
- The grade in accordance with the standards adopted by the USDA if the container holds peaches, apples, potatoes, or dry onions.

- The minimum size and variety of apples or graded peaches held by the container. If the variety cannot be identified, the term “variety unknown” should be used.

- The identity of the fruit or vegetable if it is concealed.²² Labels or stamps with the required information must use a font of adequate size²³ and be placed on the side, end, or cover of the container, the front or face of any bag, or on a tag attached to any bag.²⁴ Whenever fresh fruits or vegetables are packed or offered for sale in containers previously used by another person or in containers that were manufactured and labeled for a purpose other than the sale of the produce it contains, any old and/or inaccurate markings must be covered and new markings must be properly placed. If any type of bag is re-used, it should be turned inside out so that no previous markings are visible.²⁵

When ODA has reason to believe that a container of any fruit or vegetable has been improperly labeled, it has the authority to mark the container with a notice that the container is being detained for being improperly marked.²⁶ Once a container has been marked as mislabeled, no person is able to remove or dispose of the container without the permission of ODA or a court of competent jurisdiction.²⁷

USDA offers voluntary quality standards for fruits and vegetables and provides uniform language describing the quality and condition of the produce for sale. Information about USDA grades and standards can be found on their website: <https://www.ams.usda.gov/grades-standards>.

Sale

Fresh, unprocessed fruits and vegetables may be sold without a Retail Food Establishment License at the following locations:²⁸

1. A roadside stand where only fresh fruits and vegetables are offered.²⁹
2. A farmers market.³⁰
3. A farm product auction.³¹
4. A festival or celebration organized by a political subdivision of the state,³² and
5. A registered farm market.³³

19 OAC 901:3-12
 20 OAC 3717-1-03.2(G)
 21 ORC 925.29

22 ORC 925.22(A)
 23 ORC 925.22(B)
 24 ORC 925.22(C)
 25 ORC 925.24
 26 ORC 925.30
 27 Id
 28 ORC 3717.22
 29 ORC 3717.22(B)(3)
 30 ORC 3717.22(B)(2)(a)
 31 ORC 3717.22(B)(11)(b)
 32 ORC 3717.22(B)(15)(a)
 33 ORC 3717.22(B)(16)(a)



Am I covered by FSMA ?

- Q1** Does your farm grow, harvest, pack, or hold produce?
No: Your farm is not covered by FSMA; you are exempt.
Yes: See question two.
- Q2** In the last three years, has your farm on average had \$25,000 or less in annual produce sales?
Yes: Your farm is not covered by FSMA; you are exempt.
No: See question three.
- Q3** Is the product you would like to sell one that FDA has identified as rarely consumed raw?
Yes: Your farm is not covered by FSMA; you are exempt.
No: See question four.
- Q4** Is your produce for personal/on-farm consumption?
Yes: Your farm is not covered by FSMA; you are exempt.
No: See question five.
- Q5** Is your produce intended for commercial processing?
Yes: You may be exempt from the rule upon filing the proper documentation.
No: See question six.
- Q6** In the past three years, has your farm had less than \$500,000 in annual food sales and is a majority of the food sold directly to “qualified end-users”?
Yes: You may be eligible for a qualified exemption.
No: You are not exempt from FSMA rules.

Contacts and Resources

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