



The Kentucky Produce Safety Program

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The Food Safety Modernization Act

The Food Safety Modernization Act, also known as FSMA, was signed into law by President Barack Obama on January 4, 2011. FSMA was designed to focus on the prevention of food safety hazards and foodborne illnesses.

The Produce Safety Rule

The FSMA Produce Safety Rule (PSR) is a federal food safety law that went into effect on January 26, 2016. Before the start of the PSR, the produce industry followed voluntary guidelines for produce handling provided by the Food and Drug Administration (FDA). The PSR outlines minimum standards for safely growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. These standards are based on science. Farms covered by the rule are required to meet the standards set by the PSR. The PSR set standards in the following areas of produce production:

- Worker training, health, and hygiene.
- Agricultural water used for production and post-harvest.
- Biological soil amendments of animal origin and human waste.
- Domesticated and wild animals.
- Equipment, tools, buildings, and sanitation.
- Sprout production.

The full text of FDA's Produce Safety Rule [can be found here](#) or on the [Electronic Code of Federal Regulations](#). All hyperlinks within the document can be found in the appendix.

Some produce growers are exempt from the PSR and will be discussed later in

this paper. Additionally, compliance dates for the PSR can be found in Table 1.



Lettuce production in a high tunnel

Regulatory, Administrative, and Support Agencies

Kentucky Department of Agriculture

The Kentucky Department of Agriculture (KDA) serves as the regulatory agency for the Produce Safety Rule in Kentucky. In early 2020, the Kentucky General Assembly passed House Bill 420 assigning the KDA to this role. The full text of Kentucky's Produce Safety Statute [can be found here](#).

Additionally, KDA is responsible for overseeing Kentucky's Produce Safety Regulation (302 KAR 60:010) which further clarifies and supports the state statute. The full text of Kentucky's Produce Safety Regulation [can be found here](#).



www.uky.edu/CCD

Kentucky's state Produce Safety Statute and

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Regulation adopt the federal Produce Safety Rule by reference and add some Kentucky-specific requirements for growers which are discussed below.

The KDA will also conduct voluntary On-Farm Readiness Reviews (OFRR) when requested at no cost to the grower. The OFRR is for growers who may fall under the Produce Safety Rule. During the OFRR, KDA and University of Kentucky (UK) representatives look at a farm's growing, harvesting, packing, and holding processes, then share ideas for improving the farm's practices. The OFRR is completely voluntary and is not a regulatory visit. It is a service to help the farmer become compliant with the Produce Safety Rule. An OFRR may be requested through the [KDA Online Produce Farm Survey](#), or by contacting Dain Satterwhite at dain.satterwhite@ky.gov or 502-229-6853. More information on OFRRs [can be found here](#).

University of Kentucky

The University of Kentucky Food Systems Innovation Center through a cooperative grant with the KDA, provides farmers with the Produce Safety Alliance (PSA) Grower Training Course required by the Produce Safety Rule. This course follows a standardized curriculum on food safety and is currently offered in the form of a 7-8 hour training. Additionally, the University of Kentucky Center for Crop Diversification provides farmers with references and other trainings. For more information, [visit the UK trainings website](#).

Requirements for Kentucky Produce Growers

Produce Farm Inventory Survey

The Farm Inventory Survey can help farms see if they are covered by the PSR or if they are exempt. Regardless of farm size, sales volume, or whether you are exempt, Kentucky's Produce Safety Regulation (302 KAR 60:010) requires that all produce farms in Kentucky complete an informational Produce Farm Survey. The survey can be found on the [Kentucky Department of Agriculture Website](#). A printed version of this survey can be requested through the KDA and the contact is found in section 2 of the appendix.

Produce Safety Alliance Grower Training Course

The Kentucky Department of Agriculture Produce Safety Statute (KRS 260.765 to 260.772) requires that every Kentucky produce grower that sells over \$25,000 in annual sales must have at least one person (typically a supervisor or responsible party for the farm) successfully complete the Produce Safety Alliance (PSA) Grower training. Under KDA rules, this training requirement includes farms that are eligible for a Qualified Exemption.

Even though it is not required, we recommend that growers with less than \$25,000 on average in annual sales over the previous three years (adjusted for inflation) take this training, which can be used in place of the Produce Best Practices Training (PBPT) for farmers' market vendors offering sampling.

Under a Cooperative Agreement Grant from the FDA, KDA and UK partners offer the PSA Grower Training Course free of charge to Kentucky produce growers. Currently, the training is being offered both virtually and in-person at different times and locations across the state. Growers who complete this training will receive a certificate from the Association of Food and Drug Officials (AFDO) that can be displayed on the farm or at farmers' market locations. This course is only required to be taken once. For more information about PSA trainings or to register for an event, growers can visit the [UK trainings website](#) or call the University of Kentucky Food Systems Innovation Center (FSIC) at (859) 257-1546. More information on the Produce Safety Alliance and their role in produce safety [can be found here](#).

Farms Exempt or Excluded from the Produce Safety Rule

Farms that meet the Basic Exemption or Qualified Exemption requirements (see below) are not subject to routine regulatory inspection.

Basic Exemption Application

The Produce Safety Rule does not apply to all operations that grow, harvest, pack, or hold fresh produce. Farms that are exempt from the PSR include:

- Micro-exemption: Farms that have an average annual gross income from all produce sales of \$25,000 (as of 2011; amount is adjusted according to inflation) or less during the previous three-year period. The FDA inflation adjustment [can be found here](#).

- Rarely Consumed Raw Exemption: Produce commodities that are rarely consumed raw (as defined by the FDA; [attached is a fact-sheet with more information](#)).
- Personal Use Exemption: Produce that is grown for personal or on-farm consumption.
- Commercial Processing Exemption: Produce that is intended to be further processed to adequately reduce the number of microorganisms using approved treatments, such as tomatoes being processed for ketchup.

If you meet the criteria above, a Certificate of Exemption is not required. However, many farmers' markets and other produce related programs may request the certificate as proof of exemption status. You can request a formal Certificate of Exemption by completing an Application for Basic Exemption [which can be found here](#). Once the completed application is received and reviewed by the KDA Produce Safety Program, verified applicants will then be mailed a Certificate of Exemption. Farms need to review their operation every year to make sure they are still exempt and notify the KDA of any changes in status. If there is no change in the exemption status, there is no need to renew a Basic Exemption. Under KDA's Produce Safety Regulation, growers must immediately notify KDA if there is a change in exemption status.

Qualified Exemption Application

A farm can apply for a qualified exemption through the KDA if they meet the requirements below:

- The farm has food sales averaging less than \$500,000 (as of 2011; amount is adjusted according to inflation) per year during the previous three years. The FDA inflation adjustment [can be found here](#).
 - Note: Food sales includes produce sales, and any other food sold on the farm (beef, poultry, grains).
- The farm's food sales to qualified end-users (the consumer or a food retail establishment in the same state, less than 275 miles away from the farm) exceeds sales to all other

types of purchasers.

- Under KDA's Produce Safety Statute, the farm owner, manager, or supervisor must attend the PSA Grower Training Course.

Growers meeting these requirements who want to be Qualified Exempt must complete an Application for Qualified Exemption with KDA. Growers meeting the above items who do not submit an Application for Qualified Exemption to KDA are considered covered and subject to inspection. To be Qualified exempt, you MUST apply with KDA. A KDA issued Certificate of Qualified Exemption is valid for up to three years, however, under the PSR, growers must review their operation annually. Under KDA's Produce Safety Regulation, growers must immediately notify KDA if a grower's annual self-assessment determines that the farm is no longer eligible for a Qualified Exemption.

The Application for Qualified Exemption can be found [here](#). Once the completed application is received and reviewed by the KDA Produce Safety Program, applicants that meet the requirements for a Qualified Exemption will then be mailed an exemption certificate.



A farm pond commonly found on KY farms

Farms that have been issued a Qualified Exemption Certificate must meet two modified requirements:

- Include your name, complete business address (or street address/post office box), city,

state, and zip code prominently on the labels of produce packaging, or at the point of sale.

- Keep records that establish eligibility, including dated sales records, perform an annual review and verification of the farm’s continued eligibility for the Qualified Exempt, and provide these records if requested.

Inspection Frequency for Covered (Non-Exempt) Farms

The inspection frequency of a non-exempt, covered farm will be determined by the Kentucky Department of Agriculture based on risk profiles or groupings. These groups are based on items such as the types of commodities handled, farm acreage, annual produce sales, whether the farmer has completed PSA Grower training, compliance history, completion of an on-farm readiness review, the type of agricultural water source on a farm, the presence of a farm food safety plan, GAP certification or other food safety programs, adjacent land use, likelihood of wildlife access to the farm, and the geographical location of the farm. Farms will be assigned a risk priority which in turn determines the farm’s inspection frequency:

- Priority 1 farms (highest risk): minimum of one inspection per year.
- Priority 2 farms (medium risk): minimum of one inspection every two years.
- Priority 3 farms (lowest risk): minimum of one inspection every three years.

KDA will schedule all routine inspections with the farm owner/operator. Following an inspection, a KDA Field Representative will give an inspection report to the farm owner/operator. The report will describe any item(s) found to be in non-compliance with the PSR. Inspections are classified or graded based on how many items are in non-compliance, and how severe those items are based on the risk to food safety and public health.

There are three types of inspection classifications or grades:

- No Action Indicated (NAI)-This indicates a passing inspection with no significant items of non-compliance observed.
- Voluntary Action Indicated (VAI)-This indicates that some items of non-compliance were observed, but the risk to food safety and public health is minimal. A Corrective Action Plan is required to be submitted to KDA for a VAI classification. Corrective Action Plans are submitted by growers to verify that objectionable conditions have been or will be corrected within a specific time frame.
- Official Action Indicated (OAI)-This indicates that one or more items of non-compliance that pose a serious risk to food safety and public health were observed. A Corrective Action Plan is required to be submitted

Table 1: PSR Compliance Dates

Source: producesafetyalliance.cornell.edu

Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates ¹
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22
Small businesses (>\$250K-500K) ³	1/26/18	1/28/19	1/26/23
Very small businesses (>\$25K-250K) ⁴	1/28/19	1/27/20	1/26/24

to KDA for an OAI classification. An OAI inspection classification/grade also requires that a follow-up inspection be conducted to verify that the items of non-compliance were adequately addressed by the farm owner/operator.

A KDA Certificate of Compliance will be issued to all farms receiving an inspection classification of NAI or VAI.

In rare circumstances of serious or very dangerous conditions, additional Compliance or Enforcement actions may be required.

Summary

The Food Safety Modernization Act Produce Safety Rule was enacted to prevent foodborne hazards, particularly of microbial origin, to enhance the safety of the US food supply. State lawmakers assigned the Kentucky Department of Agriculture as the agency responsible for the implementation and administration of the Produce Safety Rule. Under the Kentucky Produce Safety Program, Kentucky fruit and vegetable growers will work with fellow Kentuckians at the Kentucky Department of Agriculture and University of Kentucky to produce a safe supply of fresh produce for state residents.

More information on the Kentucky Department of Agriculture Produce Safety Program can be found at the following website: <https://www.kyagr.com/marketing/produce-safety.html>

Growers should use social media tools to promote their operation because it is an easy way to grab consumer's attention.

Appendix

A. Common Food Safety Program Acronyms

FSMA	Food Safety Modernization Act
PSR	Produce Safety Rule
FDA	Food and Drug Administration
KDA	Kentucky Department of Agriculture
OFRR	On-farm Readiness Review
UK	University of Kentucky
PBPT	Produce Best Practices Training
PSA	Produce Safety Alliance
NAI	No Action Indicated
VAI	Voluntary Action Indicated
OAI	Official Action Indicated
AFDO	Association of Food and Drug Officials
FSIC	Food Systems Innovation Center

B. Links in order as they are found within document

1. FDA Produce Safety Rule: https://www.kyagr.com/marketing/documents/PS_PSR_CFR-2018-title21-vol2-part112_Produce_Safety_Rule.pdf
2. Electronic Code of Federal Regulations: <https://www.ecfr.gov/cgi-bin/text-idx?node=pt21.2.112&rgn=div5>
3. FDA Produce Safety Statute: https://www.kyagr.com/marketing/documents/PS_KRS_260_Produce_Safety_Law.pdf
4. FDA Produce Safety Regulation: https://www.kyagr.com/marketing/documents/PS_Kentucky_Produce_Safety_Administrative_Regulation.pdf
5. KDA Farm Survey: <https://www.kyagr.com/marketing/plant/fsma-survey.aspx>
6. OFRR: <https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review>
7. UK training website: <https://www.uky.edu/fsic/trainings.php>
8. Produce Safety Alliance: <https://producesafetyalliance.cornell.edu/>
9. FDA FSMA Inflation Adjustments: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>
10. FDA Rarely Consumed Raw Factsheet: <https://www.fda.gov/media/107445/download>

11. KDA Basic Exemption Form: https://www.kyagr.com/marketing/documents/PS_Basic_Exemption_Form_KY.pdf
12. KDA Qualified Exemption Form: https://www.kyagr.com/marketing/documents/PS_Qualified_Exemption_KY.pdf
13. KDA Produce Safety website: <https://www.kyagr.com/marketing/produce-safety.html>

References

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Produce Safety Rule Compliance Dates & Timeline | Produce Safety Alliance. (n.d.). Cornell University Produce Safety Alliance. Retrieved May 4, 2021, from <https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule-compliance-dates-timeline/>

The Kentucky Department of Agriculture, Produce Safety. (n.d.). The Kentucky Department of

Agriculture. Retrieved May 4, 2021, from <https://www.kyagr.com/marketing/produce-safety.html>

To request printed versions of documents, contact the Kentucky Department of Agriculture.

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