



Eric J. Holcomb  
Governor

Kristina Box, MD, FACOG  
State Health Commissioner

**DATE:** June 29, 2018  
**TO:** All Indiana Local Health Departments  
**FROM:** Krista Click, Director, Food Protection Program KC  
**SUBJECT:** Indiana Senate Enrolled Act 331; Produce Safety Regulations

To Whom It May Concern:

Indiana Senate Enrolled Act 331 was signed into law on March 15, 2018, with an effective date of July 1, 2018. This law adopts the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act Produce Safety Rule, 21 Code of Federal Regulation (CFR) Part 112.

Under Senate Enrolled Act 331, Indiana Code now references the FDA Food Safety Modernization Act (FSMA), and defines the term "produce farm." The adoption of the FSMA Produce Safety Rule in Indiana Code allows the Indiana State Department of Health (ISDH) to enter and inspect, at reasonable times, any covered produce farm. A decision tree is provided with this memo that outlines the coverage, exemption, or exclusion status of a produce farm. Fully covered produce farms must comply with the requirements in 21 CFR Part 112. If a produce farm has a qualified exemption, the farm is only required to comply with the specific requirements outlined. A summary of the amended Indiana Code (IC) is also included with this memo.

The ISDH Food Protection Program will be overseeing, implementing, and managing all produce safety regulations. ISDH Food Protection Program staff will be conducting outreach to produce growers in the form of education and consultation on relevant food safety practices associated with fresh produce. We are collaborating with Purdue University Extension and the Indiana State Department of Agriculture for outreach and engagement with Indiana produce growers. ISDH staff will begin inspecting produce farms that are subject to this state law in 2019. Registration of fully covered and qualified exempt produce farms is required, and is recommended for produce farms excluded from Produce Safety Rule requirements, but are wholesaling produce that is typically consumed raw.

Local health departments may support produce safety in Indiana by being aware of the Produce Safety Rule and ensuring that local produce growers and food establishments are aware of these produce safety requirements. While conducting inspections of retail food establishments, local health department food safety inspection officers may inquire if Indiana produce is being served or sold. If so, local health departments should inquire about the ISDH registration status of the suppliers. Specific questions should be referred to the ISDH Food Protection produce safety staff.

More information on the Produce Safety Rule can be found at [www.safeproducein.com](http://www.safeproducein.com) or <https://www.in.gov/isdh/25773.htm>, or by contacting JoAnna Beck, ISDH Produce Safety Supervisor, at [producesafety@isdh.in.gov](mailto:producesafety@isdh.in.gov) or 317-476-0056.



2 North Meridian Street • Indianapolis, IN 46204  
317.233.1325  
[www.statehealth.in.gov](http://www.statehealth.in.gov)

To promote and provide  
essential public health services.

#### **IC 16-18-2-124**

Sec. 124. "Federal act", for purposes of IC 16-42-1 through IC 16-42-4, refers to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.), as amended by the FDA Food Safety Modernization Act (Public Law 111-353), and amendments to those statutes.

#### **IC 16-18-2-294.1**

Sec. 294.1. "Produce farm", for purposes of IC 16-42-1 through IC 16-42-4, means a person that:

- (1) grows, harvests, packs, or holds covered produce (as defined by 21 CFR 112) that is intended for human consumption; and
- (2) is subject to 21 CFR 112.

The term does not include a person that is exempt under 21 CFR 112.

#### **IC 16-42-1-1**

Sec. 1. (a) IC 16-42-1 through IC 16-42-4 are intended to safeguard the public health and promote the public welfare by protecting the:

- (1) consuming public from injury by product use; and
- (2) purchasing public from injury by merchandising deceit;

flowing from intrastate commerce in food, drugs, devices, and cosmetics.

(b) IC 16-42-1 through IC 16-42-4 are intended to be uniform with the:

- (1) Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by the FDA Food Safety Modernization Act (Public Law 111-353); and
- (2) Federal Trade Commission Act (15 U.S.C. 41 et seq.);

including amendments to those statutes, to the extent they expressly outlaw the false advertisement of food, drugs, devices, and cosmetics.

(c) IC 16-42-1 through IC 16-42-4 thus promote uniformity of such statutes and their administration and enforcement throughout the United States.

#### **IC 16-42-1-13**

Sec. 13. For the purpose of enforcing IC 16-42-1 through IC 16-42-4, the state health commissioner or the commissioner's authorized representative may do the following:

- (1) Enter, at reasonable times any produce farm, factory, warehouse, place of production, or establishment subject to IC 16-42-1 through IC 16-42-4 or enter any vehicle being used to transport or hold food, drugs, devices, or cosmetics.
- (2) Inspect, at reasonable times, the produce farm, factory, warehouse, place of production, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, and advertisements.

#### **IC 16-42-3.5-1**

Sec. 1. (a) Subject to subsection (b), a produce farm shall comply with the requirements in 21 CFR 112. However, a produce farm that has a qualified exemption under 21 CFR 112 is required only to comply with the requirements specified for the qualified exemption under 21 CFR 112.6.

(b) The state department may suspend the requirements under subsection (a) if the federal government does not provide sufficient funds for the state department to administer and enforce the requirements in 21 CFR 112. However, if the federal government does not provide any funds for the state department to administer and enforce the requirements in 21 CFR 112, the state department shall suspend the requirements under subsection (a).

#### **IC 16-42-3.5-2**

Sec. 2. (a) The state department shall implement this chapter.

(b) The state department may adopt rules under IC 4-22-2 that are necessary to implement this chapter. However, the rules may not provide for requirements that are more stringent than required under 21 CFR 112.