

## FSMA Frequently Asked Questions: Does FSMA affect my food business?

### 1. I've heard that the Food Safety Modernization Act (FSMA) regulates just about all food production, including farming. How do I know if FSMA applies to me?

FSMA became law in 2011, and it significantly changed and expanded federal food safety law. To implement FSMA, the US Food and Drug Administration (FDA), has published 7 major rules:

- I. Preventive Controls Rule for Human Food
- II. Preventive Controls Rule for Animal Food
- III. Produce Safety Rule
- IV. Foreign Supplier Verification Program Rule
- V. Accredited Third-Party Certification Rule
- VI. Sanitary Transportation Rule
- VII. Intentional Adulteration Rule

Whether any of these rules apply to your business depends on the activities your food business performs, the foods it produces or handles, your operation's business structure, and who your customers are.

The Carolina Farm Stewardship Association and the Local Food Safety Collaborative have developed this series of Frequently Asked Questions about FSMA for:

- small-scale US farms,
- farm cooperatives,
- produce packing houses,
- food hubs, food manufacturers,
- food distributors,
- on-farm food processors,
- and other food businesses serving markets for local and regional foods.

These FAQs will help you understand these rules, who they cover, and what these kinds of covered businesses need to do to comply with FSMA.

Three FSMA Rules are highly unlikely to apply to the typical business in the list above: Foreign Supplier Verification, Accredited Third-Party Certification, and Intentional Adulteration. This FAQ series does not address these three rules.

***These materials are not intended to provide legal advice.*** If you have concerns about the specific application of FSMA to your particular business, it is recommended that you consult with an attorney or other regulatory experts. However, these materials will help you ask the right questions about the coverage of the law and give you an overview of the key requirements.

**IMPORTANT NOTE:** Whether your business is covered by FSMA or not, you can always be held liable in civil court for any illness caused to consumers by food you make or distribute, even if the contamination that caused the illness was accidental. Moreover, the Federal Food Drug and Cosmetic Act makes it a strict liability crime to distribute food<sup>1</sup> that contains any substance that could cause injury or illness; that is made or handled under unsanitary conditions; or that is improperly labelled<sup>2</sup>. 'Strict liability' means it doesn't matter if the illegal conduct was accidental: you are subject to criminal penalties even if you did not intend to do something that resulted in a violation of the Act. State food safety laws may also apply to your business.

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<sup>1</sup> Businesses producing meat, poultry, and processed egg products that are **regulated exclusively**, throughout the entire facility, **by the U.S. Department of Agriculture** are not subject to FDA jurisdiction or the Food Drug and Cosmetic Act.

<sup>2</sup> For detailed explanation of the FDA's food labelling requirements, see the FDA's [guidance for industry on food labelling](#).

## 2. So where do I start to figure out whether FSMA applies to me?

The first question to ask in deciding what parts of FSMA apply to your business, if any, is whether your business is a ‘farm’ within the meaning of FSMA. This may seem obvious, but getting the answer right is important, because if your business is a farm, then it is not a food ‘facility’. If your business is a ‘facility’ under FSMA, then it may be subject to FDA’s Preventive Controls for Human Food or Animal Food (PC) Rules, which cover food processing. The costs of compliance with the PC Rules can be tens of thousands of dollars a year for a small business.

If your business meets FDA’s definition of either a **Primary Production Farm (PPF)** or a **Secondary Activities Farm (SAF)**, then the **PC Rules do not apply** to you<sup>3</sup>. The upshot of these definitions is that things that farmers and groups of farmers do to grow raw produce crops *and to prepare them for market* are treated as ‘farm’ activities, not ‘facility’ activities. If your business:

- is a farm,
- is a cooperative of multiple farms,
- works very closely with a farm or group of farms,
- has as it’s only activities handling and packing produce,

or if you are otherwise uncertain if your business might be classified as a farm, see the FSMA FAQ [‘Is My Food Business a Farm?’](#) to learn more about FSMA’s ‘farm’ definition and how it applies.

If you know your business would not be a farm, and the business is not majority-owned by farms,

- see the FSMA FAQ [‘Is My Non-Farm Food Manufacturing Business Covered by FSMA?’](#) if the business involves making/processing and handling and distributing foods.
- see the FSMA FAQ [‘Is My Non-Farm Food Distribution Business Covered by FSMA?’](#) if the business involves only handling and distributing foods.

Also, your business may be covered by portions of FSMA’s Sanitary Transportation Rule. To learn more, see the FSMA FAQ [‘Is My Business Covered by the FSMA Rules for Sanitary Transportation of Food?’](#)

*This document is not legal advice and is for educational purposes only. It has not been approved by the FDA.*

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<sup>3</sup> Farms that manufacture foods on the farm, or that pack or hold foods in addition to their farming activities, fall into a special category: a ‘farm mixed-type facility’. The food manufacturing, packing and holding activities that are part of ‘farming’ will not be regulated under the PC Rules, but the same activities may be subject to the PC Rules if they don’t fall under of FSMA’s definition of farming. See the FSMA FAQ [‘Is My Business a Farm Mixed-Type Facility?’](#) to learn more about the PC Rules and farm mixed-type facilities.