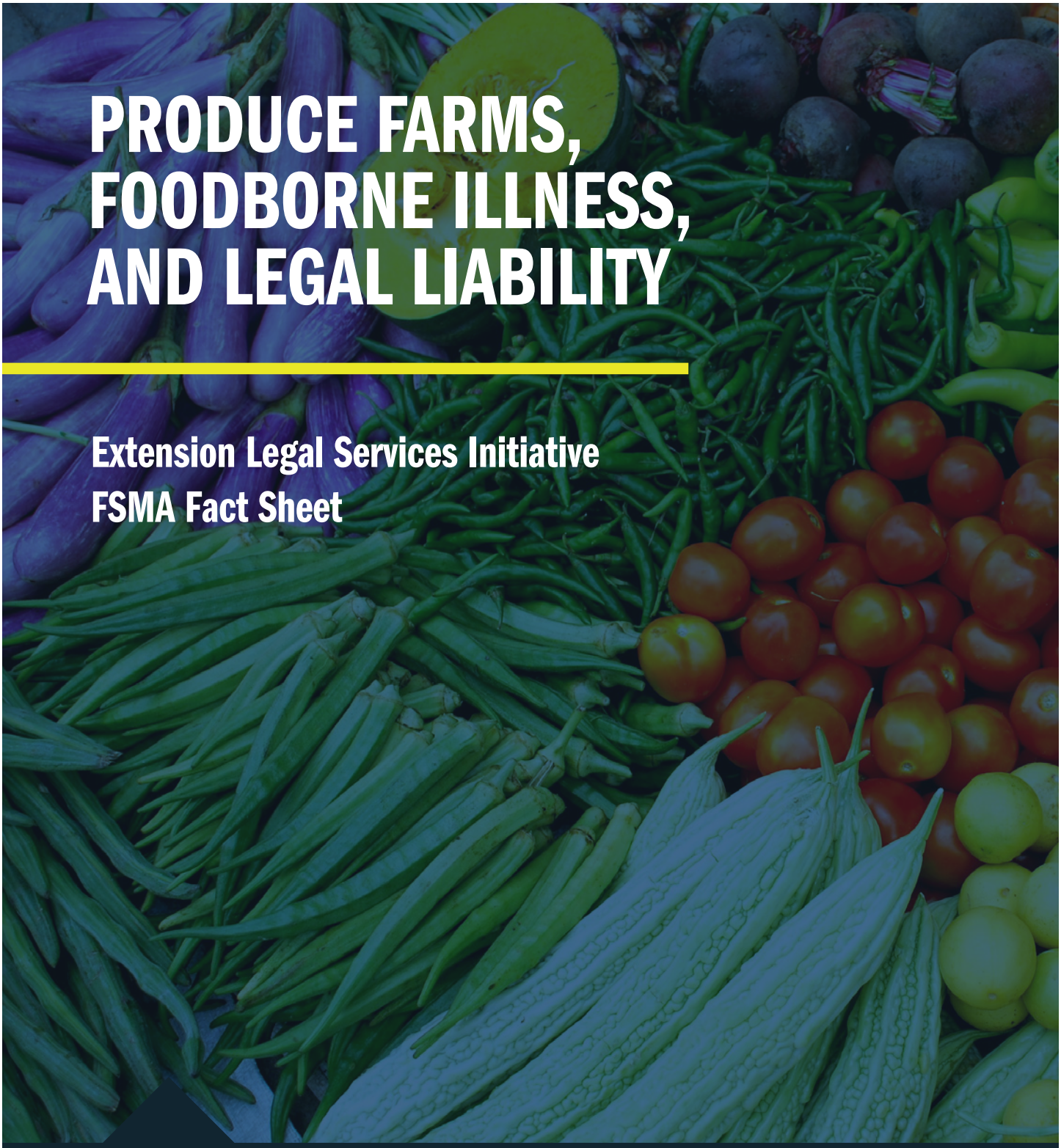

PRODUCE FARMS, FOODBORNE ILLNESS, AND LEGAL LIABILITY

Extension Legal Services Initiative
FSMA Fact Sheet

NECAFS
The Northeast Center to Advance Food Safety

VERMONT LAW SCHOOL

CENTER FOR AGRICULTURE & FOOD SYSTEMS

WHAT IS THE FSMA PSR?

The Food Safety Modernization Act's Produce Safety Rule (FSMA PSR) sets mandatory standards for growing, harvesting, packing, and holding produce for human consumption.

Producers are asking about their liability if a foodborne illness is traced back to their produce operation. Generally speaking, a producer could face civil or criminal liability regardless of whether they knew the produce was contaminated or they are covered by the Food Safety Modernization Act's Produce Safety Rule (FSMA PSR). However, compliance with the FSMA PSR may help mitigate a producer's financial or criminal responsibility in the event of a lawsuit.

CIVIL LIABILITY LAWS VARY BY STATE

Civil liability law for foodborne illness cases varies by state, so descriptions in this sheet are general and may not reflect the law in every state. See our state matrix chart for more information.

WHAT IS LIABILITY?

Liability is your legal responsibility to another or to society. There are two forms of liability: civil and criminal. An individual who has been harmed by a producer's contaminated produce may bring a civil case against that producer. This is commonly referred to as product liability. In civil cases, the penalty to the producer may be damages, which is money paid to the individual harmed to compensate them for loss or injuries associated with the product.

Criminal cases may be brought by the government, as opposed to an individual private party, against a producer suspected to have violated a law applicable to their operation. If found to be in violation, the penalty for the producer may be a fine and/or some period of incarceration.

CIVIL LIABILITY
When an **individual** brings a case against a producer

CRIMINAL LIABILITY
When the **government** brings a case against a producer

HOW DOES LIABILITY IMPACT PRODUCERS?

Generally, there are several forms of civil and criminal product liability that may impact a producer, depending on the state law that applies. Most commonly, an individual may bring a civil case against a producer if the product was defective and that defect caused an injury or loss. This type of product liability is known as strict liability, and it does not require proof that the producer failed to act with a specific standard of care. Instead, it is based on the producer's absolute duty to produce a safe product.

Additionally, and particularly in states that do not follow strict liability, a negligence case may arise if the producer failed to act as a reasonable person would under similar circumstances and this failure caused the plaintiff's injury. A producer might be negligent when he engages in activities that could cause his produce to be unsafe for consumption or fails to take action necessary to prevent contamination from occurring.

While criminal liability lawsuits arising from foodborne illness outbreaks are uncommon, it is important to know that producers, whether they intend to or not, can be held criminally liable for failure to comply with the federal Food, Drug and Cosmetic Act (FD&C Act), which prohibits the introduction or delivery of an adulterated (contaminated) food product into commerce.

HOW DOES THE FSMA PSR IMPACT OR CHANGE LIABILITY?

Liability has always existed under civil and criminal law for producers if a foodborne illness had been traced back to their farm.

In the civil context, a covered producer's failure to comply with the FSMA PSR could be used to prove that the producer was negligent. Because the FSMA PSR sets a standard of care for keeping produce safe, failing to comply is evidence that the producer didn't meet the necessary standard of care, and suggests the producer was negligent.

In the criminal context, the FSMA PSR adds an additional layer of liability for a foodborne illness. Before the rule, a producer could be found criminally liable under the FD&C Act for introducing contaminated produce into commerce, even if the producer did not know the produce was contaminated. After the rule, a producer who fails to meet the applicable FSMA PSR requirements could be found criminally liable for violating both the FSMA PSR and the general FD&C Act prohibition on adulteration.

The same criminal penalties that existed before FSMA for violating the general FD&C Act prohibition on adulteration (fines and/or jail time) now also apply to a violation of the FSMA PSR. However, the FDA or state enforcement body, depending on the state, has discretion to determine whether it will bring enforcement actions for violations of the FD&C Act generally, and the FSMA PSR specifically.

CLAIMS RELATED TO CIVIL LIABILITY

The most common claims used in produce-related foodborne illness civil liability cases are:

- Negligence
- Negligence per se: This claim includes a violation of a state or federal statute, including the Food Drug and Cosmetic Act and Food Safety Modernization Act
- Strict liability
- Breach of implied or express warranty

CLAIMS RELATED TO CRIMINAL LIABILITY

The most common claims used in produce-related foodborne illness criminal liability cases involve failure to comply with state or federal statutes, such as the federal Food, Drug, and Cosmetic Act.

HOW DOES COMPLIANCE WITH THE FSMA PSR AFFECT MARKET ACCESS?

From a non-regulatory perspective, FSMA PSR compliance may enhance a producer's business, as evidence of compliance with food safety standards is increasingly a purchasing requirement among buyers. Compliance with the FSMA PSR combined with making food safety a top priority can increase market access, reduce risk, and decrease the likelihood of a foodborne illness outbreak. It can also mitigate the risk of both civil and criminal liability.

HOW DOES COMPLIANCE WITH THE FSMA PSR AFFECT A PRODUCER'S LIABILITY?

All producers—exempt, qualified exempt, and covered—have food safety requirements they must meet, whether specifically under the FSMA PSR or generally under the FD&C Act. Complying with applicable FSMA PSR requirements does not automatically protect a producer from liability. But in the event that a FSMA PSR-compliant producer introduces or delivers an adulterated food product into interstate commerce, this compliance could reduce their civil or criminal liability.

COMPLYING WITH THE FSMA PSR

Ultimately, a producer can be held civilly or criminally liable even when complying with the FSMA PSR.

However, complying with the FSMA PSR may make liability less severe because it can:

- Show that the producer is meeting the FSMA PSR's standard of care in a civil lawsuit.
- Factor into enforcement discretion or penalties in a criminal violation.

This document provides general legal information for educational purposes only. It is not meant to substitute, and should not be relied upon, for legal advice. Each operation and situation is unique, state laws vary, and the information contained here is specific to the time of publication. Accordingly, for legal advice, please consult an attorney licensed in your state.

This fact sheet is part of a series on legal topics related to compliance with the FSMA PSR. To access additional resources, go to go.uvm.edu/fsmafactsheets. If you would like to view the legal research and citations that inform this fact sheet, please contact CAFS@vermontlaw.edu. We also encourage readers to visit FDA's website for additional information:

- https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
- https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

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