# FSMA PSR INPLEMENTATION AND STATE LAWS

Extension Legal Services Initiative FSMA Fact Sheet





#### 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. Implementation and enforcement of the Food Safety Modernization Act Produce Safety Rule (FSMA PSR) is a collaborative effort between the Food and Drug Administration (FDA) and the states. While efforts are underway to promote consistency across state lines, there is some variation by state in terms of who is implementing the FSMA PSR, and how. The Extension Legal Services Initiative's <u>FSMA Legal Resources</u> website contains an <u>interactive map</u> and table of state legal authority for FSMA PSR implementation.



This factsheet summarizes some of the information found on the <u>FSMA Legal Resources</u> website. Readers are encouraged to visit the website for additional and up-to-date information.



**STATUTE:** a law enacted by the legislature.

**REGULATION:** a rule written by an agency, often to elaborate on the agency's authority given by statute.

For more on the difference between statutes, regulations, and other agency materials, see our factsheet <u>Understanding the Relationship</u> <u>between FDA Rules, Guidance, and</u> <u>Other Communications at</u> <u>go.uvm.edu/fsmafactsheets</u>.

## WHO IS CONDUCTING FSMA PSR INSPECTIONS AND UNDER WHAT AUTHORITY?

FDA has the ultimate responsibility to implement and enforce the FSMA PSR. However, in most cases, the states are conducting all of the implementation activities (e.g., education, outreach, and developing an inventory of farms), and in all but six states the state is conducting both implementation and enforcement (e.g., inspections). States conducting implementation and enforcement themselves are doing so through either credentialing or state authority. If a state is acting under a

"credentialed" system for PSR

implementation, it is doing so under FDA's authority through the FDA Commissioning Program which "delegate[s] the authority of federal law to state and local officials." Essentially, the state is enforcing FDA's law. To date, 14 states are enforcing the PSR through FDA credentialing. If a state is acting under its own authority, it has enacted its own state statue or issued regulations governing how the PSR will be implemented. Currently, 30 states are implementing the PSR under their own authority.

Who will be conducting PSR inspections, and under what authority? State (Under State Authority) State (Credentialed) FDA NΛ MT MA WY OH **CO** MD AZ TN **OK** SC GA AL MS TX



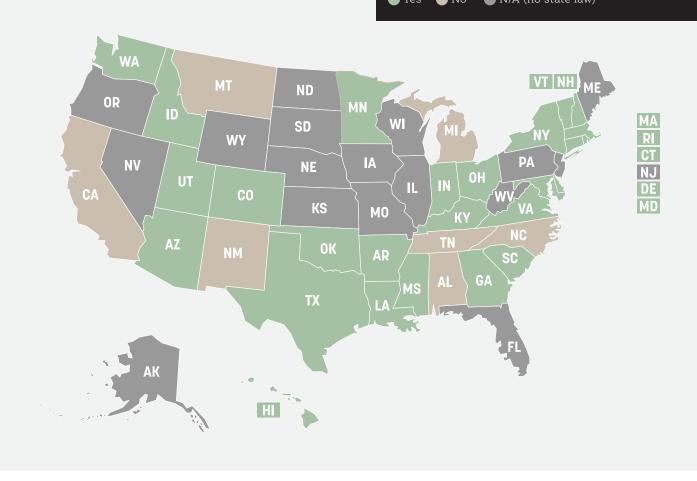
#### **COMMON TRENDS AND VARIATIONS IN STATE LAWS**

While state law cannot be less strict than the FSMA PSR in terms of the regulatory standards themselves, states may include additional provisions in state law that elaborate on the FSMA PSR, particularly with regard to state process for addressing inspections, appeals, and violations.

 The map below identifies the states whose laws address more than the PSR standards alone. In states that have their own PSR laws, the most common variations include:

- Whether the state law adopts the PSR by reference,
- Whether the implementing state agency is required to issue regulations,
- Approaches for developing a registry or inventory of covered farms,
- Procedures for inspections and granting inspection certificates, and
- Civil and criminal actions and penalties that can be imposed on violators.

**Does the state law address more than the PSR standards?** Yes No N/A (no state law)



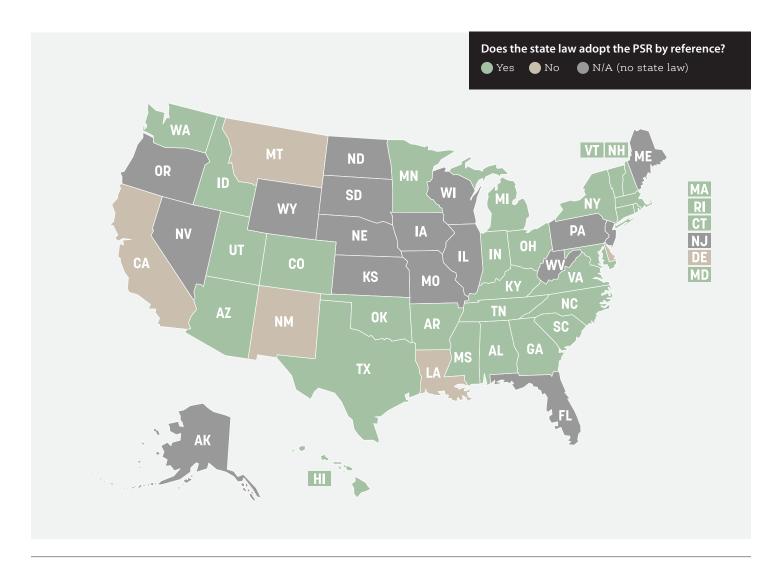
#### **PSR ADOPTED BY REFERENCE**

Most states with PSR laws have adopted the FSMA PSR by reference. This means the state law grants the state authority to enforce the federal PSR without rewriting the requirements in state law. Some of these states adopt the PSR without excluding or modifying any of its sections. In comparison, other states adopt the FSMA PSR while explicitly excluding or modifying certain sections.

Some state laws explicitly say whether the state law will or will not adopt future additions, amendments, or revisions to the FSMA PSR. If a state will not adopt future modifications, then the state will have to modify its own laws to integrate any future changes to the PSR, rather than automatically adopting the modified FSMA PSR.

#### VARIATIONS IN HOW STATES ADOPT THE PSR

Adopts the PSR generally	CO, GA, ID, IN, KY, MD, MI, MN, OK, TN
Adopts the PSR, including future additions, amendments, or revisions	DE, NH, TX, WA
Adopts the PSR, not including future additions, amendments, or revisions	RI
Adopts the PSR, with some exceptions	NY, OH



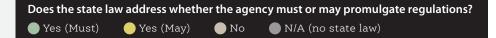
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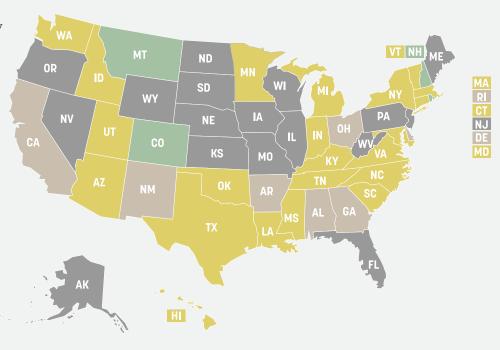
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#### AGENCY AUTHORITY TO ISSUE REGULATIONS

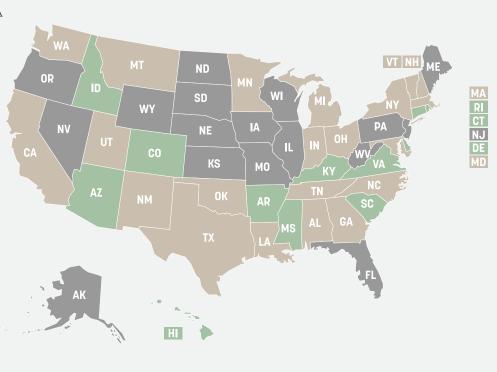
States vary on whether the relevant implementing agency must issue regulations to implement the FSMA PSR. In general, most statutes do not require states to adopt rules. Rather, statutes more commonly give discretion to the implementing agency to adopt rules as the agency deems necessary.





#### **APPEALS**

Some state laws identify when a producer may appeal a FSMA PSR enforcement decision, and the process for doing so. However, the majority of states with PSR laws do not mention appeals. **Does the state law address appeals?** Yes No N/A (no state law)

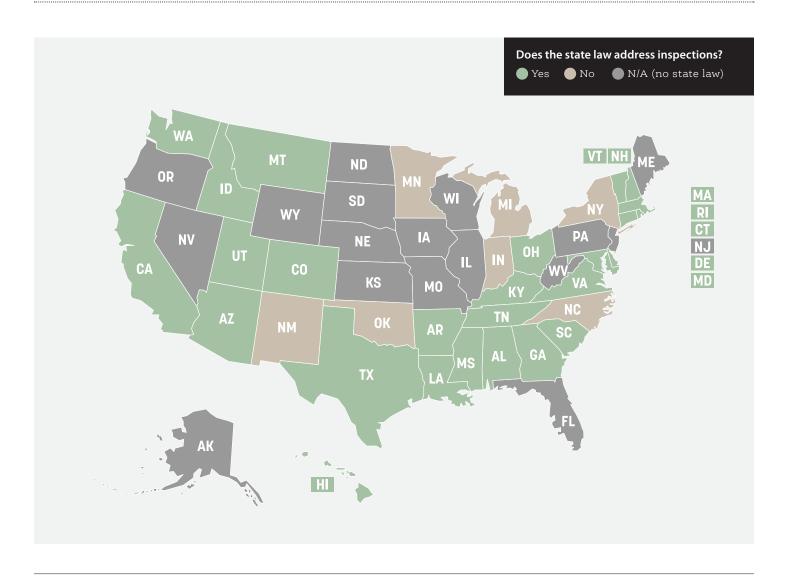


#### **INSPECTIONS AND INSPECTION CERTIFICATES**

Most state PSR laws address inspection in some manner. Generally, these laws identify under what circumstances—including when and how frequently an inspector may come onto a farm to conduct an inspection. Only four states have laws that address their policy on inspection certificates: Connecticut, Delaware, Massachusetts, and New Hampshire. Only Delaware requires an inspection certificate be issued upon completion of an inspection. In Connecticut, Massachusetts, and New Hampshire, the state may issue an inspection certificate. In New Hampshire, the state may issue a certificate at the request of the inspected party. In Connecticut and Massachusetts, the state may issue a certificate at its own discretion.

For more discussion of inspections, see our factsheet Produce Safety Rule Inspections and Third-Party Audits at <u>go.uvm.edu/fsmafactsheets</u>.



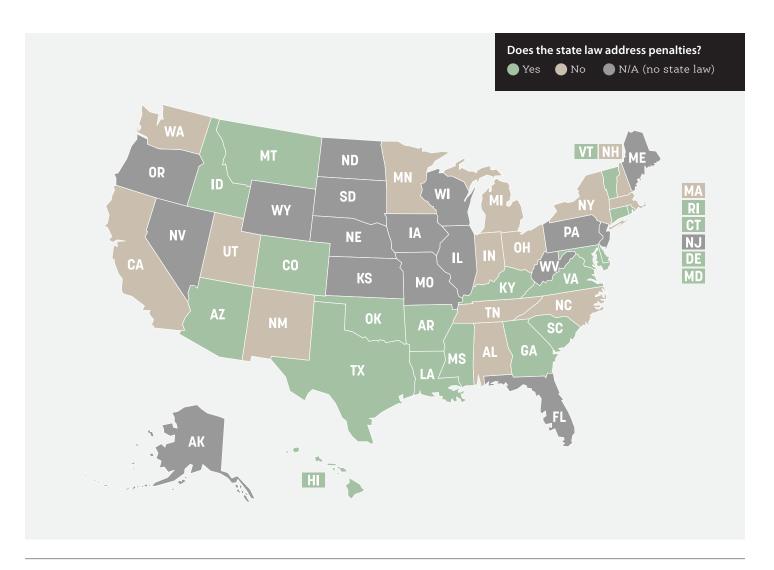




#### **VIOLATIONS AND PENALTIES**

Many state laws establish civil or criminal penalties for PSR violations. The most common variation under this category is the monetary amount for civil penalties. Civil penalties established under state law range from \$100 to \$10,000 per violation. However, the most common civil penalty throughout the states is \$1,000 per violation. States that have established civil penalties in their statutes include Montana, Virginia, Hawaii, and Idaho.

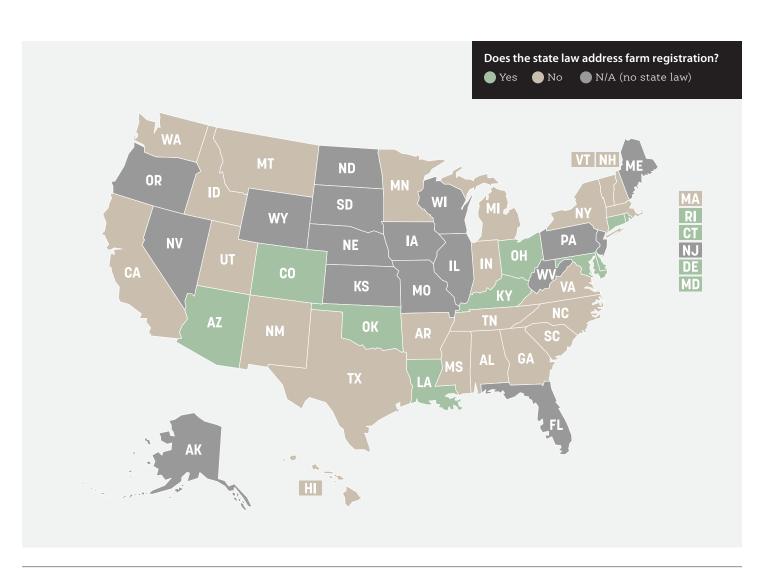
For more about how the PSR impacts producer liability, see our factsheet Produce Farms, Foodborne Illness, and Legal Liability at go.uvm.edu/fsmafactsheets.



#### **FARM REGISTRATION**

Many states are developing inventories of farms as part of their implementation programs; however, only some states address farm inventories or registries in state law. In the states with laws addressing farm registration, the relevant provisions either establish mandatory farm registration for all farms conducting activities covered under the PSR or give to the state agency the authority to adopt regulations that include a mandatory farm registration.







### Key Takeaways

In most cases, the state is the primary enforcement entity for the PSR. However, states may vary in their approach to PSR implementation and enforcement. Because the FSMA PSR is still a relatively young law, states may still be making decisions about how they will collect information from farms and conduct inspections. Some states have not issued regulations yet, but intend to. Other states may currently be operating in a credentialed capacity but intend to enact their own state law and operate under their own authority in coming years. The state implementation map and table of authorities on the Extension Legal Services Initiative's FSMA Legal Resources website provides the most up-to-date and comprehensive information about state-by-state PSR implementation. Visit <u>elsi.necafs.org</u> to learn more.

- 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.
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- This factsheet is part of a series on legal topics related to compliance with the FSMA PSR. To access additional resources, go to <u>elsi.necafs.org</u>. If you would like to view the legal research and citations that inform this factsheet, please contact CAFS@vermontlaw.edu. We also encourage readers to visit FDA's website for more information:
- www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
- <u>https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/</u> <u>state-produce-implementation-cooperative-agreement-program-cap</u>



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