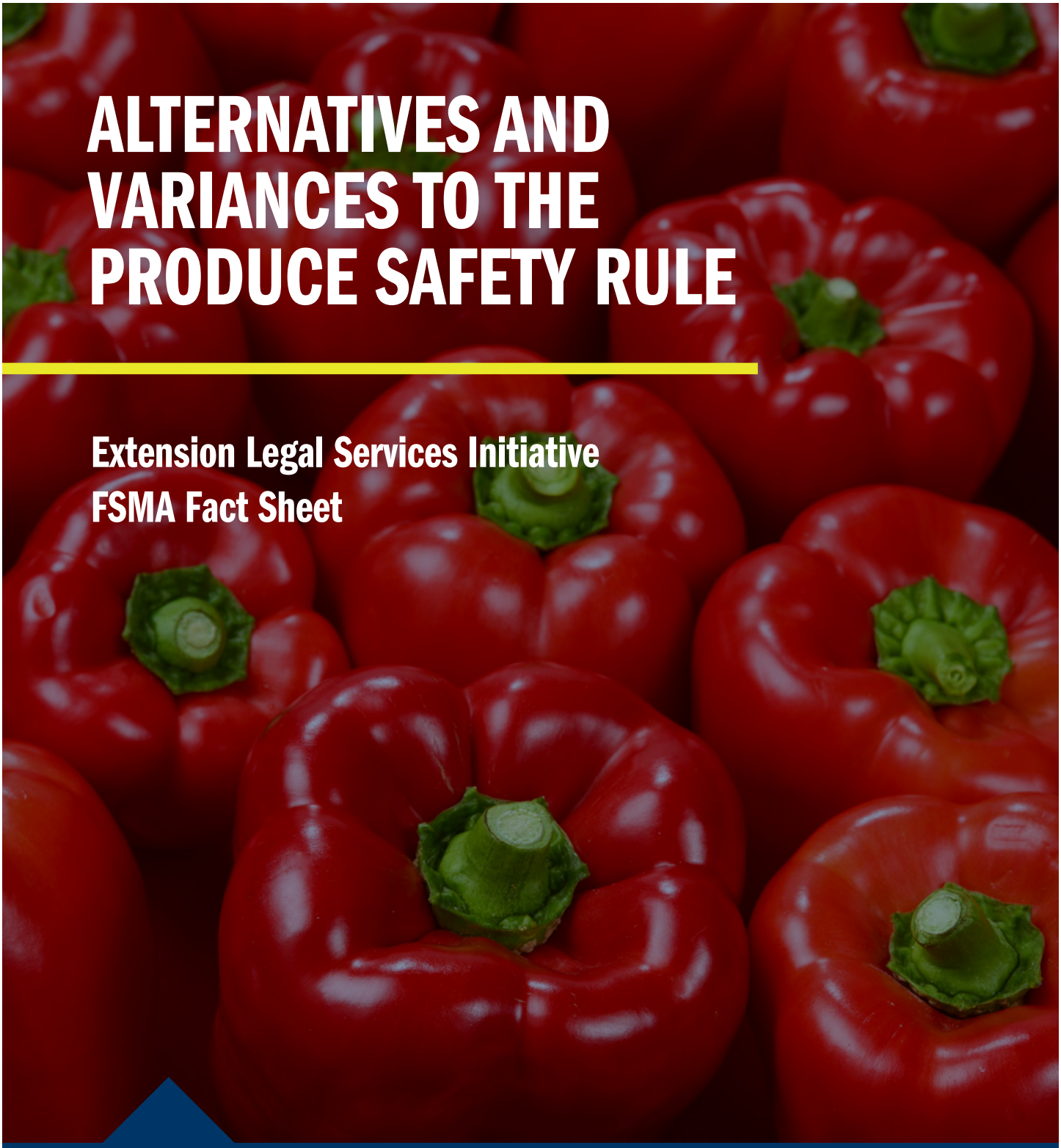


ALTERNATIVES AND VARIANCES TO THE PRODUCE SAFETY RULE

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.

The Food Safety Modernization Act's Produce Safety Rule (FSMA PSR) provides for alternatives and variances to the regulatory standards in certain circumstances. Alternatives require no preapproval and are limited to certain standards for agricultural water quality testing. Variances enable a state, foreign, or Tribal government authority to petition the Food and Drug Administration (FDA) to approve different standards for nearly all of the FSMA PSR standards. In either case, the FDA requires evidence that the different measure(s) used provides the same level of public health protection as the standards established by the FSMA PSR, which is a high burden to meet.

What is the difference between an alternative and a variance?

FSMA PSR ALTERNATIVE

Who is eligible?

An alternative allows an individual farm to develop and use different standards or methods in place of the four agricultural water quality testing requirements under Subpart E of the FSMA PSR, described in the preceding section.

Anyone can develop an alternative, including, for example, a single farm, a farm coalition or trade association, or an academic institution, as long as the developer has necessary competence and "sufficient knowledge and technical expertise" to conduct an evaluation of the alternative that is "adequate, accurate, current and reliable."

What is the approval process?

The individual seeking an alternative does not need to receive FDA approval and can begin using the alternative as soon as the individual can show that the alternative provides the same level of public health protection as the established PSR standard.

While the FDA has indicated that it may provide consultation or preapproval to those entities exploring an alternative, there is no clear process for how to seek a consultation yet.

A farm can also adopt an alternative that another farmer or entity develops, such as a trade association, University Extension, state agency, or community based organization.

! As discussed on the next page, the burden for demonstrating that an alternative meets the same level of public health protection is very high, and may be very difficult for individual producers to meet.

FSMA PSR VARIANCE

Who is eligible?

A variance allows only competent authorities to request, via petition on behalf of their constituents, that the FDA approve any range of different standards under Subparts A through O of the FSMA PSR. A variance request can therefore include, but may exceed, any of the four requirements eligible for an alternative.

A competent authority is a food safety regulatory authority for a state, federally recognized tribe, or foreign country that imports food into the United States.

What is the approval process?

The first step in the variance process is to consult with the FDA. The competent authority must then file a citizen petition with the FDA. The petition must include a "Statement of Grounds" that documents:

- that the variance provides the same level of public health protection as the FSMA PSR,
- that the variance is necessary in light of local growing conditions,
- the provision of the FSMA PSR to be substituted, and
- to whom the variance applies.

Upon approval, the FDA will designate to whom the variance applies, and only that approved group can use the variance. The FDA may also choose to apply a variance to similarly situated people outside of the jurisdiction of the authority that filed the original citizen petition, if the authority for those similarly situated people requests that the FDA extend the variance to their jurisdiction.

What PSR provisions do alternatives and variances apply to?

FSMA PSR ALTERNATIVE

Producers may only use alternatives in place of the following four requirements of the PSR agricultural water standards:

1) **Microbial Quality Criteria:** The PSR requires farms to test for generic *E. coli*, but farms may use an alternative microbial criterion, as long as it is an appropriate indicator of fecal contamination and equally protective.

2) **Microbial Die-Off Rates & Time Intervals:** Farms may adopt an alternative approximate die-off rate (other than the existing 0.5 log-per-day die-off rate, which is approximately 68% per day) and an alternative maximum time interval (other than the four-day maximum interval for allowing agricultural water to fall within the allowable range of contamination level).

3) **Sample Size for Untreated Surface Water Source Testing—Initial Test:** The PSR requires a minimum of 20 samples over two to four years, though farmers may use an alternative sample size.

4) **Sample Size for Untreated Surface Water Source Testing—Annual Test:** Following the initial testing to establish a baseline, the PSR requires farms to annually collect at least five samples from each untreated water source per year. Farms may use an alternative to comply with this requirement.

- These are currently the only four requirements for which farms may adopt an alternative.

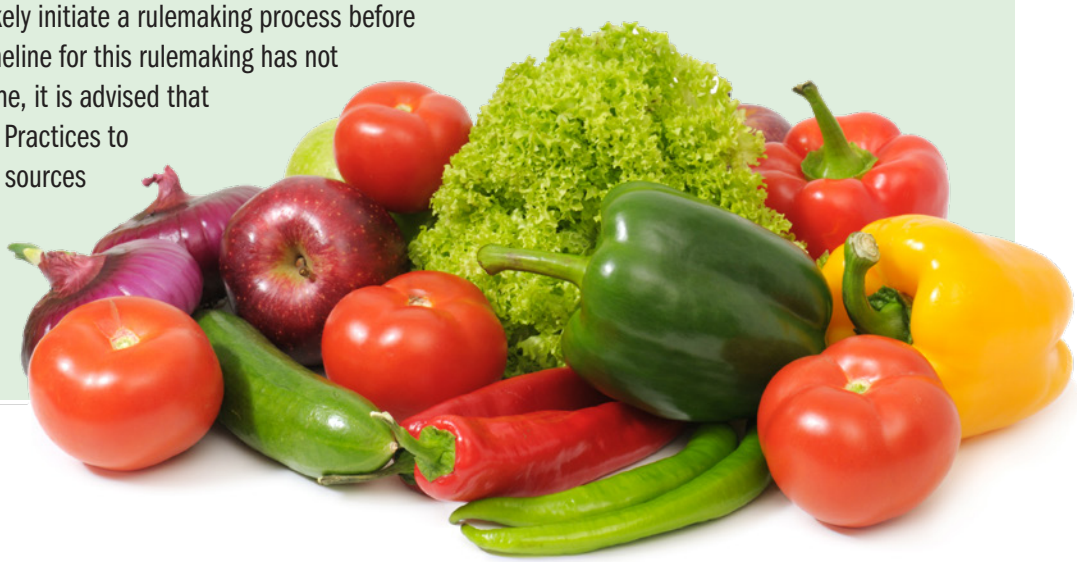
- Important Caveat: The FDA has extended the compliance dates for the FSMA PSR agricultural water requirements to Jan. 26, 2022 for large farms, Jan. 26, 2023 for small farms and Jan. 26, 2024 for very small farms. During this extension, FDA is considering the complexity and practicality of implementing the current standards across a range of farms, water sources and types of use. The FDA will likely initiate a rulemaking process before finalizing new standards. The timeline for this rulemaking has not been announced. In the meantime, it is advised that producers use Good Agricultural Practices to protect the quality of their water sources and begin some testing to ensure it is suitable for its intended use.

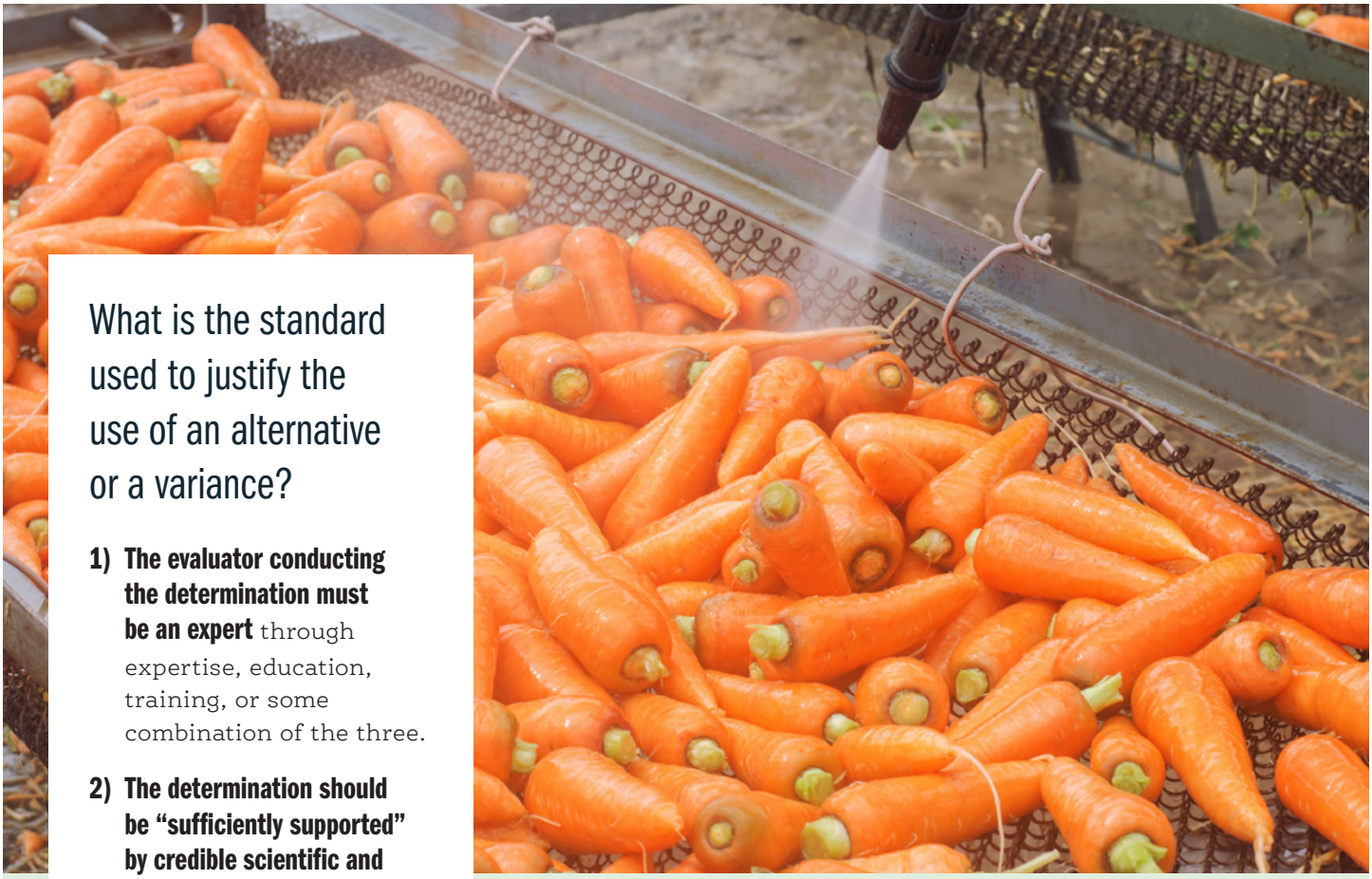
FSMA PSR VARIANCE

A variance may apply to almost any provision of the FSMA PSR, including standards and requirements for:

- Agricultural Water
- Analytical Methods
- Biological Soil Amendments of Animal Origin & Human Waste
- Domesticated & Wild Animals
- Equipment, Tools, Buildings, & Sanitation
- Growing, Harvesting, Packing, & Holding Activities
- Health & Hygiene
- Personnel Qualifications & Training
- Records & Recordkeeping
- Sprouts

- Variances can apply to Subparts A-O, including the Agricultural Water Standard (Subpart E).





What is the standard used to justify the use of an alternative or a variance?

1) **The evaluator conducting the determination must be an expert** through expertise, education, training, or some combination of the three.

2) **The determination should be "sufficiently supported" by credible scientific and technical evidence.** The evaluation should be as thorough as the FDA's analysis in developing the PSR standards and should be based on robust scientific evidence and data. The FDA will require a rigorous evaluation, using quantitative or qualitative data, that demonstrates the same level of public health protection is met when using any measures intended to substitute for the standard FSMA PSR provisions.

3) **The determination should be periodically reviewed** as new scientific evidence becomes available that potentially affects the outcome of the evaluation.

What happens if an alternative or variance is found to be insufficient after its use has started?

FSMA PSR ALTERNATIVE

An inspector may find that the evidence used to support an alternative is insufficient, which may lead to an operation being out of compliance with the FSMA PSR. Importantly, if a producer adopts an alternative developed by another party, the producer will still hold primary liability for ensuring its compliance with PSR standards.

FSMA PSR VARIANCE

If FDA approved a variance and later reevaluates it and finds it no longer provides the same level of public health protection, FDA can retract the variance approval. If a variance approval is retracted, then producers that relied on the variance must begin conforming with the FSMA PSR standards.

As of the date of publication, FDA has not approved any FSMA PSR variance requests.

How would a farm develop an alternative?

The burden on a single farm to develop and adopt an alternative is very high. The farm must collect scientific evidence demonstrating that the alternative they want to use provides the same level of public health protection as FDA's agricultural water requirements.

For example, suppose an individual farm wants to use a different indicator than generic E. coli to estimate the contamination level of agricultural water. Many other pathogens and bacteria, aside from generic E. coli, are introduced into water sources through fecal contamination. A producer may decide to test for one of these other bacteria or use a different criterion for testing, such as enterococci, general Bacteroidetes, or specific pathogen testing for bacteria like Salmonella or *Listeria monocytogenes*. To use one of these alternative standards, the farm would need to show that testing using that alternative is as effective at determining the level of fecal contamination as testing for generic E. coli.

From a practical standpoint, this is incredibly difficult as the FSMA PSR codifies the use of generic E. coli as the indicator of fecal contamination level. Special circumstances, however, may make it easier for a farm to make the argument that a different criterion is a better indicator for their water sources. Namely, farms located in tropical rainforest environments, such as those in Hawaii and Puerto Rico, have special circumstances because E. coli and other coliform species have been found to be a normal part of the tropical ecosystem.

This means that the coliforms present in agricultural water may not be introduced through fecal contamination. In that setting, farms may find scientific evidence to support using a different, non-coliform standard for testing their agricultural water sources.

Key Takeaways

Alternatives and variances can provide flexibility to farms. It is important that produce farms be able to differentiate between the two methods, including who develops them and the responsibilities associated with adopting their usage. Individuals interested in the development of alternatives and variances in their region could reach out to their regional food safety centers as the centers collaborate closely with state food safety authorities and the FDA on the implementation of PSR requirements. However, it is a high burden for individual farms to meet the standards for developing an alternative. It is therefore likely more feasible to adopt a substitute measure by developing a variance in collaboration with a state authority.

This document is for educational purposes only. It is not intended to serve as legal advice. Each operation and situation is unique, and state laws may vary. Accordingly, for legal assistance, you should contact 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, please visit 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: www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

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