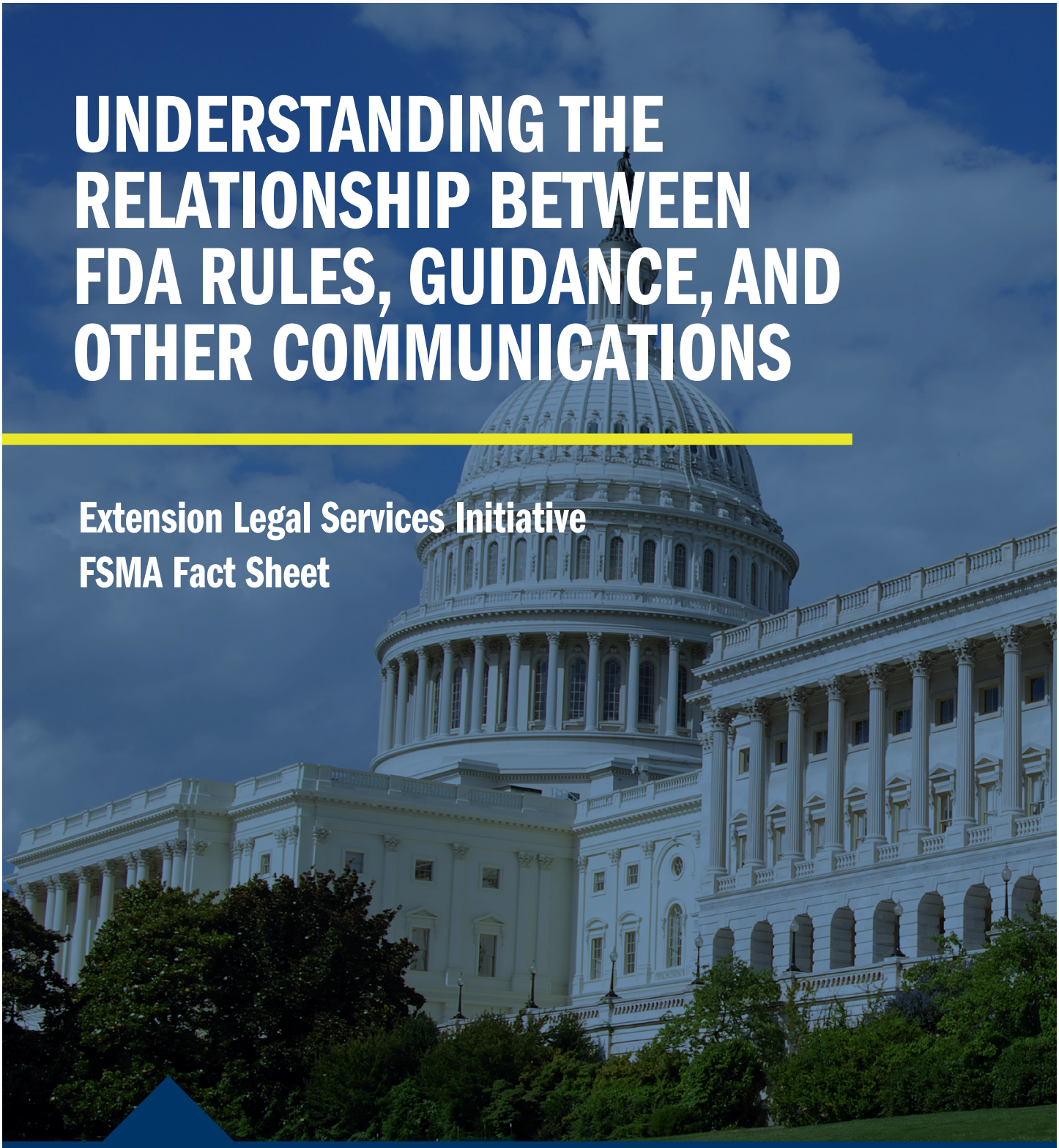
UNDERSTANDING THE RELATIONSHIP BETWEEN FDA RULES, GUIDANCE, AND OTHER COMMUNICATIONS



Extension Legal Services Initiative
FSMA Fact Sheet

NECAFS
The Northeast Center to Advance Food Safety

VERMONT LAW SCHOOL

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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 subject to the Food Safety Modernization Act's Produce Safety Rule (FSMA PSR) have asked questions about the process for changing the FSMA PSR, and about the relationship between the Food and Drug Administration's (FDA) rules, guidance, and other communications. This factsheet describes the process for establishing and changing the FSMA PSR, and explains the relative legal effect of FDA regulations, guidance, and other FDA communications, particularly those that come through the Technical Assistance Network (TAN) and Produce Safety Network (PSN).

WHERE DID THE FSMA PSR COME FROM AND CAN IT BE CHANGED?

Congress passed the Food Safety Modernization Act (FSMA) in 2010 and President Obama signed it into law in 2011. FSMA directed the FDA to issue several new regulations addressing food safety across the supply chain, including regulations for farms growing produce, now known as the FSMA PSR.

The FDA finalized the FSMA PSR in 2015 following several notice-and-comment rulemaking periods during which the public had opportunity to provide input to the FDA on the standards while they were in draft form. Both FSMA and the FSMA PSR are binding, as one is a law and one is a federal regulation, meaning entities subject to these new requirements must follow them.

Any changes to the underlying text of FSMA must be passed by Congress as an amendment to the law. Amending the FSMA PSR requires the FDA to restart the rulemaking process and propose any changes for public comment. The FDA can decide to propose a change to the FSMA PSR on its own, based on a petition from the public, or as prompted by Congress.

WHAT ARE FDA GUIDANCE DOCUMENTS AND HOW DO THEY AFFECT PRODUCE GROWERS?

Guidance documents define or explain specific standards and policies that are part of the FSMA PSR. They provide explanations and information to industry and help enable fair and consistent enforcement of the regulations. However, guidance documents only represent the FDA's "current thinking" on a topic, and therefore are not binding law.

In other words, guidance documents provide additional information to the industry on what they should do to comply with the FSMA PSR, but—as opposed to the FSMA PSR itself—producers are not legally bound to follow the information. Similarly, the FDA is not bound by the statements made in its guidance.

However, the FDA follows a notice-and-comment process in issuing most FSMA PSR guidance documents, just as it does when developing regulations. This process gives the public the opportunity to provide feedback on the content of the guidance documents. FSMA PSR

inspectors draw from these guidance documents in interpreting and enforcing the rules, and judges may give weight to the information contained in guidance documents if a farm's practices are under question in court. Therefore, while a producer may adopt practices not articulated in guidance, they should be aware that guidance is representative of the FDA's current thinking and presents a good starting point for FSMA PSR compliance.

HOW DO THE TAN AND PSN IMPACT PRODUCE GROWERS?

Like guidance documents, the TAN and PSN are not binding law. TAN responses represent the best judgment of the FDA at the time of the question. Similarly, PSN personnel provide informal communications that represent the best judgment of the FDA employee at that time. The TAN and PSN were established to support the produce industry and assist in implementing the FSMA PSR. However, the FDA is not bound to follow the information they provide in response to questions, nor are requesters bound by the interpretation or application of the law provided in agency communications (unless, of course, the communication is not an interpretation of the law but is a statement of the law or regulation itself).

Nevertheless, it is advisable that anyone who submits questions to the TAN or PSN retain a written response as a record and, in the event of a verbal communication with a member of

the PSN, request a written follow-up to the conversation. Although the communication is not binding on either party, it may serve to defend the farm's actions in the event of a lawsuit or enforcement action. The written communication demonstrates that an action was taken in good faith because of a response from the FDA, and the FDA would also likely take that into consideration when deciding whether to bring an enforcement action. For more information on the TAN, see our factsheet at go.uvm.edu/fsmafactsheets.

The **TECHNICAL ASSISTANCE NETWORK**, or TAN, is an online portal where users can submit specific questions to the FDA about FSMA compliance.

The **PRODUCE SAFETY NETWORK**, or PSN, is comprised of FDA produce safety experts available to assist produce growers, educators, and regulators with FSMA PSR compliance.

Key Takeaways

The Produce Safety Rule is legally binding. Guidance documents and responses from the TAN and PSN are informational and interpretive material that are not codified in law and are non-binding. However, such documents could be influential in court to defend a particular action taken or not taken by a producer or could influence a food safety regulator's enforcement decision.

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 the FDA's website for additional information: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety.

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