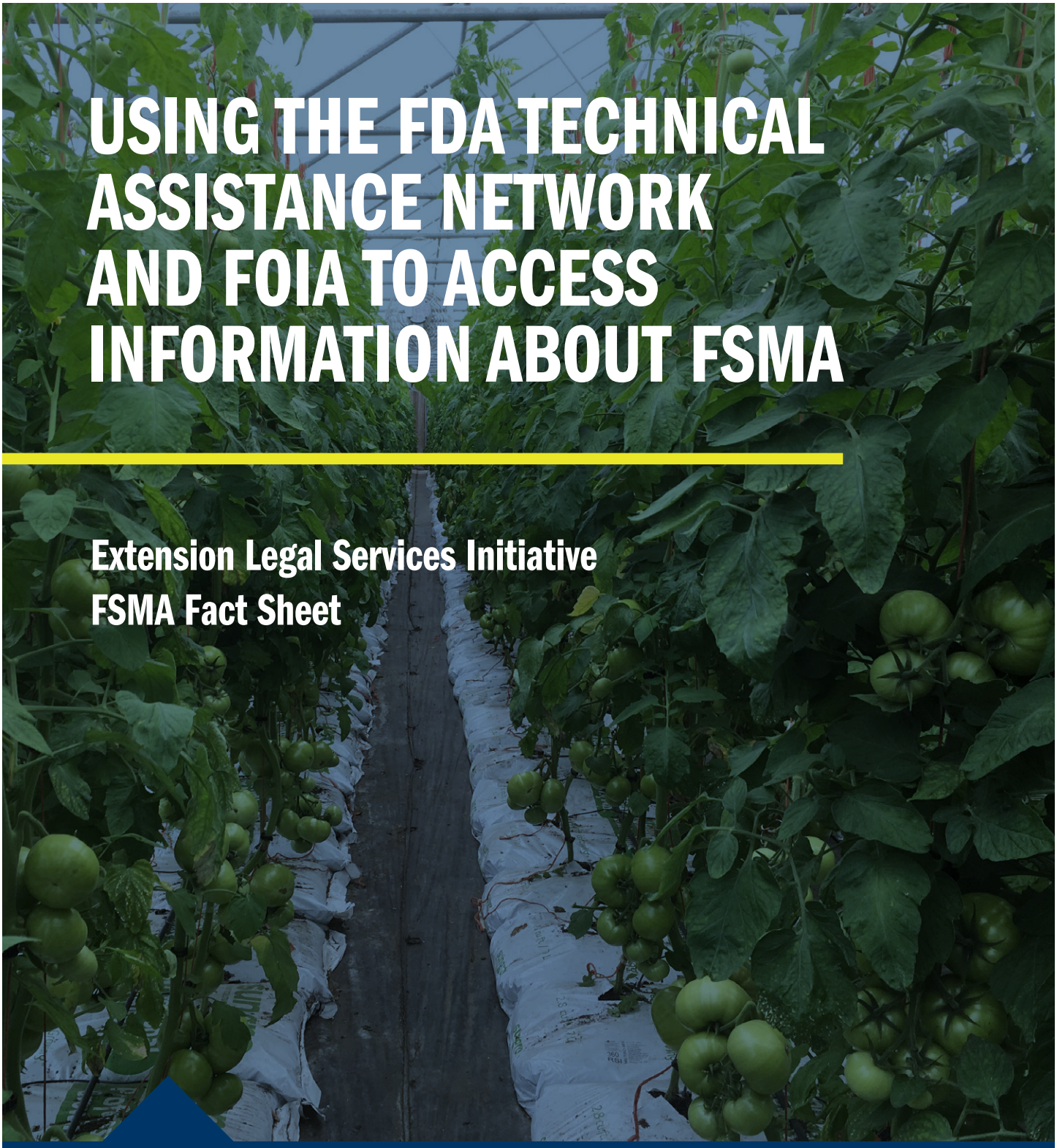


USING THE FDA TECHNICAL ASSISTANCE NETWORK AND FOIA TO ACCESS INFORMATION ABOUT FSMA

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 FDA Technical Assistance Network is a resource for the food safety community that answers specific questions about FSMA compliance. However, the answers to these questions are considered the property of the question-asker and therefore are not publicly available. The Freedom of Information Act (FOIA) provides an avenue for entities to request access to information from the federal government that is not otherwise made publicly available. There are considerations, however, that may limit the amount and type of information that the government can release in response to a FOIA request. This factsheet explores these options and the considerations relevant to making TAN responses available to the public.

WHAT IS THE TECHNICAL ASSISTANCE NETWORK?

The Technical Assistance Network (TAN) is a portal established by the Food and Drug Administration (FDA) where anyone can ask questions related to the Food Safety Modernization Act (FSMA). Questions can be submitted to the TAN online (https://cfsan.secure.force.com/Inquirypage/), or through the mail. Relevant FDA subject matter experts will then directly respond to submitted questions.

The TAN serves, in part, to assist industry with compliance by answering questions and addressing concerns about FSMA. The TAN also serves to inform the FDA about topics that are unclear and may require further guidance. While the FDA has published some of the TAN's most frequently asked questions on its website, it does not make all questions and answers available to the public due to privacy restrictions. It is important to note that TAN answers only apply to the specifics of the question asked; they do not apply to other individuals or scenarios beyond the specific inquiry submitted. Additionally, the responses do not bind either the FDA or the inquirer.

For more information about the relative weight of FDA law, guidance, and agency communications like the TAN, please see our factsheet at go.uvm.edu/fsmafactsheets.

THE TECHNICAL ASSISTANCE NETWORK

TAN is an online portal where users can submit specific questions to the FDA.

THE FREEDOM OF INFORMATION ACT

FOIA gives the public the right to request access to any information held by a federal agency.

HOW CAN AN ENTITY OR INDIVIDUAL ACCESS TAN QUESTIONS AND ANSWERS?

If an entity or individual wants to access other requesters' TAN questions and answers, they could submit a Freedom of Information Act (FOIA) request to the FDA. FOIA promotes transparency in the federal government and enables the public to request access to information held by a federal agency. This flow chart provides an overview of the FOIA request process.

STEP 1

Check to see if the information you want to request is already available elsewhere (e.g., guidance documents, searching www.fda.gov). If it is already available, the FDA may choose not to disclose it again.

STEP 2

Submit a FOIA request in writing, either by mail, fax, or through the online FOIA portal.

The FDA recommends you include some specificity and description of the content you are requesting. This will both reduce the effort needed to answer the request and ensure that the requester does not receive non-relevant information. For example, a request could ask for all TAN submissions and responses related to the FSMA PSR agricultural water standard.

STEP 3

Wait to hear back from the FDA. The FDA generally must respond to all FOIA requests within 20 business days.

- The FDA discloses all requested information.
- The FDA discloses only some or none of the information you requested.

STEP 4

If you believe the FDA made a mistake, you can appeal the decision within the agency, also called *exhausting administrative remedies*.

- The FDA corrects its mistake and discloses all requested information.
- The FDA still does not disclose information.

STEP 5

If you still believe the FDA made a mistake, you can file a claim in federal court to seek disclosure.

Note, however, that as discussed on the next page, FDA can redact certain information from disclosure.

WHAT MAY LIMIT THE INFORMATION THE FDA RELEASES IN RESPONSE TO A FOIA REQUEST?

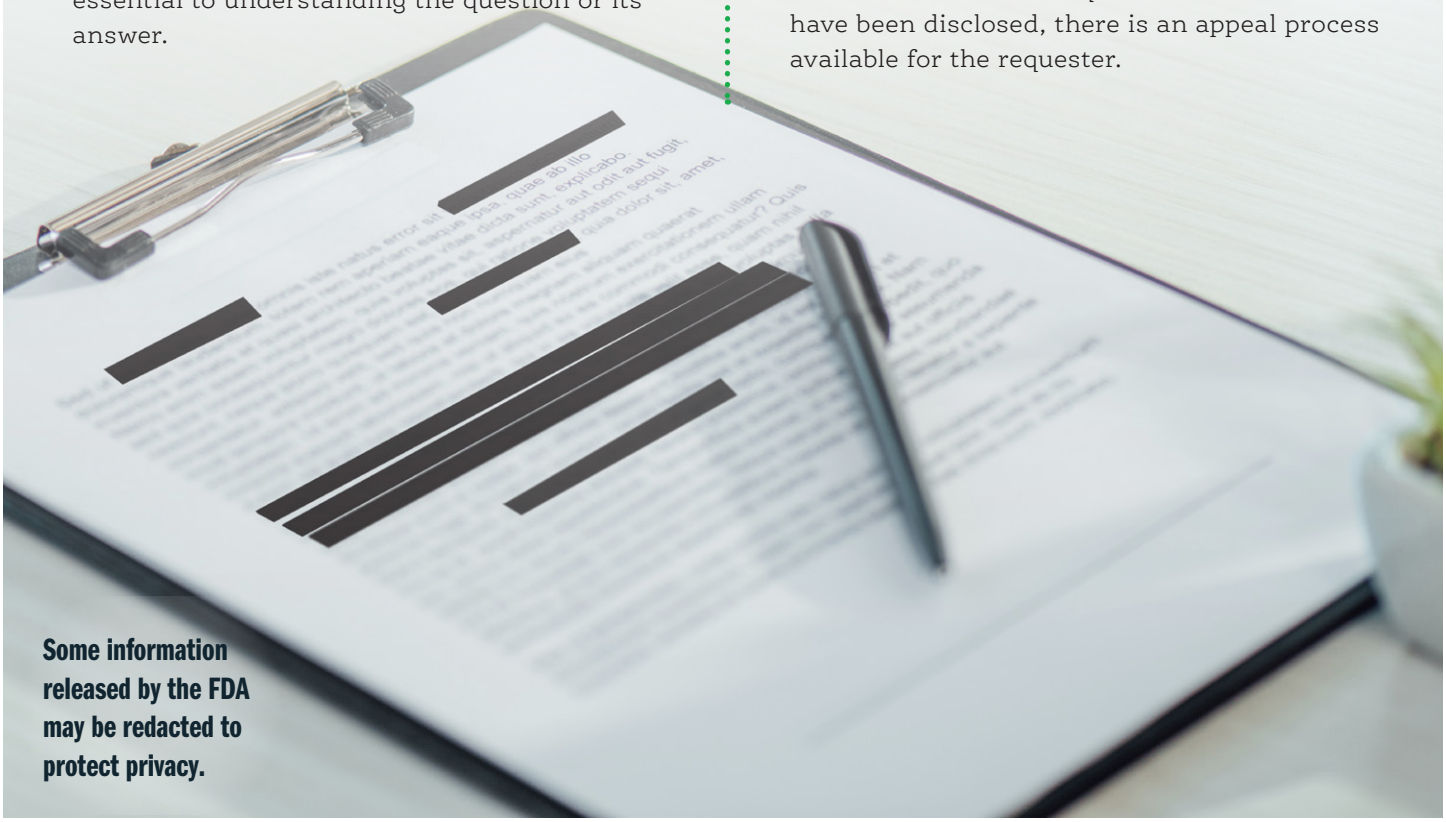
Several factors may limit the information the FDA releases in response to a FOIA request. These factors include:

- **Time:** The FDA can deny or limit a FOIA request if completing the search would unduly burden the agency.
- **Money:** There is generally no initial fee to submit a FOIA request, but costs are likely to incur if the search for information takes more than two hours. When submitting a FOIA request, an individual may choose to limit their search to two hours or indicate that they qualify to have the fees waived. See the link on page 4 for more information about fees.
- **Privacy:** It is possible that questions may contain protected, personally identifiable financial, geographic, or otherwise confidential information that the FDA, by law, cannot release. Some content may still be made available after redacting the private information, although this may limit its utility if the details redacted are essential to understanding the question or its answer.

CAN A REQUESTER AVOID ANY OF THESE LIMITATIONS?

A requester may be able to avoid some of these limitations if they are precise and clear in their request.

- **Time:** Submit a FOIA request that describes the information desired in as much detail as possible to reduce the burden on the FDA in finding the requested information.
- **Money:** Specify the amount of time and total expense the requester is willing to pay. Nonprofit or academic requesters using the information for the benefit of the public (as opposed to commercial purposes) are eligible for a fee waiver.
- **Privacy:** While FOIA promotes transparency, it limits federal agencies like the FDA from disclosing certain information that could constitute an invasion of privacy. Because TAN questions may contain personal or business information, it is likely that any content the FDA does disclose would be redacted to some degree, which may limit the utility of the information. In the event that the FDA does not release certain information that the requester believes should have been disclosed, there is an appeal process available for the requester.



Some information released by the FDA may be redacted to protect privacy.

More information

To learn more about submitting a FOIA request to FDA, visit these pages on the FDA's website:

- How to Make a FOIA Request: https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request
- FOIA Fees: https://www.fda.gov/regulatory-information/freedom-information/foia-fees
- Frequently Asked Questions for Freedom of Information: https://www.fda.gov/regulatory-information/freedom-information/frequently-asked-questions-faq-freedom-information

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
- https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

USDA United States Department of Agriculture
National Agricultural Library

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