

CHAPTER 9: VARIANCES (SUBPART P)

What is the goal of this chapter?

To explain the requirements for requesting a variance from one or more requirements of the Produce Safety Rule. Variances provide a flexibility in meeting requirements that takes local growing conditions into account while ensuring the same public health protection.

Who may request a variance?

The request for a variance must come from the regulatory authority for food safety (called the “competent authority” in the rule and the draft guidance) for a state, federally-recognized tribe, or foreign country from which the U.S. imports foods. For example, a competent authority in a state would be the Department of Agriculture or the Department of Public Health.

However, other stakeholders may assist the competent authority, such as by developing or providing supporting information, or assisting with drafting the variance request.

What are the grounds for submitting a request for a variance?

Variance requests are submitted through a petition process. Petitions requesting a variance from one or more requirements of the rule must demonstrate that different procedures, processes or practices are necessary because of local growing conditions. And the requesting authority must have also determined that these measures will still result in safe produce, providing the same level of public health protection as the requirements of the Produce Safety Rule for which the variance is requested.

The authority submitting the petition must also describe:

- the variance being requested (in other words, the details of the different procedures, processes or practices);
- the farm(s) to which the variance would apply; and
- the provisions of the Produce Safety Rule to which the variance would apply.

What other information should be included in a variance petition?

The petition should also include relevant and scientifically-valid information or materials specific to the produce or activity, to support the request and the information presented in the “Statement of Grounds.” Information submitted to support a variance could vary widely depending on the nature of the request, but some examples include information about:



- specific, local growing conditions, including crop, climate, soil, and geographical and environmental conditions relevant to the request;
- Region-specific processes, procedures, or practices followed in the growing, harvesting, packing, or holding of relevant produce.

Note that FDA will make public the information included in the variance petition.

What are some strategies that could help in preparing a variance petition?

- Participate in pre-submission consultations with FDA.
- Use several resources to gather the necessary information, such as obtaining information from scientific literature and collaborating with other stakeholders, such as industry groups, in developing the petition.
- Review variance petitions submitted by other competent authorities to see if they can be applied to other farms in a similar situation. As the competent authority, if another variance petition mirrors your own needs, options include:
 - Asking that the variance requested by another authority be applied to your similarly situated farms that operate under similar conditions, practices and procedures.
 - Accessing the publicly available scientific data and other information from another variance petition for use in your own request for a variance.

What is the procedure for petitioning for a variance?

Variance petitions can be submitted either electronically or by mail in keeping with the Code of Federal Regulations (Title 21, Volume 1, Section 10.30) requirement for citizen petitions.

The U.S. Government Publishing Office provides [information](#) about the petition format and how to submit the request to FDA.

The draft guidance contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.