



Great Lakes Fruit, Vegetable & Farm Market EXPO Michigan Greenhouse Growers EXPO

December 4-6, 2018

DeVos Place Convention Center, Grand Rapids, MI



21 Food Safety

Where: Grand Gallery Overlook Room C & D

Moderator: Phil Tocco, Michigan State University

2:00 PM Food Safety Water Testing

- Ben Phillips, Michigan State University Extension

2:30 PM What to Expect When Being Inspected: Perspectives of Three States

- Matt Fout
- Kristin Esch, Michigan Department of Agriculture and Rural Development
- Lisa Baker, Minnesota Department of Agriculture

3:30 PM Variances, Alternatives and Appeals: The finer points of FSMA Produce Safety Rule Flexibility

- Theresa Klaman

4:00 PM



FDA U.S. FOOD & DRUG ADMINISTRATION

Variations and Alternatives: The Finer Points of FSMA Produce Safety Rule Flexibility

FDA FOOD SAFETY MODERNIZATION ACT
THE FUTURE IS NOW

2018 Great Lakes Expo
Grand Rapids, Michigan
December 4, 2018

Agenda

- Variations
- Alternatives
- Produce Safety Rule Implementation Updates
 - Revisiting Agricultural Water
 - Enforcement Discretion
 - Guidance

Flexibility in meeting requirements that takes local growing conditions into account while ensuring the same public health protection.

VARIANCES §§ 112.171 – 112.182

Who May Request a Variance?

The regulatory authority or “Competent Authority” responsible for food safety may petition for a variance from some or all provisions.

- State (e.g., Department of Agriculture, or Public Health),
- Federally recognized tribe, or
- Foreign country from which the US imports food.

Note: Stakeholders may assist the Competent Authority.

How is the Variance Requested?

Submitted by a competent authority through a petition process when the competent authority has determined that they have grounds for the request. Specifically, that:

- Demonstrate that different procedures, processes or practice are necessary because of local growing conditions, **and**
- These measures will result in safe produce, providing the same level of public health protections as the Produce Safety Rule.

What else is included in the statement of grounds?

Competent Authority must also describe:

- The variance being requested (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?

Scientifically-valid information or materials specific to the produce or activity, to support the request and the information presented in the "Statement of Grounds."

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 relevant produce.

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Strategies in Preparing a Variance Petition

- Participate in a pre-submission consultation with FDA,
- Use several resources to gather the necessary information:
 - Scientific literature,
 - Collaborating with stakeholders (such as industry groups)
- Review variance petitions submitted by other Competent Authorities.

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What is the procedure for petitioning?

- Submitted either electronically or by mail in keeping with the Code of Federal Regulations requirement for citizen petitions.
Title 21, Volume 1, Section 10.30
- US Government Publishing Office provides [information](#) about the petition format and how to submit the request to FDA.

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Flexibility meeting requirements of Subpart E that provides the same level of public health protection.

ALTERNATIVES §§ 112.12 AND 112.49

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What alternatives may I establish?

On hold, pending FDAs reconsideration of ag water requirements

- Farms may establish an alternative to certain, specified ag water requirements only
- May be specific to a single farm or group of farms
- Does not require a petition or even notice to FDA but farm must have a basis for using the alternative and be prepared to share, if asked
 - Farm must have scientific information that the alternative provides the same level of public health protection as the relevant requirement and does not increase the likelihood of adulteration.

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Summary

<p>Variations</p> <ul style="list-style-type: none"> • Competent Authority • From Some or All Provisions <ul style="list-style-type: none"> – Procedures, process, or practices • Variance Petition to FDA 	<p>Alternatives</p> <ul style="list-style-type: none"> • Farm • Specified requirements of Subpart E • Do not need to notify or seek prior approval • Establish and maintain documentation of data and information
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Published FSMA Guidances for Produce Industry



Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement

- Published Draft in January 2018
- Comment Period closed May 25, 2018
- Primarily impacts FSVP and Produce Rule
- Applies to §§ 112.12 and 112.49 (Alternatives) and 112.171-182 (Subpart P – Variances) of the Produce Safety Rule

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Allows time to consider changes or other approaches to address concerns regarding the application of provisions to certain activities or entities

ENFORCEMENT DISCRETION

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PSR Implementation Updates

Current Status of Agricultural Water



- FDA is considering how best to achieve public health protections in the covered produce agricultural water arena
- Stakeholder engagement
- What input will FDA consider?

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PSR Implementation Updates

Proposed Rulemaking and Enforcement Discretion



- Proposed rulemaking to extend compliance dates for agricultural water to 2022 for the largest farms (**other than sprouts**)
 - Comment period closed November 13, 2017
- As we continue to work with stakeholders on issues regarding the agricultural water requirements, we do not intend to take enforcement action on agricultural water requirements for produce (**other than sprouts**)
- Farms may choose to continue with current water testing programs

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PSR Implementation Updates

Enforcement Discretion



- Facilities conducting farm-related activities
- Written Assurances in the PCHF, PFAF, FSVP and Produce Safety Rules
- Importation of Food Contact Substances under FSVP
- Manufacturing/Processing activities for human food by-products for use as animal food

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Resources



- FDA Produce Safety Draft Guidance Webpage: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>
 - Draft Produce Safety Guidance for Industry
 - Federal Register Notice: See Background section for specific questions for industry comment, information or data
 - <https://www.federalregister.gov/documents/2018/10/22/2018-23006/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-draft>
 - At-A-Glance Overviews and Glossary
 - Links to access the Final Produce Safety Rule



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Submitting Comments

- We encourage submission of comments by April 22, 2019 to ensure that we consider your comments before we begin work on the final version of the Produce Safety Guidance for Industry
- For more information on submitting comments:
 - Go to [regulations.gov](https://www.regulations.gov) and enter Docket Number: FDA-2018-D-3631; or
 - Go to https://www.regulations.gov/document?D=FDA_FRDOC_0001-8821

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Submitting Comments

To submit written comments, comments must be sent to:

Docket Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

All submissions received **must** include the Docket No. FDA-2018-D-3631.

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For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)



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