

# FSMA Facts

## Alternatives and Variances: What is the Difference Under the Proposed Produce Safety Rule?

### Alternatives to Some Specific Requirements

The proposed rule would allow farms to establish **alternative** practices or alternative standards for certain specified requirements of the rule and still be in compliance with the rule. The specific areas for which alternatives could be used are:

- The requirements for testing agricultural water when it is directly applied to the harvestable crop (other than sprouts) during growing, and taking action based on test results;
- Composting treatment processes; and
- The minimum application interval for untreated biological soil amendments of animal origin that are reasonably likely to contact covered produce after application; compost agricultural teas that contain compost agricultural tea additives; and biological soil amendments of animal origin treated by a composting process that are reasonably likely to contact covered produce after application.

In these cases, the proposed rule would allow farms to use alternative practices or standards to those we're proposing, if adequate scientific data or other information demonstrates those alternatives provide the same level of public health protection as the proposed rule, and would not increase the likelihood that the covered produce will be adulterated (under the Federal Food, Drug & Cosmetic Act ("FD&C Act")).

Farms would not need to ask permission or petition FDA in order to use alternative measures, provided they have adequate scientific data and documentation used to support those alternatives. That documentation could be as simple as a peer-reviewed journal article or a State Extension bulletin; something developed and used successfully by the grower, a community of growers, or a process developed or made available to the grower by a third-party. Farms would simply use the alternative measure and provide documentation if asked.

### Variances From Some or All of the Requirements

FSMA requires FDA to permit states and foreign countries to request variances from the produce safety rule. States and foreign countries may request a **variance** from some or all requirements of the proposed rule, where the State or foreign country determines that:

- The variance is necessary because of local growing conditions; and
- The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under the FD&C Act and provides the same level of public health protection as the requirements of the proposed rule.

*It is important to note that to request a variance, a State or non-U.S. country must submit a formal petition to FDA. This is different from the use of alternatives discussed above. A variance request would have to describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under the FD&C Act and that the variance provides the same level of public health protection as the requirements in the proposed rule. Variances would be granted or denied by FDA, and variances could be modified or revoked under certain circumstances.*

FDA welcomes comments on the provisions related to variances and alternatives in the proposed rule. The comment period is open until November 15 2013. Go to [www.fda.gov/fsma](http://www.fda.gov/fsma) for more information on how to comment, or submit comments electronically through [www.regulations.gov](http://www.regulations.gov).

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