

FSMA Summary for Hops Growers



The Food Safety Modernization Act (FSMA) was signed into law in January of 2011. The aim of this law is to ensure that the US food supply is safe by shifting focus from responding to food contamination to preventing it. While brewing beer greatly reduces the presence of microorganisms of public health concern through means other than a kill step (e.g. pH, alcohol content and fermentation), hops are considered “covered” produce under FSMA Produce Safety Rule. Hops are sometimes added to beer after all the brewing steps are completed in a process called “dry hopping”; hops are in this case consumed without the protection provided by a heating or cooking step. *As it is currently written, the main way hops would be exempt from FSMA Produce Safety Rule is if they were sold into commercial processing that includes a kill step.*

In 2019, the U.S. Food and Drug Administration (FDA) issued a final guidance stating the agency’s intent to exercise enforcement discretion for the requirements of the Produce Safety Rule, part of the Food Safety Modernization Act (FSMA), as they apply to entities growing, harvesting, packing and holding wine grapes, hops, pulses and almonds. The FDA announced, “In taking this step, we’ve considered the use of unique production processes that reduce the presence of foodborne pathogens. We’re announcing today that we’re not expecting hops, wine grapes, pulse crops and almonds producers to meet the requirements of the rule currently. Given the nature of these specific commodities, and the low risk that these products pose because of the way that they’re processed and consumed, we do not expect producers of these commodities to comply with the Produce Safety Rule”.

This means the agency does not intend to enforce requirements of the rule for farmers and producers of these commodities.

What FSMA Produce Rule Says

In 2019, FDA announced a policy of enforcement discretion meaning that the FSMA Produce Safety Rule requirements will not be enforced for specific commodities including hops. If the enforcement discretion is lifted, then the main way hops would be exempt from the FSMA Produce Safety Rule is if, according to §112.2(b) (1) “The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf stable tomatoes) and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products.”



Records required by FSMA

The FSMA Produce Safety Rule does not require a Food Safety Plan. However, there are a few records a farm must keep for at least two years either in paper or electronic format [§112.162(a-b)]. Hops are considered a covered produce item, and as of March 2019 they are under enforcement discretion. If, in the future, enforcement discretion is lifted by FDA and FSMA Produce Safety Rule requirements once again apply to hops, then the exemption in § 112.2(b) would come into play. Eligibility requirements include records that the farm:

- 1) Discloses in the sales documents that the hops are “not processed to adequately reduce the presence of microorganisms of public health significance,” and
- 2) Collects written assurances from the buyer that they will use the hops in a commercial process (e.g., heating or other kill step) that addresses the food safety risk.



Conclusion

Microbial contamination can occur at any point and at any time during growing, harvesting, or packing of hops. Even though most hops go into commercial processing that reduces risk to consumers, a hops producer still benefits by being aware of potential risks and establish management practices to minimize these risks at each step in the production and sales processes.

[FSMA Produce Safety Rule](https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm) (https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm)

[Records required by FSMA](https://resources.producesafetyalliance.cornell.edu/documents/Records-Required-by-the-FSMA-PSR.pdf) (https://resources.producesafetyalliance.cornell.edu/documents/Records-Required-by-the-FSMA-PSR.pdf)

This material was developed by the North Central Regional Center under a grant from the Food and Drug Administration. FDA has provided technical assistance in developing this material; however, this information has not been formally approved by FDA. It does not represent any agency determination or policy.

Funding provided through the Department of Health and Human Services Food and Drug Administration (Grant Number 1R01FD005685-01) titled “Strategies for Successful Implementation of FSMA (Food Safety Modernization Act) in the North Central Region through Adoption of a Systems Approach and Stakeholder Engagement Framework.”

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