

The Produce Safety Rule and Hops

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

2018 American Hop Convention
Palm Desert, CA
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Food Safety Modernization Act (FSMA)

7 Foundational Proposed Rules

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 16, and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Standards for the Growing, Harvesting,
Packing, and Holding of Produce for
Human Consumption

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

- *Produce Safety*
- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
- Foreign Supplier Verification Program
- Third Party Accreditation
- Intentional Adulteration
- Sanitary Transportation of food

Standards for Produce Safety

Focus on conditions and practices identified as potential contributing factors for microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities

Are Hops covered under the PSR?

- Hops are considered covered produce under the PSR.
- Farms that grow, harvest, pack, or hold hops are expected to comply with the relevant provisions of the PSR, unless otherwise exempt.



Are Hops on the Rarely Consumed Raw List?

- When developing the RCR list, FDA relied on data from the *National Health and Nutrition Examination Survey* (NHANES).
- Consumption data had to be available from NHANES and the consumption data had to show that:
 - Produce is consumed uncooked by less than 0.1% of the United States population;
 - Produce is consumed uncooked on less than 0.1% of eating occasions; and
 - Produce consumption (in any form – raw, processed, or other) was reported by at least 1% of weighted number of survey respondents.
- Hops do not meet the criteria we established for RCR (80 FR 74387) and are covered by PSR.

Does the PSR provide any exemptions for individual commodities?

- PSR establishes a risk-based exemption for individual commodities
 - Produce that will receive commercial processing that adequately reduces the presence of microorganisms of public health significance.

Are Hop growers eligible for an exemption from the PSR?

- A “farm” or farm “mixed-type facility” (as defined in [21 CFR § 1.227](#)) are not covered by the PSR if the average annual monetary value of produce sales is less than \$25,000.
- A hop grower may also be eligible for a qualified exemption and modified requirements if the average annual monetary value of food sales is less than \$ 500,000 and the majority (> 50%) of food sales were direct to qualified end users (as defined in 21 CFR 112.3(c)).

Are Hops eligible for exemptions under the PSR Requirements?

- In the PSR ([80 FR 74354](#) (Nov. 27, 2015)) we noted that hops used in the making of beer will be eligible for exemption from the requirements of the Produce Safety Rule under the provisions of [21 CFR § 112.2\(b\)\(1\)](#), provided the covered farm establishes and maintains documentation in accordance with § 112.2(b)(2).
- Brewing beer adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation).

What are the requirements for the commercial processing exemption?

1. Hops will receive 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.

What are the requirements for the commercial processing exemption?

2. The covered farm discloses in documents accompanying the hops, that the hops are “not processed to adequately reduce the presence of microorganisms of public health significance.”

What are the requirements for the commercial processing exemption?

3. Hop Growers must either:
 - a. Annually obtain a written assurance from Customer “A” that performs the commercial processing that the customer has established and is following procedures (identified in the written assurance) that **adequately reduce the presence of microorganisms of public health significance**; or...

What are the requirements for the commercial processing exemption?

b. Annually obtain a written assurance from Customer “A” that an entity (Customer “B”) in the distribution chain subsequent to Customer “A” will perform commercial processing and that Customer “A”:

- Will disclose in documents accompanying the hops, in accordance with the practice of the trade, that the hops **“are not processed to adequately reduce the presence of microorganisms of public health significance”**; and
- Will only sell to another entity (Customer “B”) that agrees, in writing, it will either:
 - Follow procedures (identified in a written assurance) that **adequately reduce the presence of microorganisms of public health significance**; or
 - Customer “A” will obtain a similar written assurance from Customer “B” that the hops will receive commercial processing and that there will be disclosure in documents accompanying the hops, that it **“is not processed to adequately reduce the presence of microorganisms of public health significance.”**

PSR Updates

Enforcement Discretion

- During the enforcement discretion period, FDA does not intend to enforce provisions as they apply to certain activities, including the **written assurances provisions** related to the control of identified hazards that are a potential risk to public health.
- Hops growers will still need to disclose to customers that microbial hazards have not been controlled but FDA will not enforce the requirement to obtain written assurances from customers.
- Those customers (and other thereafter) will be required to comply with all other applicable requirements in federal/state/local laws, including the prohibition against the introduction of adulterated food into interstate commerce.

Common Questions about Hops

- If a Hop Grower grows hops, has a hop drying kiln shed, sells more than \$25,000 a year in hops, and the processing operation is located on the farm, would this operation be covered under the rule?

Common Questions about Hops

- If the drying of hops does not create a distinct commodity, it is part of harvesting and not manufacturing/processing.
- If the drying of hops creates a distinct commodity (such as drying grapes to make raisins or drying fresh herbs), it is manufacturing/processing, but if it does not include any additional manufacturing/processing (such as cutting/slicing, chopping, grinding etc.) it is still within the “farm” definition.
- A “farm” does not have to register with FDA (see [21 CFR § 1.226](#)) and would not be subject to the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule \(21 CFR Part 117; 80 Fed Reg 55908\)](#) (CGMP & PC rule).
- If the Hop Grower engages in any additional manufacturing/processing (such as cutting/slicing, chopping, or grinding) of the hops which fall outside the “farm” definition, then they would be a farm “mixed-type facility” that would have to register (see [21 CFR part 1, subpart H](#)) and that would be subject to the CGMP & PC rule, unless an exemption applies.

Common Questions about Hops

- For the Produce Safety Rule, will imported hops be subject to the same requirements as domestic hops?

Common Questions about Hops

- Yes, imported produce sold in the United States for human consumption, including hops, will have to adhere to the same PSR requirements as domestically produced hops.

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](#)



QUESTIONS/DISCUSSION

