

## **Food Safety Modernization Act (FSMA) and Pre-Processing Considerations of Hops for Beverages**

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## Considerations of Hops for Beverages

Food safety practices during hop harvest are critically important for all growers. Good Agricultural Practices (GAPs) and Good Handling Practices (GHPs) are voluntary audits that verify that agricultural products (e.g. fruits, vegetables and certain plants) are produced, packed, handled and stored as safely as possible to minimize risks of microbial food safety hazards (USDA, 2019). Hops are ingredients in a food product; therefore, risk assessment and GAP implementation is beneficial for all concerned. GAP training opportunities are offered through the University of Tennessee Extension. A hop-specific program for growers is available through Hop Growers of America (USA Hops). An interactive educational module, “Good Bines: Foundations of Food Safety,” is available through USA Hops to aid farms in the development of a farm food safety policy by drawing on principles of operational risk assessments and industry-recognized certification programs. These education modules can be accessed at <https://www.usahops.org/growers/food-safety.html>.

Food safety training is an important element, but it is only one component of the GAP certification process. To obtain GAP certification, a third-party must certify that the farm is GAP-compliant and adhering to prescribed industry standards. Two primary events occur during a GAP audit: 1) a trained third-party representative comes to your farm and observes the practices on the farm, and 2) the auditor reviews the food safety plan, standard operating procedures (SOPs) and documentation of adherence to the food safety plan and SOPs. An audit is a means of verifying that you are complying with/following GAPs and may be required by the buyer (distributor, brewery, etc.) of your hops (Critzler & Wszelaki, 2012).

The Tennessee Department of Agriculture provides a cost-share program in an effort to increase the number of GAP certified producers offering specialty crops in Tennessee. The cost share will reimburse 75 percent of the inspection cost up to \$750. There are several organizations that conduct GAP audits. These organizations include The United States Department of Agriculture’s Agriculture Marketing Service (USDA-AMS), Primus Labs, NSF Davis Fresh Technologies, AIB International, Silliker, Scientific Certification Systems, ISO International Standards Organization and GlobalGAP. A list of websites that include various audit organizations is maintained by the national GAP program and can be accessed at <http://www.gaps.cornell.edu/weblinks.html>.

Virginia Cooperative Extension (2016) outlines some production, harvest and handling examples of GAPs that would apply to hops.

Those production examples include:

- If using irrigation methods, test water sources (i.e. well and surface water) for pathogens and contaminants.
- Pay attention to pre-harvest intervals for all fungicides, herbicides and pesticides.
- Keep records of chemical applications.
- Observe growing areas for presence of wildlife and, if necessary, take corrective actions.

Harvest and handling examples include:

- Wash and sanitize harvesters, picking and storage containers and packing tables.
- Keep harvest/cone-picking areas free of food and drinks.
- Restrict presence of animals in the harvest area.
- Provide a wash station with potable water and toilet facilities for all workers.
- Supply soap, disposable paper towels and a trash receptacle.
- Implement pest management systems.

The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. The purpose of FSMA is to ensure that the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing contamination. FSMA includes seven main rules and includes the entire supply chain. In April of 2019, the U.S. Food and Drug Administration (FDA) issued regulatory guidance detailing its intent to exercise enforcement discretion for the requirements of FSMA's Produce Safety rule as they apply to entities growing, harvesting, packing, and holding almonds, pulse crops, wine grapes and hops.

The Produce Safety rule is one of the foundational regulations that FDA has developed under Food Safety Modernization Act. Produce is not subject to the Produce Safety rule if it is identified by FDA under the regulation as "rarely consumed raw" (i.e., foods that are almost always eaten only after being cooked). Foods that FDA has determined are "rarely consumed raw" (RCR) are included in an exhaustive list at 21 C.F.R. § 112.2(a)(1) (the "RCR list"). FDA established the RCR list when it issued the final Produce Safety rule, and it based the list on consumption patterns reported in the National Health and Nutritional Examination Survey (NHANES).

FDA did not include hops on the original RCR list because it was not able to conclude that hops are not consumed uncooked in any measurable quantity by most consumers across the United States, though it recognized that hops used in the making of beer are eligible for the separate commercial processing exemption. FDA's analysis has led the agency to believe that, given hops' unique circumstances, the agency should exempt hops from the Produce Safety rule.

FDA will not expect farms growing, harvesting, packing or holding hops to meet any requirements of the Produce Safety Rule with respect to these commodities. However, the Federal Food, Drug and Cosmetic Act's (FFDCA's) prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food continues to apply to hops. The FDA's rationale for exercising enforcement discretion for hops is that hops used in the making of beer receive adequate pathogen reduction through means other than a cook step (e.g., pH, alcohol content and fermentation) and hops are not used outside of the brewing process (National Law Review, 2019 and USDA-FDA, 2019).

#### References:

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