Food Safety Modernization Act Recap – Hops

The Food Safety Modernization Act includes three programs that will impact the hop and brewing industries: (1) Produce Safety Rules (for growers), (2) Foreign Supplier Verification Program (for importers, including merchants, processors or brewers), and Preventative Controls program for processors and brewers. Our discussions have centered on the Produce Safety Rules on behalf of growers.

Guidance Offered During the Open Comment Period

On May 28, 2013 the US hop industry formally requested exclusion from Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Section 112.2 (a) (1), as follows: "We ask that hops be added to the list of produce not covered. This exemption should apply to any form of hops – whole cones, ground, powder, pellet, or extract. Hops, including any of these forms of the raw product, are not consumed raw. Hops are a raw material for the brewing industry. Hops are sold as an ingredient, and only consumed after processing into a multi-ingredient processed product, beer. In addition, the brewing process would adequately reduce the presence of microorganisms of public health significance. No hops are consumed out of hand."

Upon issuance of the final rule for produce safety, hops were not listed among the crops designated as "rarely consumed raw", resulting in hops being subject to FSMA. This came as a surprise to the industry, as available scientific literature appeared to strongly support the hop industry's position and formal comments requesting "rarely consumed raw" designation. The industry has spent the past year communicating with FDA representatives to request reconsideration of the ruling in relation to hops. The following discussion summarizes those discussions and next steps.

Communication with FDA Officials after the Final Ruling

The hop industry's efforts to determine the impact of this situation led to a meeting on March 7, 2017 with Washington State Department of Agriculture officials and Dr. Stelios Viazis, Produce Safety Network – Western Region - US FDA. Following that meeting we received the following summary from Dr. Viazis:

> In the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the Produce Safety Rule) (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) (80 FR at 74394 (Comment/Response 70)). This may be relevant to operations brewing beer because farms that sell hops may be expected to begin requesting certain documentation from their customers to meet the requirements of § 112.2(b).
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> Specifically, 21 CFR § 112.2(b)(1) states the following:
> (b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:
> (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; and
> (2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is **"not processed to adequately reduce the presence of microorganisms of public health significance;"** and
> (3) You must either:
> (i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section 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
> (ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and
(B) Will only sell to another entity that agrees, in writing, it will either:
(*1*) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or
(*2*) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance."

A second meeting and hop harvest tour were held on September 6 in Yakima. Several hop grower and merchant/processor representatives attended, along with food safety auditors, representatives from several state departments of agriculture. FDA representatives included Dr. Viazis, who has continued to work with us during the fall to clarify options for the hop industry. A 9/12/17 email from Dr. Viazis included the following:

"Furthermore, I wanted to take this opportunity to make sure we were on the same page regarding the options that were outlined in the past and during our roundtable meeting last week.

1. Compliance: Compliance dates for the rule start in January of 2018, but FDA Commissioner Scott Gottlieb just announced at the annual meeting that inspections won't start until 2019. I just wanted to make you aware of the FDA web posting with FDA Commissioner Scott Gottlieb's talk to NASDA's annual meeting that recently went live, outlining a number of immediate next steps in a comprehensive approach to ensuring successful implementation of the Produce Safety Rule: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm575532.htm.

I would like to encourage you to seek out, in collaboration with WSDA, a potential On Farm Readiness Review to assess how ready some of the hop farms in the area are for the new Produce Safety Rule.

2. Labelling: As we found out during the tour, there was some confusion regarding option 2. I want to make clear that the 2nd option includes standardized language to be added to the package, bill of lading, or other pertinent documentation of the raw agricultural commodity (hops) and ***not*** to the processed product whether that be pellets or extract. I hope this clarifies how to approach that part of this option.

3. Variance: During our meeting I stated that the FDA was aiming to release guidance on the variance process prior to the compliance date, but that is no longer a reality. As of right now, it looks like the guidance material target date is tentatively March 2018."

During a telephone discussion in January 2018 between Ann George and Dr. Viazis, he provided updates on the Variance process. The guidance for this process is being reviewed by agency counsel. It is expected to be released Spring 2018. Our variance request must be submitted by a state department of agriculture. Other states can submit a "me too" request. **Local growing conditions will be the focus of variance requests.** There is currently no activity by FDA to reopen the "rarely consumed raw" list.

Other pertinent information:
- January 2018 is the compliance date for large farms ($500,000 or more in average farm gate value for the past three years). This covers nearly all PNW commercial hop farms. Compliance dates for smaller operations will follow. Very small farms with less than $25,000 in farm-gate value are exempt.

- Inspections are postponed until 2019, and will fall under discretion of the states. The first round should be educational.