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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Rockville, MD   20852


The Beer Institute (BI) and the Brewers Association (BA) appreciate the opportunity to comment on the FDA’s proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (“Produce Safety Rules”). BI is a trade association representing U.S. brewers, importers, hops growers and other industry suppliers, large and small. BA is a trade association representing 1,931 craft brewers throughout the United States. These comments provide input and perspective with respect to Section 112.2 (a) (1) of the proposed Produce Safety Rules as it relates to one raw material critical to the brewing of beer – hops.

**Action Requested:** BI and BA request that FDA expressly state that hops are exempt from the proposed standards under the general provisions exemption of Section 112.2(a)(1), and that the exemption applies to hops in any form -- whole cones, ground and pelletized, powder or extract.

**Background:** Hops are the female flowers (also called seed cones or strobiles) of the hop plant, *Humulus lupulus* (University of Minnesota Libraries: “The Transfer of Knowledge. Hops-"Humulus lupulus"”. Lib.umn.edu. 2008-05-13). The lupulin glands of the female hop cones
contain hop resins and essential oils. These resins are composed largely of alpha (α) and beta (β) acids. Both alpha and beta acids are antibacterial agents that inhibit gram positive bacteria by causing a breakdown of their cell walls (Simpson 1993). Hops act as ionophores transporting ions across bacterial cell membranes, disrupting membrane ion gradients, causing leakage, starvation and cell death (Teuber and Schmalreck 1973).

Hops are a crop unique to the brewing industry. Indeed, the only major commercial use for hops is in beer. Brewers use hops primarily as a flavoring and stability agent. Hops impart bitterness and aromatic flavors to beer (Virgo 2010). Brewers add hops to the wort (the sugar-rich liquid resulting at the end of the mashing process) during boiling in a brewkettle (commonly known as a copper). Today, most consumers think of hops in terms of the bitterness and aromatic flavors they add to beer, but before the industrialization of brewing and the discovery of pasteurization, the anti-bacterial properties of hops were of great importance (Virgo 2010).

Ninety percent (90%) of U.S. commercial hops production occurs in three states, Washington, Oregon and Idaho. Since the late 19th century, the Pacific Northwest has been home to some of the finest hops in the world because of the ideal growing conditions and skilled hops producers in that region. The majority of the American hops industry has been and continues to be family owned and operated farms.

**Statement of Grounds:** Hops meet the general provisions exemption of Section 112.2(a)(1), because they are not consumed in raw form. Even when they are introduced to animal feed, as a natural antibiotic, the hops are processed, not raw. (Flythe 2009; Narvaez et al., 2011). Nevertheless, because some FDA representatives have described hops as “edible flowers,” brewers are concerned that the proposed Produce Safety Rules may apply unless and until FDA expressly adds hops to the list of produce exempt under Section 112.2(a)(1).

There is a well-established and sound technical scientific basis for and little risk associated with exempting hops from the proposed standard. First, brewers usually add hops to the brewkettle during wort boiling where they undergo significant heat processing. This heating or sterilization step results in hopped worts. These hopped worts are considered to be stable microbiologically largely due to boil time in the brewkettle and the addition of hops which have an antibiotic effect that
favors the activity of brewer’s yeast over less desirable microorganisms (Menz et al., 2010). Second, further food safety and quality control measures such as stabilization, filtration and pasteurization occur after wort boiling. Third, molecular hop components have well-documented natural anti-microbial properties. These properties, in the presence of ethanol and the low final pH of beer, plus the strict sanitation standards required to conduct microbiologically controlled brewery fermentations utilizing pure yeast cultures, contribute to the well-known food safety of beer (Behr et al., 2010; Behr et al., 2009; Beales 2004; L’Anthoën et al., 1996; Teuber et al., 1973). Fourth, hops act as a natural preservative preventing decomposition by microbial growth or by undesirable chemical changes. Fifth, beer with hops is bacteriostatic or bactericidal due to the presence of ethanol and hop bitter acids as well as its low pH, carbon dioxide and lack of fermentable sugar and oxygen, all of which inhibit growth of pathogenic and most nonpathogenic bacteria (Bunker 1955). Sixth, no known human pathogens are able to survive in beer regardless of the form or the manner in which the brewer utilizes hops during the brewing process (Menz et al., 2009).

In conclusion, there is a well-established, sound technical scientific basis for and little risk associated with an express declaration that the proposed Produce Safety Rules do not apply to hops.

Respectfully submitted,

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References


