



December 10, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

**Comments in regards to:** Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans, Proposed Rule; Docket No. FDA-2011-N-0920; RIN0910-AG36

The American Malting Barley Association, Inc. (AMBA) and National Barley Growers Association (NBGA) offer the following comments in response to the request for public comment on the Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans published in the September 29, 2014 Federal Register, Docket No. FDA-2011-N-0920; RIN0910-AG36.

AMBA is a nonprofit trade association with the goal of ensuring an adequate supply of high quality malting barley for the malting, brewing, distilling and food industries. NBGA is a grass-roots organization dedicated to advancing the national and international interests of US barley producers.

AMBA submitted separate comments on the FDA's handling of brewers spent grains in the supplemental notice of the proposed rule with the Beer Institute.

In writing the Food Safety Modernization Act (FSMA), Congress granted FDA the authority to exempt facilities that are solely engaged in the storage of raw agricultural commodities (RAC) except fruits and vegetables from compliance to some of registration, reporting, and inspection activities. Congress recognized the fact that facilities that store barley and other grains do not pose a significant food safety risk and an exemption would allow FDA to focus its limited resources to areas of greatest concern to public safety.

In the October 29, 2013 proposed rule, FDA granted such an exemption to storage facilities (e.g. grain elevators and warehouses) that store RACs other than fruits and vegetables recognizing that "Outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-fruit or vegetable RACs." However, the initial rule contained such a narrow definition of "holding" that few if any "off-farm" facilities storing RACs would qualify for the exemption and therefore be subject to costly CGMPs and preventive controls.

The supplemental proposed rule published in the September 29, 2014 Federal Register modifies the definition of “holding” to include practices universally used in preparing RACs other than fruits and vegetables (eg. grains) for storage or while they are in storage. Activities such as cleaning, drying, fumigating, screening and otherwise conditioning are major contributors to the reason the storage of non-fruit and vegetable RACs have not led to foodborne illness.

Removing dockage through screening or aspiration not only improve the quality and value of grain, but also reduce the amount of inert material (stones, stems, dirt...), insects, weed seeds, and other grains that could reduce the storage life of the grain. Drying barley to moisture levels of 12.5% or lower by aeration with or without added heat (105° F max) preserves germination and lessens the opportunity for mold growth or insect infestations. Fumigation has its obvious safety benefits. All of these are activities have the net result of improving food safety.

This modification of the definition for “holding” as it is applied to facilities that are solely engaged in the storage of RACs other than fruits and vegetables reflects an appropriate risk-based approach to grain storage and recognizes the lack of significant public health benefit of earlier definition. AMBA and NBGA fully support this change in the definition of “holding” made in the supplemental rule. Should this change not be in the final rule, compliance costs could result in the shutdown of facilities and drive up the cost to the processor and ultimately the consumer.

Respectfully submitted,



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