March 31, 2014

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

Re: Docket No. FDA-2011-N-0922/RIN 0910-AG10: Proposed Rule Regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Dear Madame/Sir:

On behalf of the undersigned trade associations representing wine, beer and distilled spirits, we welcome the opportunity to respond to the Food and Drug Administration's proposed "preventive controls for animal food" rules to implement the Food Safety Modernization Act. (78 Fed. Reg. 64736 (October 29, 2013).) In this rulemaking, FDA seeks comments regarding its proposed interpretation of the scope of the beverage alcohol exemptions under Section 116 of the FSMA and specifically whether the Agency's tentative conclusion that the proposed "preventive controls for animal food" rules should apply to spent grains.

We believe that FDA's tentative conclusion is incorrect. The proposal to apply preventive controls to the by-products/residues, such as spent grains, distillers' grains, grape pomace, and the like, of the beverage alcohol manufacturing process would result in only a partial as opposed to a full exemption for alcohol-related facilities contrary to the terms and scope of Section 116 and the facts of the beverage alcohol production processes.

Two salient points made at the February 5th Subcommittee on Health of the House Committee on Energy and Commerce hearing entitled "Examining the Implementation of the Food Safety Modernization Act" also should be the touchstone in reconsidering and reversing FDA's tentative conclusion about applying preventive controls to spent grains and other by-products of the beverage alcohol manufacturing process. Regarding the remaining ingredients after the manufacturing process (such as spent grains), Congressman Shimkus stated during the hearing that "our basic premise is, if it is in the entry point safe for humans…it should be safe for animal feed."

FDA Deputy Commissioner for Foods and Veterinary Medicine, Dr. Taylor, poignantly stated that "the whole goal [of the FSMA] is to achieve the food safety goal without imposing regulations, just for regulation sake." We respectfully submit that the imposition of preventive controls on spent grains and other by-products of the beverage alcohol production process would be regulation for regulation's sake and unjustifiably would circumscribe the Section 116 exemptions for alcohol-related facilities.

Executive Summary

Section 116 exemptions specifically encompass "the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages." (Emphasis supplied.) The FSMA provided several exemptions for alcohol-related facilities to, among other things, avoid duplicative regulatory schemes implemented by both FDA and the Tax and Trade Bureau; the latter of which has a well-established, comprehensive regulatory system of controls for beverage alcohol facilities, as well as in recognition of the low risk of food-borne illness associated with the activities referenced above relating to beverage alcohol facilities.

The rationale and underpinnings for these exemptions apply with equal force to the raw materials used to produce beverage alcohol products (e.g., grapes, grains and other agricultural products) and to the residues of those raw materials (e.g., grape pomace, spent grains, distillers' grains, and other by-products) of the manufacturing process. Any other approach would nullify the Section 116 beverage alcohol exemptions and result in an irrational regulatory scheme where only those facilities "warehousing" finished products, i.e., bottled spirits, beer and wine stored in a warehouse (and not those facilities producing the products) would fall within the exemption.

Distillers, brewers and vintners are in the business of producing their respective products—distilled spirits, beer and wine. They are not in the animal food business. Spent grains, distillers' grains, grape pomace, and other by-products of the manufacturing processes are a natural and necessary consequence of the production process.

To effectuate the alcohol-related facilities exemptions of Section 116 of the FSMA, all aspects of the beverage alcohol production processes, including their respective by-products (which are referred to as coproducts by the United States Department of Agriculture) should be exempt from the proposed "preventive controls" provisions of this rulemaking. Any other interpretation would lead to unintended consequences, such as rendering an otherwise exempt facility non-exempt.

Simply put, the beverage alcohol facilities exemptions logically should extend to the entire "life cycle" of the manufacturing process to produce wine, beer and distilled spirits. Just as the raw materials necessary to produce distilled spirits, beer and wine are "part and parcel" of the manufacturing process, spent grains and other by-products also are "part and parcel" of the manufacturing process.

I. Spent Grains and Other By-Products Are Integral to Producing Beverage Alcohol

FDA tentatively concludes that the "preventive controls for animal food" should apply to by-products of the beverage alcohol manufacturing process "[b]ecause those spent grains are not alcoholic beverages themselves, and they are not in a prepackaged form that prevents any direct human contact with the food." (78 Fed. Reg. at 64765.) Using this logic, the grapes and grains used to produce beverage alcohol products that also "are not alcoholic beverages themselves" and "are not in a prepackaged form" would fall outside the alcohol-related facilities exemptions set forth in Section 116 and would lead to the illogical result of excluding the raw materials necessary to produce distilled spirits, wine and beer—thereby, in essence, striking the words "manufacturing" and "processing" from the FSMA's beverage alcohol exemptions.

FDA, of course, did not follow this path of "logic" in its "preventive controls for human food" rulemaking since it would not be rational and would nullify the Section 116 exemptions. In that rulemaking, FDA acknowledged that Congress intended to exempt the raw materials used to produce beverage alcohol products ("non-alcohol food"). FDA also correctly stated in the proposed "preventive controls for human food" docket that Section 418 does not apply when "the manufacturing, processing, packing, or holding of alcoholic beverages is inseparable from the manufacturing, processing, packing, or holding of food other than alcoholic beverages." (78 Fed. Reg. 3646, 3709 (January 16, 2013).) This interpretation is entirely consistent with the Congressional intent underpinning the Section 116 exemptions and commercial realities since any other approach would be contrary to the scope of the alcohol-related facilities exemptions.

FDA's approach to spent grains in this rulemaking also should follow the same reasoning and take into account the commercial realities of producing beverage alcohol products. The same premium, high food-grade grains used to produce beverage alcohol products are the same grains that result in spent grains. To exclude the handling and distribution of such grains when used in beverage alcohol facilities to produce products yet have those same facilities fall outside of the exemption when a by-product results defies a commonsensical, rational approach in implementing the FSMA.

A. Spent Grains Are an Inevitable Part of Producing Beverage Alcohol Products

Spent grains and distillers' grains are inseparable from the brewing or distilling process and consist of proteins, fats, minerals, vitamins, and fibers that are concentrated by the removal of the grain starch in the mashing and fermentation process. After the removal of alcohol from the fermented grain mash that is produced by the grains and mixed with yeast to convert the starch into alcohol, what is referred to as "stillage" in the distilling process (the grains and liquid effluent remaining after distillation)—spent grains—may be made available to farmers as liquid or dried animal feed, used as fertilizer or otherwise disposed of via landfill.

They (along with other remaining mixtures of raw materials used to produce beverage alcohol products) are a natural coproduct/by-product of the production process and are produced in the same facility where, for example, the fermentation and distillation processes occur. These coproducts are part of the "life cycle" of producing beverage alcohol products—be it grape pomace, brewers' spent grains or distillers' grains—and are an inevitable result of producing beverage alcohol products.

B. Section 116 Exemptions Cover the "Life Cycle" of the Production Process

The "life cycle" of the raw materials, such as the grains, grapes and other agricultural products, used to manufacture beverage alcohol products are the "food stocks" for these products, as well as the "food stocks" for our nation's farmers. The mere act of separating insoluble particulates during the beverage alcohol manufacturing process should not transform an exempt activity into a non-exempt activity, thereby triggering regulation of the by-products or residues of the beverage alcohol production process.

Such a result would be rewriting the basic terms and foundation of the alcohol-related facilities exemptions of Section 116 that encompass "the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages." (Emphasis supplied.) The proposal to apply Section 418 "preventive controls" to an alcohol-related facility for spent grains and other by-products would subsume the exemption itself and result in an illogical approach from both a regulatory and production standpoint.

FDA's tentative conclusion that preventive controls should apply to spent grains assumes, incorrectly, that there is a need to regulate the natural by-products or residues of the beverage alcohol production process. Regulation of spent grains and other by-products of the distillation, brewing and winemaking processes is unnecessary given FDA's own acknowledgement that there is no known public health risk associated with these activities.

The beverage alcohol industry already is subject to heavy regulation, already engages in activities that minimize or eliminate the need for additional regulation and only will suffer severe economic hardships if the FDA limits the Section 116 exemptions in a manner that results in additional, unjustified regulatory burdens imposed upon the beverage alcohol manufacturing process. In sum, the mere act of separating and disposing of spent grains and other by-products by sale or otherwise should not trigger an obligation for onerous and unwarranted food safety regulations for the beverage alcohol industry.

II. Section 116 Alcohol-Related Facilities Exemptions Cover All Parts and All Aspects of the Manufacturing, Processing, Packing, or Holding of Beverage Alcohol Without Exception

By Section 116, Congress intended to exempt all parts and all aspects of the manufacturing, processing, packing or holding of beverage alcohol without restriction. FDA's proposed interpretation of Section 116 as applying to some, but not all discrete parts and aspects of beverage alcohol manufacturing, is unreasonably restrictive and based upon illogical and inconsistent conclusions that, if adopted in the final regulations, would have the effect of undermining and nullifying Congressional intent.

The goal of producing beverage alcohol is not to manufacture animal feed, but to produce distilled spirits, wine or beer brands offered for sale in the United States marketplace. Spent grain and other by-products or residues of producing these beverage alcohol products come into existence as the result of a necessary step in the production process, not as a discrete manufacturing objective.

The "life cycle" of "non-alcohol foods" in alcohol-related facilities is very different from the scenario discussed in the "preventive controls for human food" rulemaking about the production of non-alcoholic beverages in terms of the scope of the Section 116 exemption:

> [I]f an alcoholic beverage distillery also makes non-alcoholic beverages,...the alcoholic beverage distilling activities would be exempt from section 418 of the FD&C Act, but the activities related to nonalcoholic beverages would be subject to section 418...

(78 Fed. Reg. at 3708; emphasis supplied.) In this illustration, the beverage alcohol facility is making a non-alcohol product and the manufacture of this product would not be exempt from the proposed "preventive controls" provisions—a conclusion that we do not dispute.

Conversely, a description of the production process used to manufacture distilled spirits, beer or wine dictates a very different conclusion. For example, in whisky production, grains are mashed and fermented to produce an alcohol/water solution that is distilled to concentrate the alcohol. (Mashing consists of cooking the grain to solubilize the starch from the kernels and to convert the soluble starch to grain sugars with barley malt and/or enzymes.)

The distillation process separates and concentrates the alcohol from the fermented grain mash. After the removal of alcohol, the stillage—spent grains—may be sold as liquid "wet" or dried feed, or other secondary products described above. As stated above, distillers, brewers and vintners are not in the business of making by-products/residues from their respective distilling, brewing or winemaking manufacturing process—they are in the business of making beverage alcohol products.

Exempting the full cycle related to producing beverage alcohol products is fully consistent with the risk-based, public health principles underpinning Congress' Section 116 alcohol-related facilities exemptions. In that regard, the Agency appropriately recognized that intent per the following points in its "preventive controls for human foods" docket:

> [A]lcoholic beverages are regulated by TTB under the Federal Alcohol Administration Act and Chapter 51 of the Internal Revenue Code, which together establish "a comprehensive system of controls of alcoholic beverages, including on-site inspections and procedures that require the advance approval of statements of process and of formulas showing each ingredient to be used in the product."
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> FDA tentatively concludes that Congress intended to exempt certain alcohol-related facilities from section 418 of the FD&C Act because it found that, in light of the relatively low public health risk presented by the manufacturing, processing, packing, and holding of alcoholic beverages and their joint regulation by both FDA and TTB, the current regulatory scheme was sufficient to control the hazards associated with the manufacturing, processing, packing, and holding of alcoholic beverages.
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> FDA concludes that Congress must have considered identifying hazards and implementing preventive controls for the manufacturing, processing, packing, and holding of alcoholic beverages to warrant lower priority from a public health perspective than other foods. Congress may have made such a conclusion in light of the potential

> antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB).

(78 Fed. Reg. at 3709.)

It makes no sense to exempt the grains a beverage alcohol facility uses to produce its respective products, yet deny that facility the benefit of the exemption once the grain is spent. Setting the exemption aside mid-stream in the beverage alcohol production process is illogical from both a regulatory and production perspective. It also would be illogical to impose regulation on an otherwise exempt activity simply because a third party (e.g., a farmer or rancher) finds value in the by-products or residues of the exempt activity.

Based upon the facts of the production processes, we urge the Agency to reverse its tentative conclusion that the "preventive controls for animal food" rules apply to spent grains and other by-products. Congress intended to exempt the entire process of manufacturing beverage alcohol products, including by-products or residues of that process, even if the by-products or residues have a separate value or potential use as food. The provisions of the Section 116 alcohol-related facilities exemptions are clear –the exemptions extend to "the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages." (Emphasis supplied.) Where spent grains are residues of the exempted category (beverage alcohol products) in the FSMA, FDA should defer to the plain language of the exemptions.

For all these reasons, the alcohol-related facilities exemptions in Section 116 of the FSMA should apply to spent grains, distillers' grains and grape pomace, as well as all aspects of the production process. Any other result would mean bringing costly plans/processes to existing operations and increasing farmers' cost of purchasing animal feed, with no commensurate safety benefits. As referenced above, beverage alcohol producers already work under hundreds of rules and Congress recognized that the current oversight is sufficiently extensive when promulgating the Section 116 exemptions.

III. Section 418(m) Provides an Additional Basis to Exempt Spent Grains and Other By-Products from the Proposal

The Section 116 beverage alcohol exemptions of the FSMA standing alone cover the entire "life cycle" of producing distilled spirits, beer and wine. Any other interpretation not only would be inconsistent with the Congressional intent underpinning the FSMA, but also would undermine the very rationale for the alcohol-related facilities exemptions set forth in the Act. Pursuant to Section 116, the beverage alcohol production processes at distilleries, breweries and wineries are exempt from Section 418. As such, Congress determined that, for the purposes of FDA regulation under Section 418, the activities performed at alcohol-related facilities "warrant lower priority from a public health perspective than other foods." (78 Fed. Reg. at 3709.)

In Section 418(m) of the FSMA, Congress granted FDA the authority to "by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man ...." FDA should use this statutory authority to exempt spent grains and other by-products of the beverage alcohol manufacturing process from the requirements of Section 418. In light of the fact that beverage alcohol production processes at distilleries, breweries and wineries are not subject to Section 418 despite being human food, it would be inconsistent to interpret those same activities as precluding an exemption under Section 418(m).

To that end, FDA should exercise its authority to exempt spent grains and other by-products for the following reasons:

(1) There are established quality control systems and industry practices that ensure the safety of spent grains and other by-products for use in animal food such that application of Section 418 would be unnecessarily duplicative.

(2) Spent grains and other by-products have a long history of safe use as animal food. As stated above, the same premium, high food-grade grains used to produce beverage alcohol products are the same grains that result in spent grains. Extensive quality control systems are in place to ensure only the highest quality grains are used to produce beverage alcohol products.

(3) Failure to provide an exemption for spent grains and other by-products likely will result in their disposal via landfills.

(4) Applying Section 418 to spent grains and other by-products would impose a significant economic burden upon beverage alcohol producers with no known public health or safety benefit.

Congress in enacting Section 116 of FSMA intended to exempt the entire process—the "life cycle"—of producing beverage alcohol products from Section 418. Section 418(m) provides an alternate, supplementary basis to exempt spent grains and other by-products of the beverage alcohol manufacturing process used for animal food.

Conclusion

Distillers, brewers and vintners are in the business of producing their respective products—distilled spirits, beer and wine. They are not in the animal food business. Spent grains, distillers' grains, grape pomace, and other by-products of the manufacturing processes are a natural and necessary consequence of the production process.

A proposed interpretation of the Section 116 exemptions that would exclude by-products of that production process would nullify the alcohol-related facilities exemptions enacted by Congress. A full understanding of the production process for beverage alcohol products will ensure that the intent of Congress is fulfilled and that the scope of the Section 116 alcohol-related facilities exemptions duly is realized.

Thank you for providing us with an opportunity to comment upon FDA's proposal. We stand ready to assist FDA in these important endeavors and, if you have any questions regarding our submission, please do not hesitate to call.

Sincerely,

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Distilled Spirits Council

Mr. William T. Earle
National Association of Beverage Importers

Ms. Victoria I. McDowell
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