December 15, 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: Supplemental 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 (FDA) supplemental "preventive controls for animal food" proposed rule to implement the Food Safety Modernization Act (FSMA). (79 Fed. Reg. 58476 (September 29, 2014).) We appreciate that FDA revisited its approach apropos of the co-products of the beverage alcohol manufacturing process; however, we respectfully submit that this supplemental rulemaking still fails to comport with the terms and scope of the alcohol-related facilities exemptions pursuant to Section 116 of the FSMA. Separately, any differential treatment between wet and dried spent grains co-products under the "animal food" supplemental proposal has no justification and both of these co-products necessarily fall within the scope of the Section 116 exemptions.

Executive Summary

To effectuate the alcohol-related facilities exemptions of Section 116 of the FSMA, all aspects of the beverage alcohol production process, including their respective by-products (which are referred to as co-products by the United States Department of Agriculture) should be exempt from the "animal food" rulemaking. Any other interpretation would result in rendering an otherwise exempt facility non-exempt.

The Section 116 exemptions should extend to the entire life cycle of producing beverage alcohol products from their raw materials to their co-products. FDA otherwise would be forced to expend its limited resources inspecting alcohol-related facilities for compliance vis-à-vis activities that FDA itself has recognized as a very low-risk to human and animal food safety, and beverage alcohol producers would be saddled with unnecessary regulations for no commensurate health or safety benefit.

I. FDA's Interpretation of FSMA Is Unnecessarily Narrow and Unjustified

Neither the "animal food" proposal nor the "human food" proposal (79 Fed. Reg. 58524 (September 29, 2014)) provides any substantive basis or rationale for the interpretation taken by FDA regarding this Congressional legislative exemption. 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 operative word is "relate" in regard to the manufacturing, processing, packing, or holding of alcoholic beverages—this statutory section does not state that the exemptions encompass the activities of such facility for the manufacturing, processing, packing, or holding of alcoholic beverages.

Congress chose the wording of the Section 116 alcohol-related facilities exemptions carefully. FDA's approach to the facilities exemptions in the "animal food" rulemaking rewrites the basic terms and foundation of the alcohol-related facilities exemptions of Section 116 and nullifies Congressional intent. In the "human food" rulemaking (79 Fed. Reg. at 58558), FDA points to the rule of construction set forth in Section 116(c) to justify the application of the "animal food" regulatory provisions to spent grains and other co-products/by-products of the beverage alcohol manufacturing process.

We respectfully submit that FDA has misread and misinterpreted this rule of construction that reads in its entirety as follows: "Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act)." (Emphasis supplied.) Pointedly, Section 116(a) states and provides as follows:

> (a) In General.—Except as provided by sections 102, 206, 207, 302, 304, 402, 403, and 404 of this Act, and the amendments made by such sections, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that--
> (1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and
> (2) under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.

Separately and in addition, the title of Section 116 also makes it clear regarding the scope of the exemptions—"Alcohol-Related Facilities"—it is not captioned Beverage Alcohol Exemptions. Any interpretation of Section 116 must take into account all of its provisions and the import of those provisions.

II. Section 116 Exemptions Extend to the Entire Life Cycle of Producing Beverage Alcohol Products—from Their Raw Materials to Their Co-Products

There are five fundamental facts warranting the conclusion that distilleries, breweries and wineries should not be subject to the "animal food" provisions of FSMA and require FDA to honor the broad exemptions granted by Congress:

(1) Section 116 is a facilities exemption;

(2) spent grains and other co-products/by-products are "part and parcel," and an inevitable result of the beverage alcohol production process;

(3) spent grains and other co-products/by-products of the beverage alcohol production process are "produced" within the exempted facility and remain in that exempt facility until pick up by farmers or their agents;

(4) spent grains and other co-products of the beverage alcohol manufacturing process have a long history of safe use and there is no compelling health or safety reason to regulate these co-products under the proposed "animal food" rule; and

(5) activities conducted at an alcohol-related exempted facility are analogous to other exempt activities.

1. Section 116 Is a Facilities Exemption

Section 116 is a facilities exemption and covers all parts and all aspects relating to the manufacturing, processing, packing, or holding of beverage alcohol without exception. FDA's proposed interpretation of Section 116 as applying to some, but not all discrete parts and aspects of these activities, 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 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 and other co-products/by-products) of the manufacturing process.

In its January 2013 "preventive controls for human food" rulemaking (78 Fed. Reg. 3646 (January 16, 2013)), FDA acknowledged that Congress intended to exempt the raw materials used to produce beverage alcohol products ("non-alcohol food"). This interpretation is entirely consistent with the Congressional intent underlying the Section 116 exemptions since any other approach would be contrary to the scope of the alcohol-related facilities exemptions.

FDA's approach to spent grains and other co-products/by-products should follow the same reasoning and take into account the commercial realities of producing beverage alcohol products. 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 exemptions when a co-product/by-product results defies a commonsensical, rational approach in implementing the FSMA.

2. Spent Grains and Other Co-Products/By-Products Are "Part And Parcel," and an Inevitable Result of the Beverage Alcohol Production Process

Spent 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. 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 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—either goes back into the distillation process or may be made available to farmers as liquid or dried animal feed, used as fertilizer or otherwise disposed of via landfill.

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. 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 and other by-products are a natural and necessary consequence of the production process, not a discrete manufacturing objective.

Due to these production facts, the Section 116 exemptions logically 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.

Exempting the full cycle related to producing beverage alcohol products effectuates 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 2013 "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.)

3. Spent Grains and Other Co-Products/By-Products of the Beverage Alcohol Production Process Are "Produced" within the Exempted Facility and Remain in that Exempt Facility Until Pick Up by Farmers or Their Agents

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

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 that are "produced" within an exempted facility.

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.) We respectfully submit that FDA should defer to the plain language of the exemptions. (As set forth in 21 C.F.R. § 1.227, a facility "means any establishment, structure, or structures under one ownership at one general physical location." All of the activities described above take place within the exempted alcohol-related facility pursuant to Section 116.)

4. **Spent Grains and Other Co-Products of the Beverage Alcohol Manufacturing Process Have a Long History of Safe Use and There Is No Compelling Health or Safety Reason to Regulate These Co-Products Under the Proposed "Animal Food" Rule**

There is no 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 or safety risk associated with these activities. In fact, stillage (spent grains) is "recycled" back into the distillation process to produce beverage alcohol products. Simply put, the spent grains are safe enough that they are used again for human food products.

Spent grains and other by-products have a long history of safe use as animal food. 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. Further, 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.

In FDA's "animal food" rulemaking docket, the Agency did not identify any biological, chemical or physical hazards associated with spent grains. For human food by-products generally, FDA concluded that "while there are biological, chemical, and physical hazards that may be present in the human food by-products, the information reviewed indicates these hazards rarely occur." (79 Fed. Reg. at 58488.) In addition, none of the reference documents cited in the rulemaking revealed any health or safety risk associated with spent grains. This lack of evidence is not surprising given the 150-year record of safe use of spent grains.

Not only are spent grains and other co-products part of the life cycle of producing beverage alcohol products, but also they are part of a "community cycle" with neighboring farmers. The livelihood of these farmers is their livestock and the nutrients from spent grains are part of that livelihood. For example, the corn purchased by one distiller to produce their iconic Bourbon brand is from the same farmer that also purchases the dried spent grains from that distillery for his livestock. In

another instance, an Oregon brewery restaurant features beef from the farmer that feeds the brewery's spent grains to his cattle. The community relationship between alcohol-related facilities and the farmers in their locales is longstanding. As an illustration, three families operating their dairy farms located near a distillery have been hauling spent grains from that distillery for decades to sustain their livelihood and often their demand has outgrown the volume of this co-product/by-product of the distillery itself.

Another example of this community relationship is that a distillery still under construction has reached out to its local farmers about spent grains even before the first drop of product has been produced. Finally, in the case of one distillery, some of its retired employees now in a different business purchase spent grains from that distillery and obviously have an intimate knowledge about the quality, nutritional value and safety of those co-products/by-products as animal feed.

These "real world" examples underscore the long history of the safe use of spent grains, both wet and dried, as animal food and the "community cycle" of these neighboring facilities guarantees this result. In that regard, 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" should be the touchstone in reversing FDA's tentative conclusion about applying the "animal food" rule to spent grains and other by-products of the beverage alcohol manufacturing process. These points equally are applicable to FDA's supplemental rulemaking.

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's sake." We respectfully submit that the imposition of the "animal food" rule to 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.

As Congressman Welch stated regarding the "animal food" rule apropos of spent grains: "The FDA's rule is a solution in search of a problem. Since the time of George and Martha Washington's farm at Mount Vernon, this practice [of providing farmers with spent grains to feed their livestock] has been mutually beneficial and environmentally sound."

5. Activities Conducted at an Alcohol-Related Exempted Facility Are Analogous to Other Exempt Activities

As currently crafted, the supplemental "animal food" and "human food" proposals reflect contradictory and conflicting approaches to implementing FDA's statutory mandates and FSMA's exemptions. To demonstrate this point, activities that can be conducted on a "farm" within the "farm" exemption are the same type of activities that are conducted within the alcohol-related facilities exemptions.

For example, a farm ("an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (or seafood), or both") may conduct the following activities and still remain in its exemption: (1) pack or hold raw agricultural products; (2) manufacture or process food for on-farm consumption only; (3) dry/dehydrate raw agricultural products as long as there is no additional processing; and/or (4) label and package raw agricultural products as long as there is no additional processing.

Packing does not trigger a non-exempt status as long as the activities are done to raw agricultural products on that farm and specific activities in this definition of "packing" include packaging, mixing, cooling, filtering, and drying for purposes of storage or transport. Various "holding" activities on a "farm" are not considered "manufacturing/processing" and thereby do not trigger a non-exempt status. In that regard, these supplemental "animal food" proposals define "packing" as a means of putting food in a container and include activities that are incidental to packing (e.g., activities that are necessary to safely or effectively store or transport agricultural products).

Drying or dehydrating is considered a "holding" activity (not a "manufacturing or processing" activity) when it is incidental to storage; however, even if a "farm" dries or dehydrates a raw agricultural commodity and creates a distinct commodity, without additional "manufacturing or processing," these actions still are considered exempted "farm" activities. (79 Fed. Reg. at 58485-86; see also 79 Fed. Reg. at 58533-34, 58562.) To the same effect, if the "farm" dries or dehydrates raw agricultural commodities without doing any additional processing, this activity is considered a "farm" activity and excluded as a "manufacturing/processing" activity that otherwise would alter the non-exempt status of a "farm." (79 Fed. Reg. at 58486, 58521.)

Without any substantive rationale, FDA differentiates a set of activities that can be conducted within an exemption (e.g., on a "farm"), yet the conduct of the same or similar activities somehow would forfeit another of the Act's exemption (e.g., the alcohol-related facilities exemptions). As a matter of public policy, it makes no sense to differentiate between allowable and non-allowable activities in terms of the exemptions under the Act.

Arbitrary line drawing disserves the public interest and leaves the "regulated" community both confused and skeptical about such differential treatment. No health and safety benefits are served by such action and, at a minimum, FDA's approach to activities that can be conducted within an exemption should be applicable to its entire regulatory scheme.

III. There is No Basis to Differentiate Between "Wet" and "Dried" Spent Grains—All Should Be Exempted

Pursuant to FDA's supplemental "animal food" proposal (and the "human food" proposal), preventive controls would not apply to human food processors that pack and hold by-products for use as animal food ("wet" spent grains); however, they would apply when the human food processor further "manufactures/processes" the by-products intended for animal food ("dried" spent grains). This arbitrary line drawing between dried/dewatered spent grains (wet or less wet—the only difference

between the two is the removal of water regarding the latter) and other beverage alcohol by-products neither makes sense, nor is justified, from a production, technical, scientific, safety, or "real world" perspective.

Both "wet" and "dried" spent grains and other similar by-products are a natural and inevitable result of the beverage alcohol process. The only difference between the "two" is the level of moisture. For example, stillage, as described above, is approximately 88 to 92% moisture; wetcake has a moisture content of approximately 60 to 70% and "dried" spent grains have a moisture content ranging from 5 to 12%. There is nothing added to these various streams of co-products relating to the production of distilled spirits, beer and wine, and the relative level of moisture is an aspect of the transport and storage of spent grains for ultimate use by America's farmers.

FDA has acknowledged that "dewatering is not a process." We fully agree. The difference between "wet" and "dried" spent grains simply is dewatering. There is no activity that could be construed as further "processing/manufacturing." No chemicals or additives of any kind are or ever have been introduced into dewatering the co-products/by-products of producing beverage alcohol.

FDA's current definition of "manufacturing/processing" (21 C.F.R. § 1.227(6)) does not include "dewatering." This definition provides that:

> Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

None of the activities described in FDA's definition of "manufacturing/processing" occur vis-à-vis dried spent grains. There is no "cooking," "baking" or otherwise—just dewatering. Consequently, to deem the dewatering of spent grains as further "manufacturing/processing" is inapposite to FDA's current rules that also are referenced in both the "animal food" and "human food" proposals. Further, wet and dried spent grains are the same commodity (not distinct commodities) and should be treated equally.

Taking the moisture out of spent grains is far different than "cooking" or "baking" where the application of heat over time is for the purpose of physically and chemically transforming a product into a substantially different product, i.e., such a substantially different product would have physical and chemical properties not present prior to any "cooking" or "baking." On the other hand, the dewatering of spent grains merely reduces the total volume by reducing the water content of that co-product/by-product.

The removal of water from "wet" spent grains is not and should not be equated with or deemed to be further "manufacturing/processing." Separately, there is no scientific, technical or evidentiary basis for any safety differential between "wet" and "dried" spent grains. History also has not revealed a risk

of even unintentional contamination or adulteration of either "dried" or "wet" spent grains, nor has FDA in its rulemaking docket. An attempt to subject "dried" spent grains to the preventive control provisions of the "animal food" rulemaking is unjustified and only would result in the imposition of cost-prohibitive, needless regulatory burdens without any real food safety benefits.

These natural co-products/by-products—both "dried" and "wet" spent grains—fall within the alcohol-related facilities exemption of Section 116 and do not require additional regulation under FDA's supplemental proposals, much less differential regulatory treatment. 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.

In its March 28th submission, the Brewers Association estimated that the implementation of preventive control measures and associated recordkeeping requirements at its member company facilities would cost approximately $54 million annually—an exorbitant cost associated with an additional layer of extensive, unnecessary and burdensome government regulation that does not apply to their primary business as also would be the case for distillers and vintners under FDA's current proposal.

For example, the cost estimates for a single distiller producing a distilled spirits product recognized and protected as a distinctive product of the United States in numerous international treaties and Free Trade Agreements are approximated to be over $300k per annum (covering programmatic, recordkeeping and required measures) with further projected compliance costs of over $2.5-5M. These unnecessary financial impacts are for a co-product/by-product desired by local farmers of a distilled spirits brand sold in over 100 markets across the world and already required by the United States Government to pay a federal excise tax as is the case for all other beverage alcohol products.

Once again, all of these activities occur within the same exempted facility and the alcohol-related facilities exemptions in Section 116 of the FSMA apply to all spent grains and grape pomace, as well as all aspects of the production process within the facility. 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.

IV. The Proposed Good Manufacturing Practices Are Contrary to Marketplace Realities

Under the supplemental "animal food" proposal (and the "human food" proposal), FDA would require spent grains to comply with the following Current Good Manufacturing Practice proposed rules (GMPs):

a) containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

b) animal food for distribution must be held in a way to prevent contamination from sources such as trash and garbage ("[t]he facility would need to protect the animal food from contamination with physical hazards such as floor sweepings containing glass or metal fragments and from chemical hazards such as equipment oil, cleaning chemicals, or pesticides used in the facility");

c) labels must identify the by-product with the common and usual name, and must be affixed to or accompany the animal food; and

d) shipping containers (e.g., totes, drums and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(See 79 Fed. Reg. at 58509-10, 58513, 58488.)

Today and historically, the quality, nutritional value and safety of spent grains and other co-products/by-products have been top of mind and ensured. Distillers, brewers and vintners take every measure to guard against any contamination of their co-products. Consequently, the proposed GMP to take measures to guard against contamination already is "SOP." We respectfully submit, however, that the other three proposed GMPs do not reflect marketplace or commercial realities in terms of the holding or transport of spent grains.

Regarding the proposed GMPs pertaining to containers and labeling, 99.99% of the volume of spent grains are not held in containers, totes, drums, or tubs. Rather, the spent grains are made available to farmers in various repositories at the facility. It is very much a "self-serve" business where a farmer will come to a distillery, brewery or winery to pick up their respective co-product/by-product, such as spent grains, for animal feed.

These spent grains generally are deposited directly into the farmer's trucks in bulk—no intermediate containers and no labeling on that container. These co-products/by-products are not a "profit center"—farmers come to their facilities with their own vehicles—be it a pickup truck, a dump truck or a tank, which belong to the farmer (and/or its agent) who uses the spent grains to feed his/her livestock. For all of these reasons, the proposed GMPs relating to containers, labeling and vehicles do not reflect marketplace realities and inappropriately place obligations upon distillers, brewers and vintners for and over which they have no control.

Separate and apart from the fact that the Section 116 exemptions should preclude the imposition of any regulation, the proposed GMPs should be revised as follows in order to properly take into account commercial realities (our suggested language is shown in bold typeface and our suggested deletions are shown through strikethroughs):

Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination~~, including the following~~ **as follows**:

(1) Containers **owned and** used **by the human food processor** to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution **by the human food processor** must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) **Where feasible, the human food processor should** ~~L~~label~~ing identifying~~ the by-product by the common and usual name. ~~must be affixed to or accompany animal food.~~ **If labeling is not feasible, the human food processor may provide a written description of the by-product as appropriate.**

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles **owned and** used **by the human food processor** to distribute animal food must be inspected **by the human food processor** prior to use to ensure **that its** ~~the~~ container or vehicle will not contaminate the animal food. **Shipping containers and bulk vehicles that are owned by the party transporting or receiving animal food from a human food processor must be cleaned, maintained and inspected by that party to prevent the contamination of animal food.**

(The suggested revisions are applicable to proposed §§ 507.28 and 117.95 in the "animal food" supplemental rulemaking docket.)

These revisions to the proposed GMPs will better allocate "responsibility" regarding the current practices between distilleries, breweries and vintners with their neighboring farmers. Nevertheless, we again underscore that Congress in enacting Section 116 of FSMA intended to exempt the entire process—the life cycle—of producing beverage alcohol products from Section 418.

Conclusion

Distillers, brewers and vintners are in the business of producing their respective products—distilled spirits, beer and wine. Spent grains, grape pomace and other by-products of the manufacturing process are a natural and necessary consequence of that production process.

A proposed interpretation of the Section 116 exemptions that excludes the 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 supplemental 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.

With best regards,

Ms. Lynne J. Omlie
Distilled Spirits Council

Mr. William T. Earle
National Association of Beverage Importers

Ms. Victoria I. McDowell
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Mr. Michael Kaiser
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Mr. Eric Gregory
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