



American Malting Barley Association, Inc.

March 31, 2014

Via eRulemaking Portal: www.regulations.gov

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

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

The Beer Institute (BI) and American Malting Barley Association (AMBA) appreciate the opportunity to comment on the FDA's proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. BI and AMBA are both trade associations representing U.S. brewers, importers, maltsters and other industry suppliers, large and small. As requested by the Agency in the October 29, 2013 notice of proposed rulemaking and request for public comment, these comments provide our views on the FDA's proposed interpretation of the scope of the exemption for beverage alcohol under Section 116 of the Food Safety Modernization Act (FSMA) (21 USC 2206) (78 Fed. Reg. 64765), specifically whether the Agency's tentative conclusion that proposed Subpart C, "Hazard Analysis and Risk-Based Preventive Controls" apply to brewers' spent grain is correct.

We do not believe the Agency's tentative conclusion is correct. The Agency's proposed interpretation of the Section 116 exemption is too restrictive. It is also based on the flawed and erroneous assumption that the mere act of separating insoluble particulates during brewing amounts to a separate manufacturing process, transforms an exempt activity into a non-exempt activity, and triggers regulation of the by-products or residue of beverage alcohol manufacture¹ if they are used as animal food. Likewise, the proposed interpretation assumes, incorrectly, that

¹ The by-products or residue of beer manufacture include brewers' spent grain (the residue of malted, unmalted, and refined grains), grain and malt dust or screenings, brewers condensed soluble, spent yeast slurry, and spent hops.

there is a compelling need to regulate the natural by-products or residue of brewing. Brewers' spent grain and other by-products exist as a natural and necessary result of the brewing process (*Mussatto et al. 2004*). The mere act of separating and disposing of those by-products by sale or otherwise should not trigger an obligation to meet onerous and expensive food safety regulations. Likewise, regulation of brewer's spent grain and other by-products of brewing is unnecessary given FDA's own acknowledgement that there is no known public health risk. The brewing industry is already subject to heavy regulation, already engages in activities that minimize or eliminate the need for additional regulation and will suffer severe economic hardship if the FDA limits the Section 116 exemption in a manner that results in additional, unnecessary regulatory burdens on brewing operations.

1. The Section 116 Alcohol Exemption Covers All Parts and All Aspects of The Manufacturing, Processing, Packing or Holding of Alcoholic Beverages Without Exception.

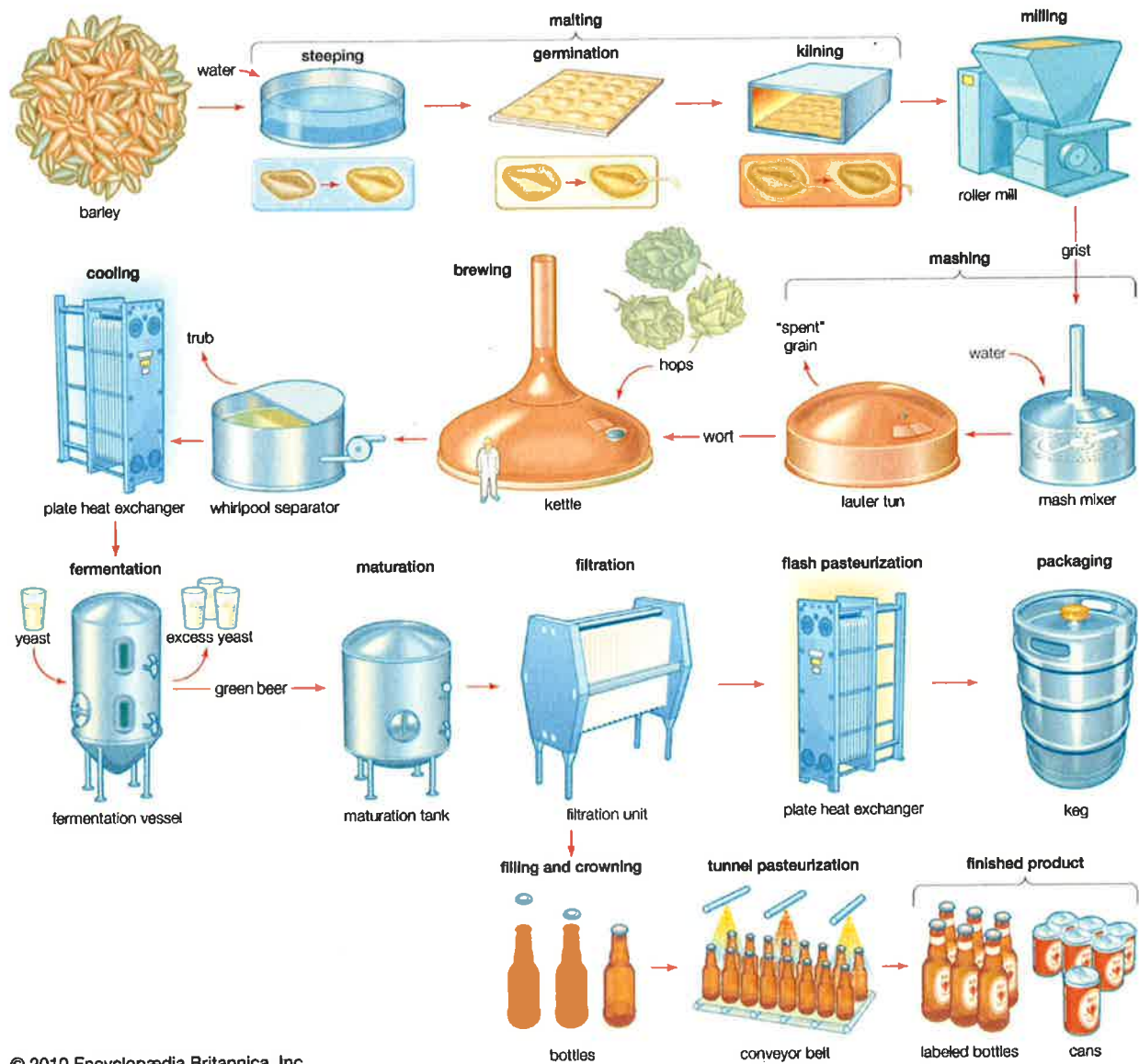
By Section 116, Congress intended to exempt all parts and all aspects of the manufacturing, processing, packing or holding of beverage alcohol without restriction. FDA's proposed interpretation of Section 116 as applying to some, but not all discrete parts and aspects of beverage alcohol manufacture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

FDA acknowledges that Congress intended to exempt the raw materials used to produce beverage alcohol products ("non-alcohol food"). FDA also correctly stated in the proposed human food rule 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. 3709). This interpretation is entirely consistent with Congressional intent underpinning the Section 116 exemption and commercial realities since any other approach would only allow those facilities holding finished beverage alcohol products (and not those facilities producing the products) to fall within the exemption. FDA's analysis fails, however, when it concludes that subpart C of the proposed rule for animal food would apply if a brewery's by-products are used as animal food because the by-products are "not alcoholic beverages" and are "not in a prepackaged form that prevents any direct human contact with the food."

FDA's analysis both misstates the nature of brewing and has the effect of unduly restricting the scope of the exemption for alcohol-related facilities under Section 116 in a manner inconsistent with Congressional intent.

The goal of brewing is not to manufacture animal feed. The goal of brewing is to manufacture beer. Spent grain and other by-products or residue of brewing come into existence as the result of a necessary step or steps in the brewing process, not as a discrete manufacturing objective. The brewing process involves the extraction and degradation of proteins,

carbohydrates and lipids from malted grain and various adjuncts in hot water. As shown below, spent grain, the largest by-product of brewing, is the residue of malt and grain, and sometimes corn and/or rice that remains in the mash-kettle after the mashing and lautering stages of brewing. Other by-products like excess yeast are removed at other stages of the brewing process.



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Again, the goal of brewing is not to make spent grain or excess yeast; spent grain and excess yeast are the main by-products or residue of brewing.

The same premium, high food-grade grain used to produce beer is the same grain that results in brewers' spent grain. It makes no sense to exclude the handling and distribution of those grains while the brewery is using it to produce beer, yet deny that brewery the benefit of the exemption once the grain is spent. Setting the exemption aside mid-stream in the brewing process is illogical from both a regulatory and production standpoint. It is likewise illogical to impose regulation on an otherwise exempt activity simply because a third party (e.g, a farmer or rancher) sees value in the byproducts or residue of the exempt activity.

A more reasonable interpretation of Congressional intent underpinning the exemption for alcohol-related activities is that Congress only intended to pull within the scope of Section 418 of the FD&C Act those activities affirmatively undertaken by an alcohol-related facility with the *primary objective* of making of a non-alcoholic beverage or a non-alcoholic food. In other words, Congress intended to exempt the entire process of manufacturing beverage alcohol products, including by-products or residue of that alcohol manufacturing process, even if the by-products or residue have separate value or potential use as food.

Exempting the entire process of manufacturing beverage alcohol products, as well as the by-products or residue of that manufacturing process is fully consistent with the risk-based, public health principles underpinning Congress' Section 116 alcohol-related facility exemptions. In that regard, the Agency appropriately recognized that intent per the following points:

[A]lcoholic beverages are regulated by Alcohol and Tobacco Tax and Trade Bureau (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.”

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.

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 TTB.

(78 Fed. Reg. at 3709.)

For all these reasons, the alcohol-related facility exemptions in Section 116 of the Food Safety Modernization Act should apply to all aspects of the beverage alcohol manufacturing process and all resulting beverage alcohol products, by-products and residue. Any other result would mean bringing costly plans/processes to existing operations and increase the cost of animal feed for farmers and ranchers, with no commensurate safety benefits. Beverage alcohol producers already work under hundreds of rules. Congress recognized that the current oversight is sufficiently extensive when promulgating the exemption under Section 116.

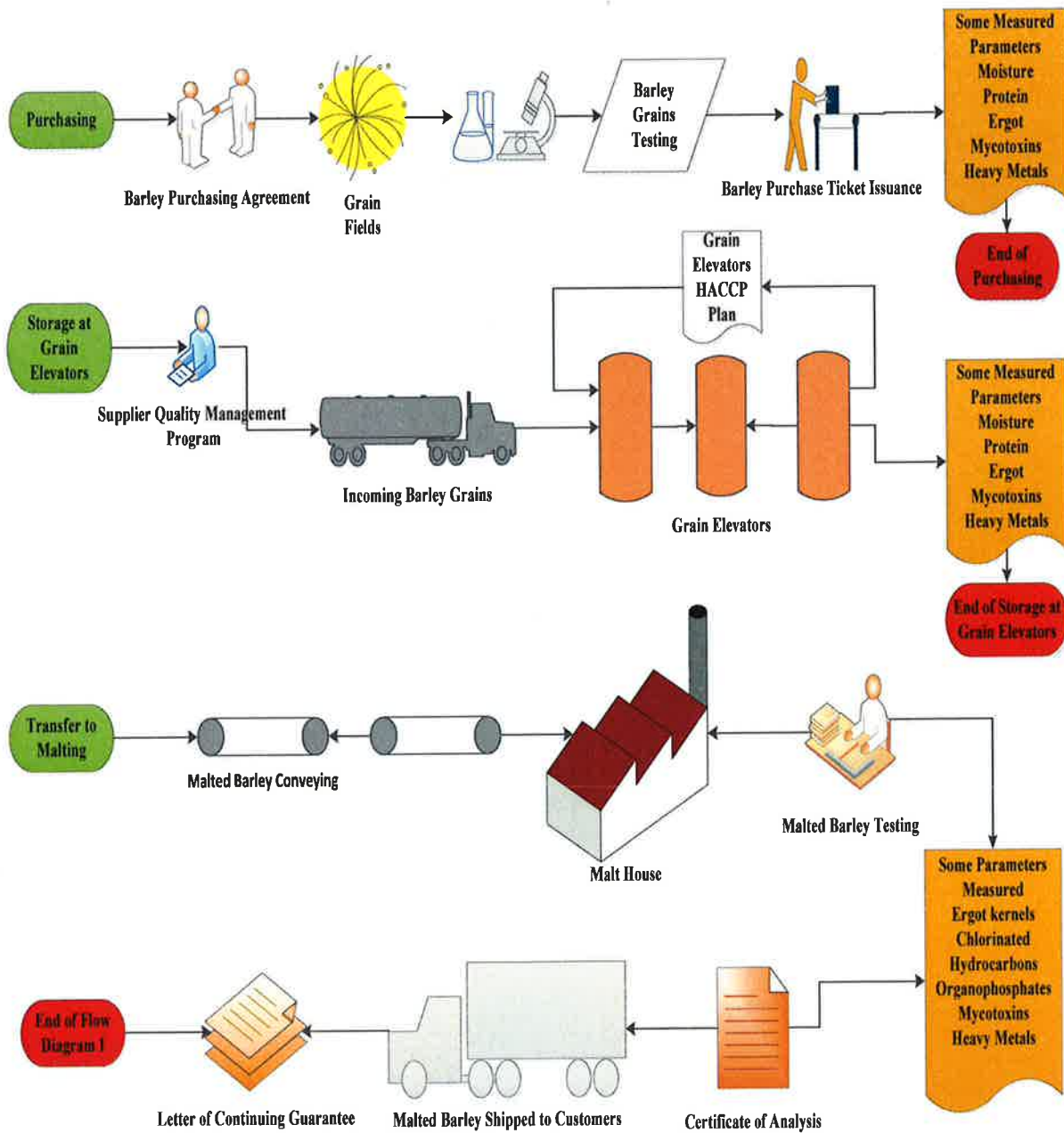
2. There is No Compelling Health or Safety Reason to Regulate Brewers' Grain or Other By-Products of Brewing.

There are no compelling health or safety reasons to regulate brewers' spent grains or other by-products or residue of brewing, nor any compelling reason to impose additional, burdensome regulations on brewers. These by-products are valuable to farmers and ranchers, and any risk is exceedingly low.

a. The Risk is Exceedingly Low.

Regulation of brewers' spent grain and other brewing by-products is not necessary to protect public health, because any risk of these by-products is exceedingly low.

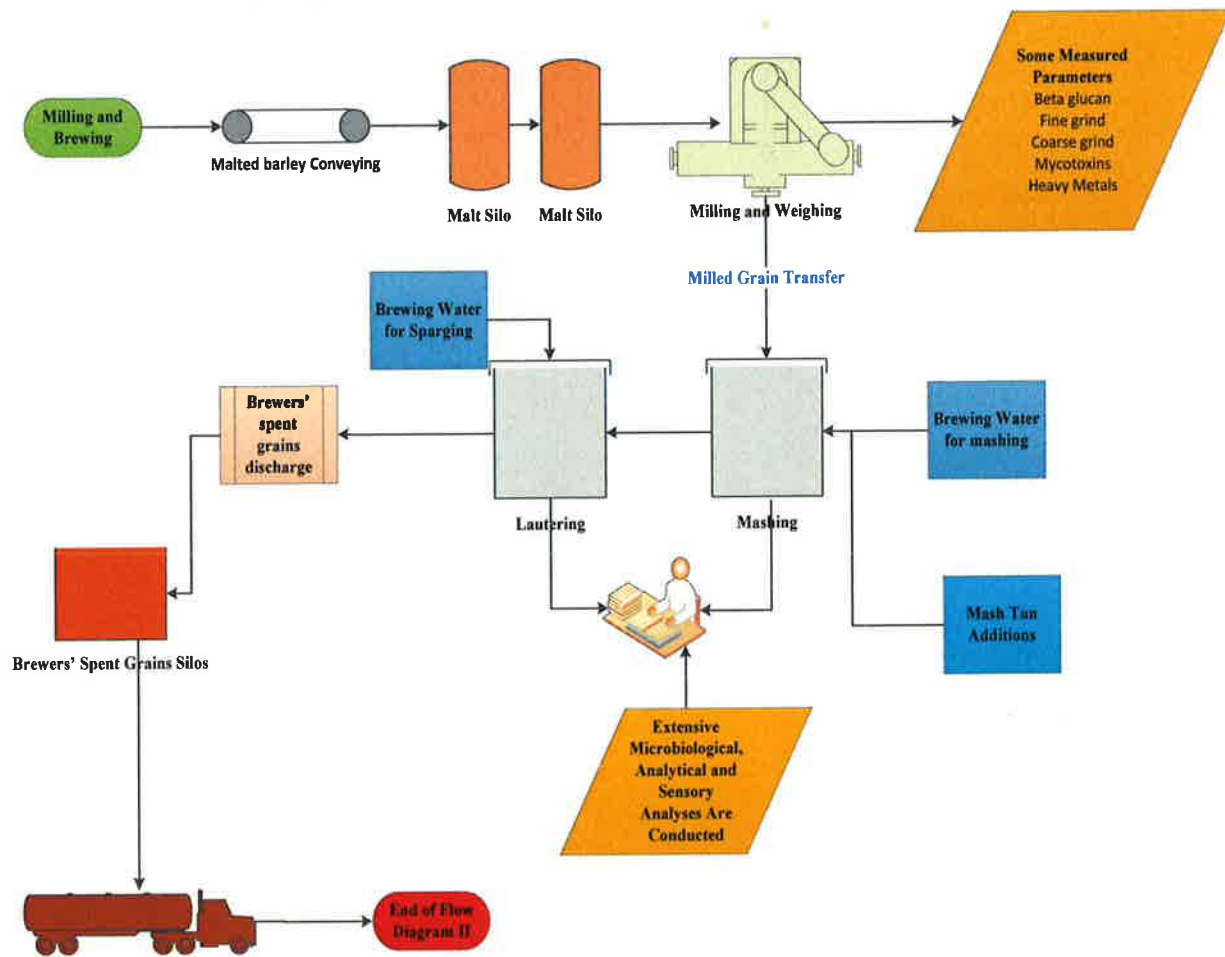
Brewers have food safety and quality assessments built into the entire brewing process, from barley purchasing; to storage of barley grains at the grain elevators; to the malting process ending with shipment to its customers. The following flow diagram illustrates these safety and quality assessments, and shows why additional regulation is unnecessary.



The brewing process itself and the speed with which brewers dispose of spent grains also limit any perceived risks. In the early stages of brewing, the brewer creates a mash using processed grains (grist) and water. The mash is heated and the soluble components removed from the grist are separated (lautering) into a liquid (wort) and the brewers' spent grains. The brewer adds hops, yeast, sugars and syrups after removing the spent grains. Any risk for brewers' spent grain from a food safety point of view must then come from the grain used in brewing; however, the grain itself also meets strict human food requirements, which generally exceed animal feed requirements. U.S. brewers also employ a comprehensive chain of custody that makes them, and their beers, models of product management, handling and safety. From agriculture to sale – beer goes through a complex production process before it reaches the

consumer. There are federal, state and internal brewery safeguards built in at every step throughout the U.S. supply chain, including the handling of brewers' spent grain. Brewers' spent grain is micro-biologically stable at the point of production (*Robertson et al. 2010*), and goes quickly from production to farmers and ranchers in close proximity to the brewery who feed it promptly to their livestock. The entire process generally takes less than 24 hours.

Flow diagram II below shows the process flow from milling, to brewing, to the discharge of brewers' wet spent grains to spent grain silos. Again, brewers conduct food safety and quality assessments at every stage of the process.



All these industry safeguards negate any health or safety concerns regarding spent grains and other by-products of brewing, and show that additional regulation is unnecessary.

b. Malted Barley Used in Brewing is Safe.

Malted barley, the primary ingredient used in brewing and the primary component of brewers' spent grain, is unique among grain commodities in several respects. Maltsters and brewers contract directly with farmers for most of the barley they use, specifying standards for the grain purchased. Even if grains are not purchased under direct farm contract, they are tested, lot by lot, and segregated by variety and region, if not by individual farm field. Malting and brewing companies also routinely test barley grown in certain geographic regions like the upper Midwest and eastern prairies of Canada. Brewers using malt produced from barley from these geographic regions also specify that purchased grains must meet or exceed any standards set by the FDA for advisory levels in finished wheat products.² Malting barley is also not an issue. For malting, barley needs to have a demonstrated high level of germination vigor. Any grains that would be of concern to FDA would not be used in the malting process because they would have insufficient germination vigor and therefore could not generate quality malt suitable for brewing. To retain germination vigor, malting barley must also be stored at a low temperature and moisture, further reducing any potential concerns.

Similarly, there should be no concerns regarding brewers' spent grain from adjuncts used in brewing like rice and corn. Brewers take care to purchase products that meet FDA action levels for food products. Brewers adding various corn syrups also do so *after* removing the brewers' spent grain, further reducing any concerns regarding spent grain. Likewise, nearly all brewers' spent grain is sold at 65-80 percent moisture, further reducing any potential concerns about health or safety.

c. Brewers' Spent Grain Do Not Contain Antibiotic Residues.

We are aware that the FDA has expressed concerns regarding the safety of dried distillers' grains (DDGs) from fuel ethanol production based on antibiotic residues. There is no need to regulate brewer's spent grain or other by-products of brewing because of concern over DDGs from fuel ethanol production, because unlike these DDGs, the spent grains that are the by-products of brewing, are antibiotic-free (*McCabe, 1999*).

Bacterial contamination is an ongoing problem for commercial fuel ethanol facilities (*Beckner et al. 2011*). Both chronic and microbial contamination is a pervasive problem in any fuel ethanol system. One of the ongoing challenges in fuel ethanol production facilities is to control bacterial contamination during fermentation. In order to control the growth of acid producing bacteria, many ethanol plants add antibiotics (*Compart et al. 2013*) to the fermentation tanks. The antibiotics kill much of the acid bacteria without harming the yeast. The main disadvantage of antibiotics is that they carry through the fermentation and distillation processes and end up in the spent distillers' grain.

² FDA does not have advisory levels for barley.

While there has been a dramatic increase in fuel ethanol production and the use of residual DDGs in animal feeds, it is not appropriate to regulate brewers' spent grain based on concerns about the safety of distillers' grain from fuel ethanol production. Brewers' spent grain contains no antibiotic residues, because brewers have no reason to add antibiotics to control bacterial contamination during fermentation. However, even if a brewer added antibiotics, no antibiotic residue would show up in the brewers' spent grain since fermentation occurs after removal of the spent grain. While a brewery will generate spent grain at roughly a rate of 30 percent of the weight of the initial malt grist, overall production of brewers' grain is much smaller than overall production of distillers' grain. In fact, one must count all the brewers' grain worldwide to reach production levels for distillers' grain in the U.S. alone. It is not appropriate to regulate the smaller universe of antibiotic-free brewers' grain based on concerns about fuel ethanol distillers' grain.

d. There is a Low Risk of Hazards Associated With Spent Grain and Other By-products of Brewing.

There is low risk of biological³, chemical⁴, physical⁵, allergenic or radiological⁶ hazards associated with the manufacturing, processing, packing, and holding of beverage alcohol products, especially fermented beverages, or the by-products or residue of brewing, including spent grain. The following Risk Assessment Summary illustrates this point by identifying and assessing the likelihood that the listed by-products, when consumed by animals, would cause serious injury, adverse health consequences, or death.

³ Biological risks associated with pathogens.

⁴ Chemical risks associated with chemical residues from cleaning solutions and pesticides.

⁵ Physical risks associated with foreign material (e.g. field components, pests, machinery parts, etc.) and metal shavings.

⁶ Radiologic hazards are included, not because there is a likelihood of them occurring with respect to fermented beverages, but because they are a standard category of the safety system known as hazard analysis and critical control point (HACCP).

Risk Assessment Summary

By-products	Likelihood of Hazards				
	Biological	Chemical	Physical	Allergenic	Radiological
Grain and Malt Dust	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Grain and Malt Screenings	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Grain and Malt Sprouts	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Brewers' Condensed Solubles	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Feed Malt	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Spent Grain	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Spent Yeast Slurry	Low	Low	Low	<i>Note 1</i>	<i>Note 2</i>
Spent Hops	No	Low	Low	No	<i>Note 2</i>

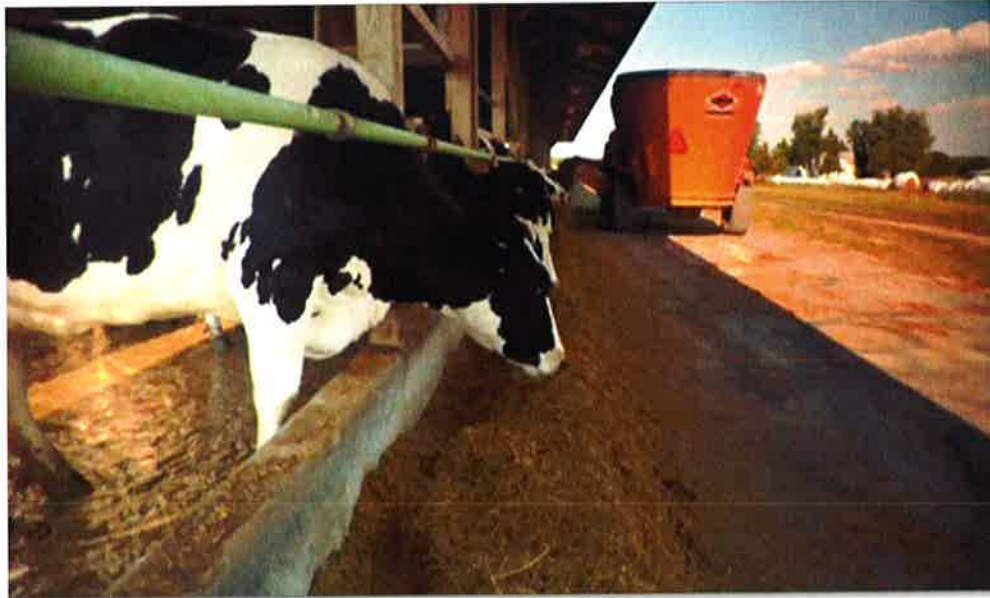
Notes:

1. Exempted under a 2006 Tax and Trade Bureau (TTB) Interim Rule (71 Fed. Reg. 42260-42270).
2. Radiological hazards are an HACCP category and included for completeness only. Radiological hazards are extremely unusual and must be assessed on a case-by-case basis when and if there is a release of radioactivity within a specific geographical location and country of origin.

This summary table shows that brewer preventive controls significantly diminish or prevent the likelihood of the aforementioned hazards to cause serious injury, adverse health consequences, or death when animals consume brewers' spent grain and other by-products of brewing.

3. Regulation of Brewer's Spent Grain Would Impose Burdens on Farmers and Ranchers.

As they have done for many centuries,⁷ brewers, large and small, dispose of their spent grain and other by-products by giving or selling them to farmers and ranchers. Brewers are rightfully proud of green initiatives like this. In 2009, for example, Anheuser-Busch, aired a television commercial⁸ sharing the story of how, since 1899, they have recycled spent grain, and how hundreds of thousands of dairy cows feed on the spent grain from the company's 12 breweries across the United States.⁹



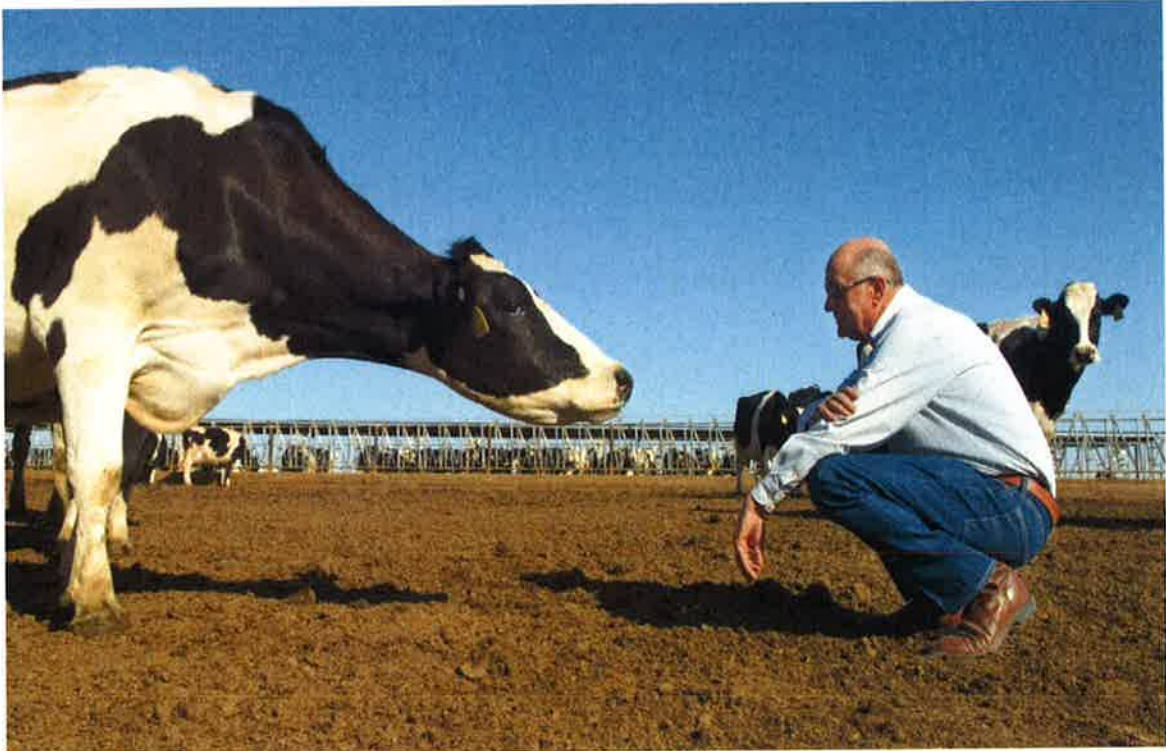
Farmers and ranchers see brewers' spent grain as excellent, low-cost feed for ruminants such as beef and dairy cattle, or for other livestock, including pigs, poultry, goats and horses. By adding brewers' spent grain, farmers and ranchers can offset the per bushel cost of feed and reduce overall feed costs significantly. The nutritional properties of brewers' spent grain have also been long understood (*Preston et al. 1973*). Although the composition varies with the particular barley variety, brewers' spent grain contains moisture, cellulose, proteins and lipids or fats. Brewers' spent grain has a high content of total digestible nutrients due to the digestibility of the available fiber (*Thomas et al. 2010*). This high concentration of fiber is because the starches and sugars are removed from the barley grain during the malting process leaving mainly the structural cell wall carbohydrates of cellulose and hemicellulose (*Westendorf et al. 2002*). Brewers' spent grain provides ruminants with needed fiber and a significant amount of protein,

⁷ There is evidence that as far back as the Neolithic Era, brewers' spent grain was a source of animal feed for cattle and pigs (*Dineley 2010*).

⁸ A copy of the commercial is available on request.

⁹ The cows enjoy eating brewers' spent grain so much, that some refer to feed time on the farm as "Happy Hour."

which for dairy cattle leads to higher milk and milk protein production than alternative protein sources such as soybean meal (*Thomas et al. 2010*). Farmers and ranchers also find greater feed efficiencies with brewers' spent grain as compared with soybean meal and urea for beef cattle (*Klopfenstein et al., 1977*).




Chicago Tribune/Getty Images. Used under license.

Access to brewers' spent grain is especially important to farmers and ranchers without sources of natural forage. Hein and Ellen Hettinga and their son, Gerben, co-owners of GH Dairy, Chico, California are among the farmers who have to obtain feed off-farm. Access to low-cost brewers' spent grain is critical to the success of their business. Mr. Hettinga is a Dutch immigrant who began working on dairy farms shortly after his family emigrated from the Netherlands to the United States after World War II. The Hettingas produce milk on their own farms and bottle that milk for sale to schools, consumers, food service companies, milk dealers, and major retailers. They rely on brewers' spent grains from a nearby major brewery as part of their feed ratio. Brewers' spent grain is an important source of protein for their cows. The wet spent grains make feed moist and their cows love to eat them. Any change in the availability or cost of brewers' spent grain would have a negative impact on their dairy operations, especially since they would have to truck in other feed sources at significant expense from other states.


As the following advertisement demonstrates, access to brewers' spent grain is especially critically important to farmers and ranchers in times of extreme drought or other severe weather conditions.

WHO KNEW? COORS IS IN THE CATTLE BUSINESS?



Well maybe not exactly in the business, but we are trying to help our friends and neighbors who are. This winter has been especially hard for farmers and ranchers in Colorado. It's been hard to find enough feed to just keep the herds alive. That's why Coors is donating one million pounds of spent grain from its brewing process. That's enough to feed 200,000 cows for a day. Jim Rogers (pictured here, second from left) is just one of those who is grateful for the help. "Coors' generous donation is a tremendous relief for area livestock producers. It is heartwarming to know that a longstanding Colorado company has stepped to the forefront."

COORS. OUR NEIGHBORS ARE REALLY OUR FRIENDS.



Coors
Committed to being part of the solution.

Farmers and ranchers are also not the only ones who look to brewers for help in terms of access to spent grains in times of extreme drought or other severe weather conditions. In 2008, the Colorado Division of Wildlife asked for and received more than 100,000 pounds of spent grains to aid hundreds of starving deer in the Gunnison Valley when snow made it difficult to find natural forage. See <http://www.outdoorlife.com/blogs/newshound/2008/02/deer-receive-rocky-mountain-refreshment>. Such efforts might not be possible if the brewers had to meet burdensome and unnecessary food safety regulations before providing spent grain to starving animals.

4. Disposal of Brewers' Spent Grain in Landfills is a Poor Alternative.

Disposal of the by-products or residue of the brewing process, especially brewers' spent grain, is often an environmental issue (*Mussatto et al. 2004*). In 2012 alone, U.S. brewers ended up with approximately 2.7 million tons of wet brewers' spent grain as a necessary by-product or residue of brewing beer.¹⁰ Currently, less than 10 percent of all brewers' spent grain is composted or disposed of via landfill, energy production or through other channels. While brewers certainly prefer to put these resources to good use as animal feed, if the FDA applies proposed Subpart C, "Hazard Analysis and Risk-Based Preventive Controls" to brewers' spent grain, some brewers may be unable to absorb the cost of compliance and may have no choice but to dispose of their spent grain in other ways. Landfilling the grains, while unfortunate, may be their only cost-effective option. Of course, while the cost of landfilling is likely less than the cost of complying with unnecessary food safety requirements, landfill and transportation costs could easily exceed \$210 million per year should all brewers elect to landfill spent grain that would otherwise be repurposed as animal feed. Landfilling spent grain is also not just a matter of trucking the by-products to a location for dumping. To ensure proper aeration and effective decomposition, it is necessary to add a significant high carbon-bulking agent. (See Smeek, J., "Using Spent Brewery Grain in the Alaska Compost Pile," 2010.)

5. Regulation of Brewers' Spent Grain Would Impose a Significant Economic Burden on Domestic Brewers.

Given the many centuries of safe use of brewers' spent grain and other brewing by-products, there is no reason to require brewers to implement expensive safety protocols, submit to FDA inspections, and face possible recall requirements for a mere by-product that is produced, distributed and consumed in typically less than 24 hours. We do not understand why FDA did not apparently consider that regulation of brewers' spent grain and other by-products of brewing will cost the industry millions of dollars in annual compliance costs, millions in disposal costs,

¹⁰ While fifty years ago, brewers dried two-thirds of all brewers' spent grain before transport, modern practice is to transport brewers' spent grain wet (65-80% moisture). Drying is highly impractical for many breweries, and transporting the grains wet increases brewery efficiencies and greatly reduces capital and energy costs associated with drying.

and many millions of dollars in lost revenue without improving public health and safety. We also do not understand why FDA would impose Subpart C, “Hazard Analysis and Risk-Based Preventive Controls” on brewers’ spent grain without considering the negative impact on farmers and ranchers in terms of potential loss of a valuable and affordable source of feed. The loss in income, and costs to dispose of brewers’ spent grain would greatly disadvantage the domestic brewing industry and favor importers that are not subject to these new FDA regulations since their spent grain and brewing by-products do not enter the United States. No other domestic industry would suffer such a potential disadvantage in comparison to its import competitors.

The following three tables illustrate the likely substantial financial impact that compliance with the proposed rule would have on a domestic brewer for a single brewery location.¹¹

1. Table A shows estimated financial impact by expense categories.
2. Table B shows the estimated financial impact in terms of one-time costs, re-occurring costs (per annum), re-occurring costs (per day), and brewhouse loss of efficiency based on capacity (per day).
3. Table C shows the estimated impact of the proposed regulations in terms of time-weighted annualized costs.

Again, these tables illustrate the effect of the regulations on a single brewer, but the expense categories and overall financial impact are not unique to this brewer. On an industry-wide basis, the financial impact will be much greater. There can be no doubt that the likely financial impact will greatly exceed any measurable benefit to public health and safety, especially given the rigorous food safety and quality assessments currently employed throughout the entire brewing process.

¹¹ These are actual estimated costs for a specific, albeit unnamed domestic brewer.

Table A –Estimated Financial Impact - Expense Categories

Descriptions	Average Costs Range
Employee Training	\$101,088
Installation of Cleaning and Monitoring Systems and Infrastructure	\$3,200,000
Transfer Lines Cleaning	\$336,960
Waste Water Treatment and Sludge Removal	\$675,000
Loss of Brewhouse Throughput	\$1,400,000
Cleaning and Sanitation	\$1,944
Sampling and Testing	\$6,574,356
Design Modification of Spent Grain Silo and Scanning System for Spent Grain Collection	\$160,000
Standard Operating Procedures (SOP) Development	\$58,320
Systems Monitoring	\$5,832
Specifications Development	\$19,440
Verification and Validation Audits	\$1,109,334
Issuance of Certificate of Analysis (COA) and Truck Wash Certificates	\$3,888
Issuance Letter of Continuing Guarantee (LOG)	\$0
Contractual Agreement with Farmers Regarding Receipt of Brewers' Spent Grain	\$0
Total Costs	\$13,646,162

Notes:

- The total costs are raw numbers.
- The total costs include one-time costs, per day costs and per annum costs.
- Frequencies have not been factored into total costs.
- Letter of Continuing Guarantee will be issued on an annual basis during contractual agreement.
- Protocol for receipt of brewers' spent grain by farmers must be discussed and agreed upon during contract negotiations.

Table B – Estimated Financial Impact - Time-Weighted Costs

Financial Impact Statement Summary – Single Brewery Design	
Frequency	*Average Costs Range (Not Annualized)
One-time costs	\$11,107,842
Re-occurring costs (per annum)	\$1,128,600
Re-occurring costs (per day)	\$9,720
Brewhouse loss of efficiency based on capacity (per day)	\$1,400,000
Total Costs	\$13,646,162

Notes:

- Re-occurring costs have not been annualized.

Total costs do not include annualized amounts.

Table C – Estimated Financial Impact - Time-Weighted Annualized Costs

Financial Impact Statement Summary - Single Brewery Design	
Frequency	Average Costs Range (Complete)
One-time costs	\$11,107,842
Re-occurring costs	\$1,128,600
Re-occurring costs (previous per day costs annualized)	\$3,547,800
Brewhouse loss of efficiency based on capacity (per annum)	\$511,000,000
Total Costs	\$526,784,242

Notes:

- One-time costs and re-occurring costs are annualized.
- Brewhouse loss of efficiency represents yearly figure.
- Total costs include annualized numbers.

There is simply no legitimate health or safety concern with respect to brewers' spent grain that warrants imposition of costs and loss of efficiency at this level for any brewer.

6. FDA Should Use Its Statutory Authority under Section 418(m) to Exempt Brewers' Spent Grain From the Proposed Rule.

FDA should use its statutory authority under Section 418(m) to exempt brewers' spent grain from the requirements of FDCA § 418 in light of industry practices that ensure the safety and quality of the spent grain. In Section 418(m), Congress granted FDA the authority to “by regulation, exempt or modify the requirements for compliance under [FDCA § 418] with respect to facilities that are solely engaged in the production of food for animals other than man” The Section 116 alcohol exemption is broad enough to encompass spent grain and other brewing by-products, however, the Agency may also use its authority under Section 418(m) to implement the intent of Congress and provide an exemption for brewers' spent grains and brewing by-products used for animal food.

FDA should exercise its authority under Section 418(m) to **exempt** spent grain and other by-products of brewing from unnecessary and costly regulatory controls for reasons:

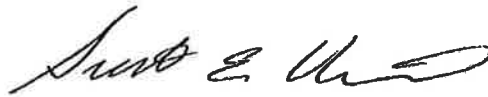
- (1) The process of brewing beer is already subject to extensive regulation.
- (2) By Section 116, Congress exempted beverage alcohol manufacturing facilities from the requirements of Section 418. As such, Congress has already determined that, for the purposes of FDA regulation under Section 418, the activities performed at breweries “warrant lower priority from a public health perspective than other foods.”
- (3) Brewers have established quality systems and industry practices that ensure the safety of spent grains and other brewing by-products for use in animal food such that application of Section 418 would be unnecessarily duplicative.
- (4) Brewers' spent grain and other brewing by-products have a long history of safe use as animal food and represent a low risk of food borne illness.
- (5) Failure to provide an exemption for brewers' spent grain and other brewing by-products may result in the landfilling of these items, thus potentially depriving farmers and ranchers of a low cost, nutritious and safe food source for their livestock.
- (6) Applying Section 418 to brewers' spent grain and other brewing by-products would impose a significant economic burden on brewers and adversely affect farmers and ranchers with little or no public health or safety benefit.

In conclusion, given the extensive regulation of alcohol beverages and the low risk of food borne illness associated with beer, brewers' spent grain or other by-products of brewing, as well as the serious economic burden on the U.S. brewing industry in terms of compliance costs, it is completely unnecessary for FDA to add additional regulation to spent grain and other by-products of brewing.

Respectfully submitted,



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Scott E. Heisel
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