FSMA Animal Food Rule: Spent Grains
DISCUS-OIRA Meeting
August 10, 2015

FDA's Supplemental NPRM Regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animal Food proposes to subject dried spent grains produced by beverage alcohol manufacturers, an inevitable and necessary by-product of the production process, to the Part C HACCP controls pursuant to the Food Safety Modernization Act (FSMA). If finalized as is, these exempt beverage alcohol facilities would be required to implement preventive control requirements that include a hazard analysis, employee training, product testing and sampling, systems monitoring, verification procedures, and additional measures to meet the proposed requirements. These proposed rules would require capital expenditures and daily and annualized costs for FSMA exempted alcohol-related facilities that are not in the animal food business.

Based on the discussions with our members, we estimate the per facility costs to be $4.9 million in the first year, with recurring costs of $1.2 million every year thereafter. FDA has identified no benefits from these provisions, and there is no reason from a scientific or substantiated basis to speculate there will be benefits of any kind. This lack of evidence is not surprising given the 150-year record of safe use of spent grains. Further, FDA has not only the authority to exempt dried spent grains from its Animal Food rulemaking, but also a legal requirement from FSMA to do so. The spent grains provisions should not be included in the final Animal Food rule, nor subject to the Part C HACCP controls.

Background

Grains are the necessary raw materials to produce beverage alcohol products and when that process is complete, the remaining "spent grains" are a natural and necessary by-product that must be disposed of. Throughout the decades, distilleries and other beverage alcohol producers have formed mutualistic partnerships with local farmers and the local community to provide spent grains as a nutritional animal food. Distilleries sell or provide free of charge their wet spent grains to local farms, but that local demand for wet spent grains is not sufficient to consume the entire volume and, consequently, many producers dry their spent grains so that they can be used and transported to farmers not located adjacent to beverage alcohol facilities. Spent grains sales are not profit centers for beverage alcohol producers—the offering of these spent grains to farmers as animal food simply offsets some of the costs associated with spent grains (both dried and wet).

If finalized, FDA's "spent grains" provisions imposing HACCP controls would apply to dried spent grains upon the assertion that "drying" these spent grains in an exempted beverage alcohol facility somehow converts this by-product into a regulated "animal food" for purposes of preventive controls under the FSMA. As described below, the application of the FSMA provisions to either dried or wet spent grains is unjustifiable and only would result in large costs/burdens for no benefits whatsoever.

FSMA specifically exempts alcohol facilities

Section 116 exemptions of FSMA specifically encompass "the activities of such facility that relate to the manufacturing processing, packing, or holding of alcoholic beverages." Spent grains are an inherent part of producing beverage alcohol and, thus, qualify for the Section 116 facilities exemption.

Including spent grains is arbitrary and creates an inconsistency with FDA's Human Food and Animal Food rules

In an attempt to capture dried spent grains under the structure of the FSMA, the Animal Food rule treats "drying" the wet spent grains as a form of processing, which would subject it to the Part C provisions. The distinction that the Agency wishes to draw is both arbitrary and inconsistent with the rest of the FSMA rules. Further, it is not clear how an objective assessment about whether grains have been "dried" would be made for purposes of subjecting this natural and necessary by-product to Part C of HACCP controls.

First, FDA provides no definition of when spent grains become "dried." 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.

Wet spent grains must be consumed as a feedstock fairly quickly; whereas, dried spent grains can be used as a feedstock over time for farmers both near and far from a distillery. Simply put, the distinction between wet and dry grains is ultimately an arbitrary one.

Second, treating drying grains as a form of "processing" (and thus triggering Part C controls) would create an inconsistency with FDA's Human Foods and Animal Food rules. In the Human and Animal Food rulemakings, drying/dehydrating is specifically identified as an on-farm activity that does not trigger Part C requirements and sustains the farm exemption. FDA's determination regarding farm activities in the Animal Food rule is sensible and any deviation from that standard for spent grains creates inconsistency and confusion.

Including spent grains has no benefits of any kind

FDA failed to quantify any benefits likely to result from including spent grains in the Animal Food rule, and there is no reason to believe that there would be benefits of any kind. The Agency cited mycotoxin contamination as a potential hazard to be mitigated, but did not present any evidence that this contamination actually occurs and were not able to document a single illness or other negative outcome that might be linked to spent grains. In fact, in the Human Foods NPRM, they acknowledged 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."

Indeed, spent grains from distilleries have been used as animal feed in the U.S. for at least 150 years, and there has never been an associated illness in humans or animals. Including this provision in the final rule would have no benefits whatsoever.

Costs per facility: $4.9 million in the first year, $1.2 million thereafter

While there are no benefits to the spent grains provision, the costs are very high. It is difficult to make precise estimates of the cost because FDA's proposal is unclear regarding exactly what mitigation procedures would be required. Nevertheless, we have surveyed our members and we believe that the following table accurately reflects the average costs of compliance with the proposed rule.

Representative Preventative Controls Program Implementation Costs Per Facility

Program Implementation Costs	**Estimated Cost**	**Frequency**
Implementation of Feed Safety Team	$20,000	One time
Feed Safety Plan Development	$100,000	One time
Standard Operating Procedure Development	$40,000	One time
Sampling and Testing Plan Development	$10,000	One time
Specifications Development	$10,000	One time
By-Products Facilities, Laboratory, Analytical Equipment for Compliance Monitoring	$2,000,000	One time
Specifications Development	$10,000	One time
Minimum Process Improvements to Support Additional CIP and Sampling	$1,500,000	One time
Total One-Time Costs	**$3,690,000**	
Additional Daily CIP/Sanitation Costs	$500,000	Annual
QC – Food Safety Compliance Specialist	$150,000	Annual
Lab Facilities Maint. and Operating Costs	$75,000	Annual
Compliance and Analytical Testing	$500,000	Annual
Total Recurring Costs	**$1,225,000**	

Conclusion

FDA's decision to include spent grains in its Supplemental NPRM is mistaken and these provisions should not be included in the final rule. FSMA created exemptions for alcohol-related facilities, and on that basis alone, they should not be included. But even if that exemption did not exist, FDA has failed to prove that the costs of this action are justified by the benefits, as required by Executive Order Nos. 12866 and 13563. There are no identified benefits whatsoever and the costs are high; this provision should not be finalized.

Full Text of the Food Safety Modernization Act (FSMA)

The full text of the law found on this page is being provided as an additional service from the FDA. The official and authoritative source of the law is the version offered by the Government Printing Office (GPO), found at http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf.

[111th Congress Public Law 353]
[From the U.S. Government Printing Office]

Also available in PDF (351KB).

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Public Law 111-353
111th Congress
An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply. <<NOTE: Jan. 4, 2011 - [H.R. 2751]>>

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, <<NOTE: FDA Food Safety Modernization Act.>>

SEC. 116. <<NOTE: 21 USC 2206.>> ALCOHOL-RELATED FACILITIES.

(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.
(b) Limited Receipt and Distribution of Non-alcohol Food. <<NOTE: Applicability.>> --Subsection (a) shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that such paragraph shall apply to a facility described in such paragraph [[Page 124 STAT. 3923]] that receives and distributes non-alcohol food, provided such food is received and distributed--
(1) in a prepackaged form that prevents any direct human contact with such food; and
(2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.
(c) Rule of Construction.--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).

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