AFIA
AMERICAN FEED INDUSTRY ASSOCIATION

July 8, 2015

Honorable Members of the Appropriations Committee
The U.S. House of Representatives
Washington, DC 20515

RE: Human Food Coproducts (Dried Spent Grains) in Animal Food, Further Processing, FSMA

The American Feed Industry Association (AFIA) is concerned with language in the 2016 agriculture appropriations suggesting particular animal feed ingredients should be unregulated in the context of FDA's implementation of the Food Safety Modernization Act (FSMA). The bill text says no funds may be used to implement or enforce "regulation of the distribution, sale, or receipt of dried spent grain byproducts of the alcoholic beverage production process, irrespective of whether such byproducts are solely intended for use as animal feed." Yet finished product manufacturers will still be required to develop a fully function animal food safety plan. Implementing a food safety plan while exceptions are provided for ingredients is problematic.

Furthermore, the bill and report language differ. The bill does not allow regulation/enforcement for dried grains, while the report language suggests the intent is to treat dry and wet spent grains the same. Yet wet spent grains may be regulated by other FSMA rules (i.e. sanitary transportation), and thus would not be treated equally with dried grains.

AFIA has promoted animal food safety for more than 100 years. We take animal food safety seriously. With over 575 members, AFIA represents 75% of the 173 million tons of ready-to-eat animal feed manufactured in the U.S and 70% of the non-grain ingredients used in feed. Our members represent a diverse set of ingredient suppliers. Different ingredients have different hazards and risks, and we should not pretend they do not exist.

AFIA strongly supported the development of FSMA, and is equally committed to ensuring reasonable regulations and a smooth implementation. AFIA has already submitted two sets of extensive comments. Over 60 companies were directly involved in these comments. Our experts have also hosted over eight trainings and given several dozen presentations on FSMA, with another phase of training planned.

AFIA is committed to a continuing dialogue with FDA on FSMA implementation and encourage the Appropriations Committee to refrain from singling out particular ingredients for deregulation, action which undercuts the goals and congressional intent of FSMA.

Sincerely,

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Our Industry. Our Passion. Our Voice.

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Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Hazard Analysis and Risk-Based Preventive Controls

FDA's View of "Significant Hazard" Will Drive Compliance Costs

- The NGFA generally believes biological hazards are not of concern to livestock and poultry feed and that physical and chemical hazards associated with feed do not reach the threshold of being "significant."
- If FDA's view is that such physical and chemical hazards are "significant," compliance costs will escalate dramatically and FDA's proposed definition for a "very small business" would create significant disparities in compliance obligations; i.e., many of the largest animal feed facilities in the United States have no sales.

PRIA Total Cost Estimate for CGMPs and Preventive Controls:

- $13,200 - $18,300/annually per facility (8,130 facilities)

NGFA Cost Estimate for Preventive Controls *(Animal Feed Facilities Only)*:

- $73,000/annually per facility *for labor only* (impacts 4,165 facilities)

Current Good Manufacturing Practices (CGMPs)

FDA's Final CGMPs Must be Realistic For Animal Feed

- The NGFA believes many of the CGMP provisions in the supplemental notice are unnecessary and would require reconstruction or redesign of facilities and/or equipment. Examples of unnecessary CGMPs include:
  - Constructing separate buildings to house certain chemicals
  - Redesigning/reconstructing facilities, fixtures, ducts, and pipes so as to prevent potential condensation
  - Redesigning plumbing systems to demonstrate to FDA that such systems are not a "source of contamination" for animal feed
  - Modifying facilities so that "all conditions and controls" associated with animal feed manufacturing "minimize the potential for growth of undesirable microorganisms.

NGFA Cost Estimate for CGMPs:

- $55,000/annually per facility (impacts 7,632 facilities)
  - $39,000 annually per facility for capital (redesigning and constructing facilities)
  - $16,000 annually per facility for labor

NGFA Total Cost Estimate for CGMPs and Preventive Controls

If FDA concludes that animal feed facilities are a low risk for significant hazards and if the CGMP section of the final rule does not have the effect of requiring animal feed businesses to use capital to redesign and construct facilities, the *total cost of the final rule could be as low as $16,000 annually per facility*, which is the labor portion of the estimated CGMP cost.

However, if preventive controls must be implemented and if the CGMP section of the final rule has the effect of requiring facilities to be redesigned and new facilities constructed, *the total cost of the final rule could be at least as high as $128,000 annually per facility* ($73,000 in labor only for preventive controls + $55,000 in labor and capital for CGMPs).