February 8, 2005

Gentlemen:

In reference to the AFSS documents to be published on Monday, I have concerns regarding the substance of the discussion “Process Control for the Production of Feed Ingredients and Mixed Feed.”

Attached and imbedded is the May 26, 2004 joint press release of Pet Food Institute and National Grain and Feed Association, referring to the work just then completed by the Codex Alimentarius Animal Feeding Task Force, and adopted later by the full Codex Commission.

Referencing this document, I would submit that the US government already has a position on what controls are necessary in feed production. The final code provides for the use of good manufacturing practices (GMPs) and, where applicable, hazard analysis and critical control point (HACCP) principles to control “to the extent reasonably achievable” hazards that may affect the safety of foods from food-producing animals. But importantly, the code does not state a preferred approach between GMPs and HACCP, thereby preserving flexibility, without a preference for either method. The pertinent areas of the letter are bolded and underlined in the imbedded document.

I would request that you these comments and the Codex document be thoroughly reviewed so that we’re on the same page regarding our international, and thus what should be, our domestic positions. It would not appear that holding one position in the international arena and another domestically would be acceptable. I’m sure that we would welcome the opportunity for further discussion before the scheduled AFSS meeting in April.

Best Regards,

*Nancy K. Cook*

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For Release

IMMEDIATE (May 26, 2004)

# NGFA, PFI Commend Successful Outcome of Negotiations on First International Animal Feed Safety Code

COPENHAGEN, DENMARK – The National Grain and Feed Association (NGFA) and the Pet Food Institute (PFI) are commending the successful outcome of a meeting here last week that brought the first international animal feed code of practice to the threshold of final adoption.

The Codex Alimentarius Commission's *Ad Hoc* Intergovernmental Task Force on Animal Feeding reached agreement on three remaining issues that last summer had delayed adoption of the code, whose objective is to help ensure the safety of food from food-producing animals and facilitate fair trade. The next, and final, step for the code is the Codex Alimentarius Commission, which is scheduled to consider and adopt it during its June 28-July 3 meeting in Geneva, Switzerland.

Codex, established in 1963 by the United Nations, develops science-based international food safety standards designed to protect human health, while facilitating trade in food, feed and agricultural products. Codes of practice adopted by Codex are important because they are recognized under the World Trade Organization as the basis for resolving international trade disputes. Such codes also frequently serve as the basis for formulating domestic standards by individual member countries. Because the Codex animal feeding code closely mirrors existing U.S. regulation governing animal feed and

feed ingredient manufacturing and animal feeding practices, no changes in existing U.S. laws or regulations are anticipated to result from the code's adoption.

"**This is a landmark achievement that will bring about the first internationally accepted feed safety system applying to the manufacturing, distribution and use of feed and feed ingredients for food-producing animals," the NGFA and PFI said. "It contains prudent quality-assurance principles to be observed by both commercial and farm operations so as to protect the safety of foods from food-producing animals and thereby protect human health, which is in keeping with Codex's mandate.**

The NGFA and PFI also praised the Codex task force for acting during previous meetings to omit inappropriate references to animal welfare, animal health and the environment that are outside the mandate of a Codex food safety code, as well as for deleting extraneous labeling, recordkeeping and other requirements that did not pertain to feed safety.

"The positive outcome at the final meeting was made possible by consultations that occurred during preceding months between the United States, European Union, Canada, Australia, Japan, New Zealand, South American countries and other nations that helped bring about a consensus on the most contentious issues that remained to be resolved," the NGFA and PFI said. "It also required effective and energetic on-the-ground leadership and execution during the meeting itself, which resulted in further improvements in the code. We particularly commend Dr. Stephen Sundlof, director of the Food and Drug Administration's Center for Veterinary Medicine, who headed the U.S. delegation, and the U.S. Codex Office whose stellar leadership, persistence and effective interaction with the delegations of other countries were instrumental in achieving this commendable result."

Nancy K. Cook, PFI vice president for technical and regulatory affairs; and Randall C. Gordon, NGFA vice president for communications and government relations, were among those appointed to serve as advisers to the U.S. delegation.

During the just-completed meeting, the Codex task force reached final agreement on the animal feed code's provisions governing recordkeeping for traceability and product tracing; the definition of feed additives; and labeling of feed and feed ingredients containing products derived from modern biotechnology.

Concerning the recordkeeping obligations required of feed and ingredient manufacturers – including on-farm operations – the task force adopted language that advises that production, distribution and use records be sufficient to "facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source and trace-forward to the next subsequent recipients" to facilitate a timely and effective withdrawal or recall from the market if "known or probable adverse effects on consumer health are identified."

This "one-step-forward, one-step-back" approach to product tracing adopted in the Codex animal feed code mirrors the recordkeeping requirements that the Food and Drug Administration proposed in its regulations implementing the U.S. bioterrorism-preparedness law.

The task force agreed that detailed measures on traceability/product tracing should be delayed until after similar discussions are completed within the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

The task force also agreed to defer action on whether and how to label animal feed and feed ingredients derived from modern biotechnology, pending the outcome of discussions on food labeling being considered by the Codex Committee on Food Labeling.

The task force adopted a definition for feed additives that reads, "any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritive value, which affects the characteristics of feed or animal products." The task force also adopted a footnote that states that this definition encompasses microorganisms, enzymes, acidity regulators, trace elements, vitamins and "other" products depending on their purpose and method of administration.

Finally, while work on the code has been completed, the task force at its final meeting recommended to the Codex commission that it consider requesting specific project proposals for "new work…in the area of animal feed" for food-producing animals.

**The overall animal feed code includes provisions concerning sourcing of safe ingredients; appropriate steps for manufacturing and distributing feed and feed ingredients, including on-farm feed manufacturing and grazing practices; recordkeeping; proper labeling of feed and feed ingredients; and appropriate scientific and risk-based government regulatory and inspection programs. The final code provides for the use of good manufacturing practices (GMPs) and, where applicable, hazard analysis and critical control point (HACCP) principles to control "to the extent reasonably achievable" hazards that may affect the safety of foods from food-producing animals. But importantly, the code does not state a preferred approach between GMPs and HACCP, thereby preserving flexibility.**

**The NGFA and PFI noted that the code's provisions concerning the manufacturing of commercially produced feed and feed ingredients mirror FDA's current good manufacturing practices for non-licensed medicated feeds. Among other things, this section of the code contains provisions calling for:**

- **buildings being constructed and grounds being maintained in a way that permits ease of operation, maintenance and cleaning, thereby minimizing the potential contamination of feed and feed ingredients;**
- **keeping work and equipment areas free of chemicals, fertilizers and pesticides that could contaminate products;**
- **training personnel;**
- **using water that meets hygienic standards;**

- **regularly testing the accuracy of scales and meters used in manufacturing feed and feed ingredients;**

- **using mixers that are appropriate for the types and volumes of feed and feed ingredients being manufactured;**

- **using manufacturing and clean-out procedures (such as flushing, sequencing and physical cleanout), that avoid cross-contamination;**

- **maintaining records sufficient to identify and recall products that pose a human health risk;**

- **implementing sanitation and pest control practices;**

- **controlling the presence of undesirable substances and pathogens that may adversely affect human health; and**

- **transporting feed and feed ingredients in clean conveyances.**

Established in 1896, the NGFA consists of 1,000 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. With more than 350 member companies operating commercial feed mills and 30 integrated livestock and poultry feed manufacturing operations, the NGFA is the nation's largest trade association representing feed manufacturer interests. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations.

PFI is the trade association of dog and cat food manufacturers and those who supply goods and services to the pet food industry. It represents the manufacturers of 97

percent of the total dog and cat food produced in the United States, a $12.5 billion domestic industry, with an additional $1 billion in pet food exports.

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