NOPA
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VIA OVERNIGHT MAIL

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

Re: Comprehensive Risk-Based Animal Feed Safety System (FDA Docket No. 2003N-0312 (68 Fed. Reg. 44344 (July 28, 2003)))

The National Oilseed Processors Association (NOPA) submits these comments in response to a notice published by the U.S. Food and Drug Administration (FDA) on July 28, 2003, regarding a September 23/24 public meeting to discuss the Agency's potential development of a comprehensive risk-based animal feed safety system. NOPA is a national trade association comprised of 12 companies that process oilseeds to produce edible oils and vegetable protein products used primarily for animal feed. These 12 member firms process more than 1.6 billion bushels of oilseeds annually, at 68 plants located throughout the country, and employ more than 4,500 workers. Any new animal feed safety system would thus have a major impact on NOPA's member companies.

1. Background

During the past decade, NOPA has consistently and repeatedly opposed the imposition by FDA of mandatory new processing requirements for animal feed. Such requirements were initially referred to by FDA as "Hazard Analysis and Critical Control Point" (HACCP) programs and are now referred to as "Animal Feed Safety System" (AFSS) programs. Regardless of the terminology, any mandatory process controls would impose substantial additional costs and burdens on the U.S. animal feed industry, including the animal feed ingredient industry, without any scientifically documented benefit either to animal or human health.

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Enclosed with these preliminary comments is prior correspondence between NOPA and the Agency that discusses NOPA's concerns about mandatory regulatory approaches to animal feed safety:

- Enclosure 1: NOPA comments on proposed seafood regulations for Hazard Analysis and Critical Control Points (May 31, 1994)

- Enclosure 2: NOPA comments on an FDA advanced notice of proposed rulemaking on HACCP systems (December 2, 1994)

- Enclosure 3: FDA-prepared Minutes of a meeting between FDA and NOPA regarding an FDA HACCP rulemaking for feed ingredients (December 3, 1998)

- Enclosure 4: Feed and Feed Ingredient Safety and Quality Coalition letter to CVM Director Stephen F. Sundlof regarding the potential for mandatory HACCP requirements (September 14, 1999)

- Enclosure 5: Agenda and handout for meeting of NOPA with CVM officials on HACCP (April 25, 2002)

To summarize, FDA has failed to present a sound risk-based scientific rationale for imposing extremely costly and burdensome process requirements on the animal feed industry.

2. Summary of NOPA Position

Because we are attaching prior correspondence between NOPA and FDA on this matter, it is appropriate only to summarize the basis for NOPA's strong and continuing opposition to mandatory new regulatory process controls over the animal feed industry:

- FDA has identified no sound scientific study demonstrating that animal feed is a significant source of pathogenic microorganisms that increase animal or human disease.

- FDA has failed to demonstrate through credible scientific evidence that animal feed significantly increases the level of pathogenic microorganisms (e.g., E. coli and salmonella) that are ubiquitous in the urban and rural environment.

- FDA has not demonstrated through a valid scientific study that animal feed significantly increases the level of pathogenic microorganisms found in all barnyards throughout the country.

- FDA has failed to explain how mandatory process controls for the animal feed industry will reduce the existing level of pathogenic microorganisms in every barnyard throughout the country.

- FDA has not acknowledged that existing oilseed extraction processes are sufficient to kill any pathogenic microorganisms prior to completion of manufacture (see the flowchart of the oilseed extraction process included with Enclosure 5).

- FDA has not demonstrated through a current peer-reviewed scientific study that there is significant introduction of pathogenic microorganisms into finished vegetable protein products after the manufacturing process kills any pathogens that may be present.

- To the extent that the transportation industry represents a potential source of contamination of animal feed after it leaves the manufacturing facility, FDA has available to it the provisions of the Safe Food Transportation Act of 1990 to remedy any such contamination problem.

- FDA has provided no rationale for regulating the animal feed industry and leaving the rest of the animal feed distribution system, including noncommercial feed mixers and the barnyard environment, unregulated.

- FDA has identified no reliable scientific evidence that animal feed presents any significant hazard to animals or to humans other than the theoretical potential for pathogenic microorganisms.

- Specifically, FDA has identified no reliable scientific evidence demonstrating that physical and chemical contaminants in animal feed pose a significant risk to animal or human health.

- FDA has failed to address a General Accounting Office (GAO) Report on Food Safety (September 2000) which found no chemical contamination in the food chain caused by animal feed.

- FDA has not acknowledged that its existing food GMP regulations already incorporate HACCP principles as one approach to achieving adequate GMP compliance (21 C.F.R. 110.3(e) and 110.80(b)(13)(i)).

- FDA has failed to recognize that the feed and food industry in general, and the oilseed extraction industry in particular, have recommended to their memberships the voluntary use of HACCP and other related manufacturing controls as one element of a broad approach to adherence with GMP.

- FDA has not acknowledged the substantial economic impact of mandatory process controls for the animal feed industry, and the disproportionate impact on small business.

- FDA has failed to provide a rationale for focusing mandatory process controls on the animal feed industry, which presents no significant risk to animal or human health, before it imposes similar controls on other areas in the food chain which the Centers for Disease Control have identified as significant sources of food contamination (e.g., restaurants).

NOPA supports the continuing education of the animal feed industry to utilize good manufacturing practices that have been demonstrated to reduce the potential for product contamination to the lowest feasible level. As the points summarized above demonstrate, imposing mandatory process controls on the animal feed industry cannot be supported either by sound scientific evidence or by appropriate risk analysis.

3. Conclusion

For the above reasons, NOPA strongly opposes the imposition of HACCP, AFSS, or other similar mandatory process control systems on the animal feed industry and urges a voluntary, education-based approach in order to continue the excellent record of safety that has been demonstrated by the U.S. animal feed industry.

Thank you for giving serious consideration to our comments. Please contact me at 202-452-8100 if you have any questions.

Sincerely,

David C. Ailor, P.E.
Director of Regulatory Affairs

Five Enclosures