National Grain and Feed Association

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

RE: Docket No. 2003N-0312 Animal Feed Safety System

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's request for comments regarding the potential development of a comprehensive, risk-based animal feed safety system.

The NGFA, established in 1896, 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 300 member companies operating feed manufacturing and integrated livestock and poultry operations, the NGFA is the nation's largest trade association representing commercial feed manufacturer and integrator interests.

The NGFA's membership encompasses all sectors of the industry, including country, terminal and export elevators; feed mills; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries, such as railroads, barge lines, banks, grain exchanges, insurance companies, computer software firms, and engineering and design/construct companies. The NGFA also consists of 36 affiliated state and regional U.S. grain and feed associations, as well as two international affiliated associations. The NGFA has strategic alliances with the Grain Elevator and Processing Society and the Pet Food Institute, and a joint operating and services agreement with the North American Export Grain Association.

The NGFA commends the agency for organizing the September 23-24 public meeting to explore the concept of developing a comprehensive, risk-based animal feed safety system. The NGFA was an active participant in FDA's public meeting, with 10 members representing NGFA's Animal Agriculture Committee, Feed Legislative and Regulatory Affairs Committee, and Feed Manufacturing and Technology Committee, as well as staff members, in attendance. We believe the forum resulted in a constructive exchange of views by a significant cross section of the commercial feed ingredient,

2003N-0312 C5

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rendering, feed manufacturing and pet food sectors, federal and state government officials, academicians, and consumer interests, although we wish that more representation had been present from the producer/on-farm and transportation sectors. We believe the public meeting succeeded in giving participants an opportunity to begin framing the myriad and complex issues involved in considering a comprehensive, risk-based approach to animal feed safety.

Conceptually and in principle, the NGFA believes that taking a risk-based approach to food and feed safety makes sense from a scientific, public health and resource-allocation standpoint. But as FDA evaluates whether and how to proceed, there are two major overarching factors that the NGFA believes strongly need to be uppermost in the agency's deliberations:

- First and foremost, the NGFA believes that as FDA considers whether to proceed with the development of a federal animal feed safety system – in whatever form that eventually may take – the agency needs to embrace a much more comprehensive approach that is inclusive of all sectors of the animal feeding industry. FDA has promulgated a comprehensive set of current good manufacturing practices (CGMPs) for both licensed and non-licensed medicated feed manufacturers, which establish a recognized feed regulatory compliance bar for the production and distribution of medicated feeds. Ensuing federal and state feed regulatory programs have focused almost exclusively on commercial medicated feed manufacturers, even though such establishments represent only a fraction of the feed and feed ingredient tonnage produced in the United States. Several incidents of concern involving various hazards and contaminants (e.g., dioxin, microbial concerns, mineral excesses, mycotoxins, pesticides and residues of other unsafe substances in transport conveyances) have generated increased awareness about the role of other sectors and the importance of FDA adopting a more inclusive approach to feed safety that recognizes the diversity of the industry.

  The NGFA believes the commercial medicated feed manufacturing sector of the animal feed chain has done a commendable job in manufacturing and distributing products, and has a proven record of safety. That record has been documented through FDA and state inspections and enforcement. It also was examined in the September 2000 report on food safety by the General Accounting Office (GAO) – the investigatory arm of Congress – which concluded that, "[i]n the United States, only a relatively few incidents of human illness have been traced to contaminated animal feed."[1] The GAO report went on to add: "Public health officials have identified only two incidences of human illness resulting from bacteria-contaminated animal feed in the past 30 years"[2] – both involving *Salmonella* and one of which was still

[1] "Food Safety – Controls Can be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed." General Accounting Office, September 2000. Page 4.

[2] IBID. Page 9.

under investigation at the time GAO issued the report. The GAO report also found that as of July 2000, there had been "no reported cases in the United States of human illness resulting from chemically contaminated animal feed" and that during fiscal years 1998 and 1999, "less than 3 percent of animal feed samples tested for pesticides contained residue levels above established tolerances."[3]

- Second, when evaluating whether and how to proceed with the development of a comprehensive, risk-based approach to animal feed safety, we believe it is important for FDA to recognize and factor into its deliberations the considerable initiatives that the private sector already has taken to adopt a wide range of quality-assurance practices. Various sectors of the industry, including organizations that consist of commercial feed manufacturers, certain sectors of the ingredient industry, and the livestock and poultry industries, have developed quality-assurance programs and educational initiatives for their respective sectors.

  For instance, the NGFA in 1994 developed the commercial feed industry's first and most comprehensive model feed quality assurance program, and has conducted 17 educational workshops since that time that have attracted more than 600 commercial feed manufacturers. Participants in the NGFA's model feed quality assurance program have included large and small medicated and non-medicated feed manufacturers, integrators and allied industries (including representatives of firms providing product liability insurance to the commercial feed industry).

  The proliferation of private-sector quality-assurance initiatives over the past two decades has been spurred by several factors. For one, such systems are being adopted because the private sector takes its responsibility to produce safe feed seriously. There also are powerful market-based incentives for doing so, including customer demand, requests for contractual assurances and guarantees, and the need to control product liability losses and manage resultant product liability insurance costs.

The NGFA believes FDA generally has done a good job in developing a scientific, risk-based assessment on which to establish tolerances for animal drug carryover in feed – as evidenced by its CGMP regulations that apply to commercial feed mills that manufacture medicated feeds. The CGMPs for medicated feed represent a set of requirements and a compliance bar that is recognized and well understood by FDA-regulated medicated feed facilities. FDA's medicated feed CGMPs also have served a useful role by providing the foundation for, and encouraging development of, U.S. industry-based quality-assurance programs, such as the previously cited ***Model Feed Quality Assurance Program*** developed by the NGFA.

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[3] IBID. Page 10.

The medicated feed CGMPs also have served as the basis for developing draft codes of practice for animal feeding in international fora[4] such as the United Nations' Food and Agricultural Organization and the Codex Alimentarius Commission. The CGMPs also formed the foundation for the Association of American Feed Control Officials' (AAFCO) ***"Guidance/Framework for Best Management Practices for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients,"*** a voluntary guidance document that was finalized in 2002, as well as a subsequent AAFCO "Checklist" based on the Guidance/Framework document that was adopted in 2003. We believe more can and should be done by FDA and others to promote the positive contribution that the medicated feed CGMPs have played in enhancing feed and food safety.

The NGFA believes that developing and implementing a more comprehensive, scientific and risk-based approach to animal feed to protect human and animal health would carry with it several prerequisites that FDA should acknowledge in advance and incorporate into any such approach:

- First, FDA would need to have the financial resources to fund much more research to determine which – and what levels of – substances are most critical to feed safety. FDA currently embraces a zero or near-zero tolerance for several contaminants (e.g., salmonella, dioxin, microbes, etc.) that is not sufficiently grounded in science nor risk assessment. One of the disturbing undercurrents at FDA's September 2003 public meeting was a misperception – in our view – that the research on which to base a prudent animal feed safety system already had been completed. We believe that is an erroneous assumption.

- Second, the agency would need to use these research findings to conduct a risk-based hazard analysis to determine which products or steps in the process need to be addressed by each respective sector (e.g., ingredients, transporters, on-farm mixers, commercial mills, etc.), and the degree to which such hazards already are being minimized through existing regulations (in the case of commercial medicated feed manufacturers) and the use of sector-specific quality-assurance practices.

- Third, once hazards are identified and a risk-assessment performed, various industry sectors would need to have access to quick, inexpensive and reliable diagnostic tests (such as quick tests and assays) to monitor and detect feed safety hazards (e.g., pathogens, dioxins, pesticides, mycotoxins, etc.) that are identified. Further, these diagnostic tests would need to be validated as yielding accurate, and consistently repeatable results.

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[4] Food and Agriculture Organization's Expert Consultation on Animal Feeding and Food Safety, Rome, Italy March 10-14, 1997; and Codex Alimentarius Commission's *Ad Hoc* Intergovernmental Task Force on Animal Feeding, 1999- .

- Fourth, to be successful, a comprehensive, risk-based animal feed safety system would require "buy-in" from a diverse array of state regulatory agencies, producer groups, commercial industry sectors and allied industries (such as transporters) to achieve a level playing field. It also would require much more coordination on an ongoing basis between FDA, state feed control agencies and other entities (such as universities and state laboratories) than currently exists.

The NGFA respectfully submits that each of the four aforementioned conditions is a necessary precursor to a prudent, risk-based animal feed safety approach.

Importantly, the NGFA believes the federal government also should start by rectifying shortcomings in its implementation of existing laws and regulatory authority that are designed to minimize feed-borne hazards. One glaring example is the failure of the U.S. Department of Transportation to finalize regulations to implement the Safe Food Transportation Act of 1990, which is designed to prevent unsafe backhauling of food or feed products in conveyances that also are used to haul hazardous substances, such as fertilizer, unless such conveyances are cleaned properly by the carrier. Another example is the lack of enforcement at both the federal and state level against unapproved novel feed ingredients/additives being incorporated into animal feed and pet food. While AAFCO and FDA are making initial strides to identify illegal feed ingredients/additives for enforcement action, unapproved feed additives continue to be advertised and offered for sale in inter- and intra-state commerce.

As FDA considers components that could be considered for inclusion in a potential federal animal feed safety system, the NGFA believes:

- Such an approach should focus on further enhancing the safety of feed for food-producing animals, thereby protecting human and animal health and retaining consumer confidence. As such, the NGFA believes that FDA should place a priority on those sectors of the industry most directly linked to safe food animal production that – unlike the commercial medicated feed industry – are not already subject to FDA regulation, guidelines or ongoing oversight.

- FDA should consider the effectiveness of initiatives already being pursued. These include the role played by:

  - existing private-sector initiatives, including quality-assurance programs, voluntary best management practices and industry trade rules developed by trade associations and individual companies that are being adopted across a wide spectrum of feed and feed-ingredient-related sectors;

  - AAFCO's ***"Guidance/Framework for Best Management Practices for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients"*** and "Checklist" alluded to previously. The NGFA and other organizations actively participated in the development of these documents,

and are actively distributing them to our respective industry sectors. These documents may be particularly useful models for FDA to consider as it considers whether and how to proceed with an animal feed safety system; and

- the Model National Medicated Feed Program developed through AAFCO.

Each of these initiatives share a common characteristic – flexibility and the ability to tailor practices to the specific type, size and characteristics of each facility. A one-size-fits-all approach will not work.

- FDA should incorporate the principles contained in the Voluntary Self Inspection Program (VSIP) as a major component, and should broaden it to encompass both medicated and non-medicated feed and feed ingredients. Doing so would provide an important additional incentive to encourage the adoption of quality-assurance programs in the private sector, while enabling government to more effectively target its scarce inspection, compliance and enforcement resources. It is our understanding that FDA currently is considering whether to initiate VSIP as a pilot project for medicated feed manufacturing establishments for which CGMP regulations already exist.

  Under the VSIP approach, developed through AAFCO with active input and support from the NGFA, establishments would be encouraged to develop and implement quality-assurance programs that meet federal standards or guidelines. Among other things, VSIP includes the following concepts: 1) Establishments would enter into a binding agreement with FDA committing to develop and implement a written Q/A program that meets FDA standards or guidelines; 2) participating establishments would conduct annual self-inspections of their operations and correct deficiencies; 3) participating establishments would submit summary results of their inspections to FDA and state feed control authorities; and 4) participating establishments would be subject to random spot-check audits by government to ensure the quality-assurance programs are being implemented. In return, participating establishments would be a low priority for federal (and the NGFA submits should be for state) inspections, except for cause.

- More emphasis needs to be placed on the safety of feed once it leaves the commercial feed mill. Feed has the potential to be contaminated with salmonella depending upon how it is transported, stored and handled once it leaves the control of the commercial mill.

- Given the proliferation of various types of quality-assurance methods (e.g., HACCP, HACCP-like, ISO, etc.), it may be beneficial for FDA to consider developing basic guidelines concerning the elements or components that should be included within each of these Q/A methods to enhance the level of understanding about what each does – and doesn't – encompass. Again, however, it is important that the agency not attempt to develop a "model standard" or attempt to devise a "one-size-fits-all" approach.

If grounded in sound science that is based upon solid research and truly risk-based, the NGFA believes that a comprehensive, risk-based federal feed safety program has the potential to:

- Establish a baseline and provide a more uniform framework to guide activities of federal and state government, and the feed ingredient, feed manufacturing, transport, and on-farm and commercial mixer-feeder sectors in addressing those hazards most important to preserving and enhancing feed safety. In so doing, such a federal initiative could provide a more level playing field in the market.

- Enable government agencies to better focus scarce human and financial resources on those areas most critical to feed and food safety, while reducing the need to respond to perceived or actual feed safety "emergencies."

- Further enhance consumer confidence in the safety of meat, milk and eggs.

The NGFA believes a government-based animal feed safety system will **not** have a major impact on the domestic or international competitiveness of the U.S. feed or animal agriculture industries, since market forces already have encouraged the development and implementation of quality-assurance programs by industry sectors in response to customer preferences. U.S. competitiveness in world markets is influenced to a far greater degree by the supply and demand for raw grains and other ingredients (which can be influenced by U.S. farm policy), the efficiency and cost-competitiveness of the transportation sector, and other "macro" factors. However, we do believe that a federal approach to animal feed safety can be of value in overcoming non-science-based trade barriers, particularly for products for which regulatory standards or guidelines are not implemented currently. In addition, commercial firms may request government-based certification that such firms are adhering to various quality systems implemented in response to customer demand.

At this conceptual stage – without knowing what might be encompassed in a federal animal feed safety system – it is impossible to estimate the potential burdens a comprehensive, risk-based approach might impose. But it is likely that the burdens would take different forms – in both human-resource and economic terms – on government and industry:

- Potential Burdens for Government:

➢ Developing a risk-based federal feed safety program would require that FDA: 1) consider whether it is necessary to amend the Federal Food, Drug and Cosmetic Act to provide the agency with the statutory authority needed to implement such an approach; 2) develop a much more seamless ongoing working relationship with other federal agencies (e.g., the U.S. Department of Agriculture's Agricultural Marketing Service, Department of Transportation,

etc.) that could be involved in developing guidelines/standards and/or certifying private-sector industry quality-assurance initiatives, as well as states, which likely would be on the front lines in overseeing or encouraging the adoption of such a system; and 3) conduct the necessary research to provide the scientific underpinning for identifying and setting potential limits for feed-borne hazards that truly affect human or animal health.

- Implementing a comprehensive, risk-based federal feed safety program would require that FDA and state governments: 1) spread limited human and financial resources across a much broader spectrum of the feed ingredient, feed manufacturing and feeding industries than has occurred previously; 2) develop a much more coordinated and integrated relationship with state feed control agencies, which likely will – and should – bear much of the responsibility for educating and providing oversight of various industry sectors with whatever risk-based animal feed safety program is developed; 3) fundamentally change the mind-set of federal and state feed inspectors to focus on hazards that truly affect human and animal health (whereas, the current tendency of some inspectors and agencies is to spend significant time on such "economic" issues as label guarantees); and 4) improve the training of inspectors (both federal and state) to refocus and improve the quality and consistency of whatever government-based inspections that are eventually incorporated into a risk-based animal feed safety approach.

- Potential Burdens for Private Sector:

  Depending upon its scope and nature, developing and implementing a comprehensive, risk-based federal feed safety program may entail the "up-front" expenditure of considerable human and financial resources for certain establishments or sectors of the industry that have not adopted quality-assurance programs yet. But the actual additional operating costs imposed on the feed industry to meet the demands of additional requirements (e.g., procedure modifications, documentation and recordkeeping, etc.) cannot be quantified until FDA's approach is known. Likewise, some establishments or industry sectors may need to expend human and/or financial resources to retool existing quality-assurance programs to focus on areas determined through a risk assessment to be critical to feed safety.

  However, long-term, the NGFA believes that quality-assurance programs that are truly science- and risk-based have the potential to pay for themselves through enhanced plant and employee productivity; fewer reworks/recalls; fewer product liability complaints; and reduced premiums for product liability insurance.

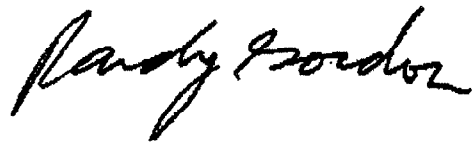
Finally, as FDA is aware, AAFCO has initiated the development of what it calls a ***"Model Feed Safety Program"*** that contains elements that mirror those being considered by FDA as part of the latter's federal animal feed safety system initiative. Rather than

viewing these as mutually exclusive or parallel efforts, the NGFA encourages FDA and AAFCO to work together and with affected producer and industry sectors so that whatever emerges from both pursuits represents a well-reasoned and consistent approach, and not duplicative.

In closing, the NGFA is confident that FDA – when analyzing how to proceed – will guard against the inevitable attempts by some companies or organizations seeking to benefit from such an initiative by advocating proprietary products, services or certifications that do not address legitimate feed safety risks borne out by sound science or prudent risk assessment, or which would undermine government-based inspection programs.

The NGFA appreciates FDA's consideration of its views, and looks forward to being a fully engaged and constructive participant in future discussions with the agency and other interested parties on this important matter.

Sincerely yours,



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