



National Grain and Feed Association

1250 Eye St., N.W., Suite 1003, Washington, D.C. 20005-3922, Phone: (202) 289-0873, FAX: (202) 289-5388, Web Site: www.ngfa.org

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***RE: Docket No. 2003N-0312 – Animal Feed Safety System;
Notice of Public Meeting; Request for Comments on Draft Framework***

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's request for comments regarding the agency's draft Framework document consisting of four major components that the agency envisions comprising a comprehensive and risk-based Animal Feed Safety System (AFSS).

The NGFA, established in 1896, consists of 900 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 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 35 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 has been an active participant in FDA's consideration and development of an AFSS, and in an extensive statement dated Sept. 14, 2004 provided input concerning two critical components of the agency's initiative: 1) draft definitions of "comprehensive" and "risk-based"; and 2) draft elements that could be considered for incorporation into an AFSS.

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The NGFA also previously submitted a statement, dated Nov. 5, 2003, in which it commended FDA for exploring the development of a comprehensive, risk-based approach to food and feed safety. NGFA members also were active participants in the September 23-24, 2003 FDA public meeting at which the agency launched the AFSS. Members of NGFA's three principal feed-related committees – the Animal Agriculture Committee, Feed Legislative and Regulatory Affairs Committee, and Feed Manufacturing and Technology Committee – intend to do likewise during the April 5-6 public meeting scheduled for Omaha, Neb.

As it has stated previously, the NGFA conceptually supports FDA's effort to develop a more comprehensive and risk-based approach to feed safety that is inclusive of all sectors of the animal feed and feed ingredient industry. FDA has promulgated a comprehensive set of current good manufacturing practice regulations (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. As noted in FDA's draft Framework document, those regulations in practice have been applied and enforced predominantly – if not almost exclusively – on the commercial medicated feed manufacturer, 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, mycotoxins, pesticides and unsafe substances in transport conveyances) have reinforced the importance of FDA adopting a more inclusive approach to feed safety that recognizes the industry's multiple sectors and their respective diversities. **Thus, the NGFA believes a priority should be placed on addressing those industry sectors for which cGMPs and oversight inspections currently do not exist.**

Completing the Definitions of 'Comprehensive' and 'Risk-Based'

In reviewing FDA's draft Framework document, it is obvious that the agency has incorporated several of the concepts contained in its previously issued documents pertaining to draft definitions of "comprehensive" and "risk-based." For instance, the draft Framework incorporates references to an approval process for feed ingredients; the need to address the safety of feeds for both food- and non-food-producing animals so as to protect both human and animal health; and the importance of building upon the relationship between federal and state feed regulatory agencies as part of future regulatory oversight. However, other concepts included in these draft definitions appear to be missing from the Framework – particularly the importance of providing flexibility in determining whether outcomes from the AFSS are process- or product-oriented, as well as comments submitted by the NGFA that FDA commit to the research needed to base any hazard assessments on sound scientific principles.

Because we believe that arriving at final definitions for "comprehensive" and "risk-based" is critical to the determining the future direction of the AFSS, the NGFA strongly recommends that the agency consider the comments already submitted and issue revised definitions prior to or during the AFSS public meeting in April.

The NGFA offers the following comments on each of the components and identified “gaps” cited in FDA’s draft Framework document:

Component #1 – Ingredients and the Approval Process

The NGFA commends FDA for including the feed ingredient-approval process as an integral component of the AFSS. But we believe that the stated “objective” is far too passive and does not accurately grasp the enormity of the challenge at hand. Rather than to “describe” the process relied upon by the agency to ensure that all feed ingredients and additives used in animal feed are safe for their intended effect, the NGFA suggests that this objective be rewritten to state as follows [*suggested deleted language stricken through; proposed new language boldfaced and underscored.*]:

*“Objective: To describe **formalize, expedite and enforce** the processes relied upon by FDA for ensuring that all ingredients and additives used in animal feed are safe for their intended effect, **and to ensure that labels and claims reflect the conditions of their approval.**”*

Implicit in the NGFA’s suggested redraft of this objective is our belief that the current method relied upon by FDA to approve feed ingredients has not kept pace with the veritable explosion of these products in the marketplace in recent years, particularly of so-called novel ingredients (e.g., nutraceuticals), as well as botanical and herbal products. Many of these products first were developed as human dietary supplements. But many of those same ingredients are being marketed for use in feed for companion, as well as some food-producing, animals. Two of the most common are chondroitin sulfate and glucosamine hydrochloride, which have been marketed for use in horse feed and pet food. Others include such botanical and herbal products as Echinacea, devil’s claw, raspberry, ginko, ginseng, milk thistle, nettle and yucca.

The growing number of novel ingredients, botanicals and herbs has caused the Association of American Feed Control Officials (AAFCO) – the professional organization of state and federal feed regulatory agencies – in cooperation with FDA, to establish an “Enforcement Issues Committee” (formerly the “Enforcement Strategy for Marketed Ingredients Working Group”) to recommend potential strategies for addressing those products that have not been authorized for use in animal feed, as well as those ingredients that are approved but are being distributed for a purpose or intended use that is not approved.

The NGFA is a strong proponent of the processes currently available to ingredient suppliers to gain authorization for use of ingredients in feed, which were captured well in an AAFCO Ingredient Approval Fact Sheet issued in 2001. Several of those processes are reflected in FDA’s draft Framework, and include:

- obtaining an AAFCO ingredient definition, which includes an assessment by FDA of the safety and effectiveness of the ingredient for its intended use;

- submitting a food-additive petition to FDA [21 CFR 573];
- classifying a product as “generally recognized as safe (GRAS),” either through FDA- or self-affirmation, which reflects a consensus about the product’s safety among qualified experts [21 CFR 570.30 and 21 CFR 570.35(b)(1)];
- recognition of the ingredient under a “common or usual name,” such as salt, water, corn, etc.;
- approval by a state secretary of agriculture under AAFCO Model Regulation 6(a); and
- filing a new animal drug application [21 CFR 514].

In the NGFA’s view, what currently is lacking – and what needs to be addressed through the AFSS – is not so much the ingredient-definition process itself. Rather, it is a clear delineation by FDA through regulation of: 1) what the processes are; 2) creating a more expeditious mechanism for reviewing the safety and efficacy of ingredients; and 3) developing an aggressive enforcement strategy for addressing unapproved ingredients being marketed for use in animal feed and pet food.

In the “identified gaps” section of this component, FDA states that it is developing a Compliance Policy Guide to explain the relationship between FDA and AAFCO in the ingredient-definition and approval process, as well as to formally establish as FDA policy a recognition of ingredients defined in AAFCO’s *Official Publication*. The NGFA certainly concurs in the wisdom of FDA doing so. But we believe even more important is the need for FDA to expeditiously pursue the promulgation of binding regulations that incorporate the aforementioned methods whereby petitioners can gain approval of feed ingredients, which is referenced among the “identified gaps.”

Further, we believe that FDA should also include among the “identified gaps” the following concepts:

- Develop and codify a streamlined, risk-based approach for assessing the safety and efficacy of such ingredients to encourage regulatory compliance by ingredient manufacturers. In this regard, perhaps FDA could look to safeguards and disciplines contained in the process agreed to by AAFCO, FDA and industry for addressing the marketing of enzymes. FDA currently utilizes its regulatory discretion in regulating feed enzymes that present no safety concerns. Further, all marketed enzymes are required to meet at least one of the following criteria: 1) be published in the AAFCO *Official Publication*; 2) be the subject of a Food Additive Petition; 3) be affirmed as GRAS; 4) be GRAS; or 5) be the subject of an informal “No Objection” letter from the FDA. It is our understanding that the current process for addressing enzymes also requires the sponsor of an unpublished enzyme/source organism to provide information that addresses issues of safety and functionality for the target animal species, as well as labeling and

manufacturing. FDA then is asked to evaluate the information and determine if the enzyme/source organism does not require an approved food additive petition to ensure its safe use; importantly, FDA also advises the sponsor and AAFCO of any restrictions on claims and use conditions of the product. If FDA determines the enzyme/source ingredient is safe, AAFCO then proposes a new or revised definition under which the enzyme/source organism is published in its *Official Publication*.

- Develop an aggressive enforcement strategy for removing from the marketplace feed ingredients that are found through scientific risk-assessment to pose a danger to human or animal health, or which are not otherwise safe or efficacious.

Component #2 – Limits for Animal Feed Contamination

The NGFA believes that FDA’s stated objective for Component #2 omits two important concepts that warrant inclusion. First, it is important to make specific reference to **utilizing the best-available science** in the development of risk-based mechanisms that are to be used to identify and develop any limits on hazardous contaminants. Second, we believe that the objective for Component #2 should include a specific reference that such risk-based mechanisms be utilized to address hazards that pose a challenge to **human and/or animal health**. As noted in our previous statement dated Sept. 14, 2004, not all hazards are harmful to human and/or animal health – which we believe should be the focus of the AFSS.

Finally, the NGFA believes FDA should be extremely cautious about using the term “potential” to refer to hazardous contaminants in the context of this statement of objective, as well as elsewhere in the draft AFSS Framework document. We believe that the AFSS should be a dynamic system that is flexible and responsive to address hazards that may be discovered in the future and are shown through the application of science and risk analysis to pose a danger to human and/or animal health. But the use of the term “potential” ushers in a degree of subjectivity and theory that we believe is inappropriate in a science- and risk-based approach. Indeed, the use of this very phrase was vigorously – and ultimately successfully – resisted by the U.S. delegation to the Codex Alimentarius Commission’s *ad hoc* Intergovernmental Task Force on Good Animal Feeding during the development of the first international animal feeding code of practice. For the same reasons, we believe use of the term “potentially” in the first sentence of the Scope section of this component also is inappropriate and should be deleted.

For these reasons, the NGFA recommends that the draft objective for this component be reworded to read as follows [*suggested deleted language stricken through; proposed new language boldfaced and underscored.*]:

“Objective: To use risk-based mechanisms to identify and develop limits, *based upon the best-available science*¹, for *minimizing* ~~potentially~~ hazardous

¹ The first international code of practice on good animal feeding states, in relevant part, “Risk assessment methodology utilized should be consistent with internationally accepted approaches. Risk assessment

contaminants in animal feeds and feed ingredients that may pose a danger to human or animal health."

The NGFA recognizes that a central element of a science- and risk-based approach to feed and feed ingredient safety entails the development of a science-based method for ranking risks to animal and/or human health posed by biological, chemical and physical contaminants. But as noted in our Sept. 14, 2004 statement, the task of developing and maintaining such a hazard risk-ranking approach is enormous.

Further, it is important to stress that the vast majority of the contaminants that may pose such a danger are not created by the commercial feed manufacturer. The record of commercial feed manufacturers in this regard has been documented through inspections and enforcement by FDA and states of medicated feed mills. It also was examined in a September 2000 report on food safety by what then was known as the General Accounting Office [subsequently renamed the Government Accountability Office(GAO)] – the investigative arm of Congress. That GAO report concluded that, “[i]n the United States, only a relatively few incidents of human illness have been traced to contaminated animal feed.”² 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”³ – both involving *Salmonella* and one of which was still 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.”⁴

This record on feed safety is a result of industry’s conscious efforts to implement effective feed safety and quality programs. Many commercial feed manufacturers voluntarily operate quality-assurance and safety systems that exceed regulatory requirements in response to customer demands and business needs. Moreover, there are powerful incentives to produce feeds that are safe and of high quality to meet customer demands and reduce product-liability risks in a highly competitive market.

Rather, to the extent any hazardous contaminants are identified through the AFSS process, they likely will need to be controlled by feed ingredient manufacturers and suppliers. In this regard, the NGFA believes that a significant “gap” that should be expressly identified in “**Identified Gap #1**” is the absence of universally accepted guidance, standards or regulations for ingredient manufacturers and suppliers. Ultimately, the hazard risk-ranking process envisioned by FDA under the AFSS may well

should be based on current available scientific evidence.” See Code of Practice on Good Animal Feeding, Codex Alimentarius Commission, June 2004.

² “Food Safety – Controls Can be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed.” General Accounting Office, September 2000. Page 4.

³ IBID. Page 9.

⁴ IBID. Page 10.

validate what we believe is a need to develop and implement current good manufacturing practices or other product- or processed-based approaches that are appropriate to manufacturers and suppliers of various feed ingredients, and to which they are required to adhere to minimize contaminants upstream from feed manufacturers and feeders.

In addition, the NGFA recommends including feed ingredient manufacturers and suppliers in the list of identified types of facilities referenced subjected to risk-ranking under “**Identified Gap #1**” cited under this component. The AFSS should address the responsibility of feed ingredient suppliers to ensure the safety and purity of the products they provide to the feed manufacturing and feeding sectors.

We believe “**Identified Gap #1**” also should include a statement to the effect that FDA will undertake the scientific research that may be needed to determine which – and at what levels – contaminants pose a danger to human and/or animal health. 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 or 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.

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, and the degree to which such hazards already are being minimized through existing regulations (in the case of commercial medicated feed manufacturers) and through the use of sector-specific quality-assurance practices. We believe this concept also should be incorporated into “**Identified Gap #1**.”

“**Identified Gap #2**” associated with this component contains a rather “matter-of-fact” closing sentence that presumes that industry and government already have access to “rapid, inexpensive and reliable test kits for monitoring of feed and feed ingredients.” That most emphatically is not the case today. Further, these diagnostic tests would need to be validated as yielding accurate and consistently repeatable results before they could be used in any meaningful way by various industry sectors.

In addition, FDA’s discussion of testing appears to presume a process- versus product-oriented outcome of the AFSS with respect to all industry sectors. The NGFA believes this is at best premature, and that as FDA identifies and ranks various hazards that may pose a danger to human or animal health, it will be important to conduct a cost-benefit analysis of the practicality of setting process-based regulatory limits versus other alternatives – such as cGMPs – that may be equally effective in reducing risk at a fraction of the cost.

The NGFA concurs with “**Identified Gap #3**,” which addresses feed hazards that may arise from deliberate contamination as a result of a bioterrorism act. The NGFA agrees with FDA that the AFSS should lead to a more seamless process in which FDA,

states and the U.S. Department of Agriculture work together to improve methods of preventing, coordinating responses to, and investigating terrorist incidents involving the deliberate contamination of feed or feed ingredients with an exotic animal disease.

Component #3 – Process Control for the Production of Feed Ingredients and Mixed Feed

The NGFA commends FDA for stating in the “identified gaps” that the agency already has a set of comprehensive cGMP regulations and inspections that apply to medicated animal feed, and that a “broader regulatory approach” may be warranted to address feed ingredients and nonmedicated feed. Indeed, as FDA notes, licensed medicated feed manufacturers represent the **only** industry sector with mandatory cGMP regulations, and licensed feed mills are the **only** segment with mandatory routine inspections [with the exception of establishments inspected for compliance with FDA’s regulations designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE)]. The NGFA has stated previously that it does not believe that additional mandatory regulations should be developed for the commercial medicated feed manufacturing industry.

For the commercial feed manufacturing sector, the NGFA strongly supports these cGMP-type regulatory approaches. We urge that the agency be cautious about committing – as it does in the sole “identified gap” in this section – to the “development of process control approach(es)” as a presumed outcome of the AFSS. Indeed, this outcome contradicts the statement made in the narrative description of Component #2 that “...risks from the contaminants can be controlled by **either product- or process-based approaches**, either initiated by industry or required by a federal or state regulatory agency.” [*Emphasis added.*] Such an outcome also would contradict and contravene the successful outcome of the previously referenced Code of Practice on Good Animal Feeding developed through the Codex Alimentarius Commission, which 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, this international code does **not** state a preferred approach between GMPs and HACCP, thereby preserving flexibility.

Further, this “identified gap” contradicts the concept of flexibility embodied in one of the core concepts contained in FDA’s draft definition of “comprehensive” developed as part of the AFSS initiative in the summer of 2004. Specifically, the fourth component of the definition stated that the AFSS should “*have the flexibility to be process- or product-oriented, depending on the situation.*” We believe it is imperative for FDA to devise an AFSS approach that provides the flexibility for different sectors of this broad and diverse industry to adopt those quality-assurance methods that are most appropriate, relevant and effective for their respective sector.

In that regard, as noted previously, medicated feed manufacturers have operated under cGMPs and have an exemplary record in producing wholesome, safe products for

use in the production of meat, milk and eggs. We are not aware of any scientific evidence that would justify additional process-control regulations for this industry sector. Some commercial feed mills also voluntarily have chosen – or may choose in the future – to include hazard analysis and critical control point (HACCP or HACCP-like) **principles** (not government-mandated standards) as part of their quality- assurance and cGMP-based programs. But it is important to stress that many feed industry sector participants have concluded, after thoroughly analyzing their own quality-control and cGMP-based programs, that HACCP principles are inappropriate, do not demonstrably reduce feed safety hazards, are too costly for their type of business or operation, or are not their preferred quality-assurance approach.

For these reasons, the NGFA urges FDA **not** to develop HACCP standards for the commercial feed manufacturing industry as part of its AFSS initiative. Instead, as stated by the NGFA in its Nov. 5, 2003 statement to FDA, there may be an appropriate role for the agency in developing **basic guidelines or principles** concerning the elements or components that should be addressed by establishments that voluntarily choose to adopt one or more of the proliferating types of quality-assurance methods (such as HACCP, HACCP-like, ISO, etc.) **as a means of enhancing the level of understanding about what each method does – and doesn't – encompass**. To reiterate, however, the NGFA believes it is important that the agency **not** attempt to develop a “model HACCP standard” under the umbrella of the AFSS.

Component #4 – Regulatory Oversight

The NGFA supports this component's stated objective to develop a framework to prioritize and allocate inspection and enforcement resources to minimize risks to animal and human health as part of the AFSS. The NGFA strongly supports government-based inspections and oversight. In this regard, the NGFA reiterates its support for enhanced partnership, coordination and interaction between FDA and other governmental regulatory authorities. State and provincial feed control agencies, in particular, play a key role in providing government-based oversight to address animal feed safety matters.

The NGFA submits that FDA should incorporate as an integral component of an AFSS prioritized inspection approach the principles contained in the so-called “Voluntary Self-Inspection Program” (VSIP). We also believe FDA should use the AFSS as an opportunity to broaden VSIP – following the completion of a pilot project – 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 principles by the private sector, while enabling government to more effectively target its scarce inspection, compliance and enforcement resources.

Under the VSIP approach, developed through AAFCO with the 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:

- 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.
- Participating establishments would conduct annual self-inspections of their operations and correct deficiencies.
- Participating establishments would submit summary results of their inspections to FDA and state feed control authorities.
- 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.

The NGFA offers the following comments on the “Identified Gaps” cited under Component #4:

- **Identified Gap #1:** FDA cites its BSE inspection program as an example of a prioritized inspectional approach. But we submit that it has been difficult for FDA and states to implement a “true” trace-forward, trace-back inspection system to verify compliance with its BSE-prevention feed regulations. Specifically, a truly science- and risk-based inspection approach would target inspection resources at those renderers, feed manufacturers and feeders that actually utilize prohibited mammalian protein and also handle products intended for feeding to ruminant animals. While BSE inspections have focused predominately on commercial feed manufacturers and renderers handling prohibited mammalian protein, other industry sectors – such as transporters and feeders – have not been subjected to date to the degree of regulatory oversight that might be warranted.

We do commend FDA’s for stating in this section that its Center for Veterinary Medicine is working to develop a risk-based inspectional approach for animal feed and feed ingredients. Again, we believe such inspection resources need to correspond with the degree of risk-related hazards associated with the respective industry sector. We would ask that this component also include reference to the fact that risk-related hazards will be determined through science-based risk assessment. The likely outcome of FDA’s analysis of its inspectional approach based upon this new paradigm will be the need to reallocate inspection resources to better encompass feed ingredient manufacturers and suppliers, transporters, distributors and other sectors of the industry that have not been subjected to the routine cGMP inspections conducted of licensed medicated feed manufacturers.

- **Identified Gap #2:** We concur with FDA’s statements that regulatory oversight to date “has focused principally on the commercial medicated feed industry, even

though there has been a shift to more on-farm production of all types of feed.” Further, we support FDA’s statement that the AFSS Team is “developing a more comprehensive regulatory approach that will cover all segments of the animal feeding industry, including transporters, mixer-feeders and livestock producers.” In this latter regard, we believe that FDA needs to work with AAFCO and the relevant departments of state government (such as state departments of agriculture) to ensure that authority exists to conduct “for-cause” inspections on-farm to address feed manufacturing, operations or feeding practices that pose a danger to human or animal health.

- **Identified Gap #3:** The NGFA strongly supports this gap, which relates to having a competent and proficient inspection force at the federal and state levels. For the regulated industries, this would help achieve a degree of inspection consistency and uniformity that is appropriate to the relevant sectors and which too often is lacking today.

Conclusion

If grounded in sound science that is based upon solid research **and** if truly comprehensive and risk-based, the NGFA believes that an AFSS has the potential to:

- Establish a baseline and provide a more uniform framework to guide activities of federal and state governments, as well as the feed ingredient, feed manufacturing, transport, and on-farm and commercial mixer-feeder sectors, in addressing those hazards most important to protecting human and animal health. In so doing, such a federal initiative could provide a more level playing field in the market. As noted previously, the current regulatory and inspection focus of FDA and states is placed squarely and almost exclusively on the commercial medicated feed manufacturer. And far too often, this sector has been placed in the untenable and unjustifiable position of being an “enforcer” of feed safety on feed ingredient suppliers and on-farm mixer-feeders – entities for which the commercial feed manufacturer is not responsible.
- Enable government agencies to better focus scarce human and financial resources on those areas most critical to feed and food safety.
- Further enhance consumer confidence in the safety of meat, milk and eggs.

As FDA proceeds, it will be important to incorporate a flexible approach into its AFSS that permits individual industry sectors and establishments to tailor their practices based upon the type, size and characteristics of each facility within this diverse industry. A one-size-fits-all approach will not work.

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 initiative.

Sincerely yours,



Joseph Garber
Chairman, Feed Legislative
and Regulatory Affairs Committee



Randall C. Gordon
Vice President, Communications
and Government Relations

cc: Dr. Stephen F. Sundlof
Dr. Daniel G. McChesney
Dr. George A. Graber
Ms. Gloria Dunnavan
Mr. Paul Bachman
Mr. Steve Traylor