October 29, 2009

Senate Committee on Health, Education, Labor and Pensions
Washington, D.C. 20510

Dear Senators:

As organizations representing a broad spectrum of U.S. agricultural production, marketing, commodity storage, manufacturing, processing and export sectors, we are committed to providing safe, abundant and affordable food and feed for U.S. and world consumers.

As the Senate begins consideration of comprehensive food and feed safety legislation, the undersigned agricultural and agribusiness associations wish to provide their collective thoughts on S. 510, as well as refinements that we believe would improve the bill. We also take this opportunity to alert the Committee to several major provisions that we find particularly objectionable in the House-passed bill (H.R. 2749); we would strongly oppose their inclusion in legislation being considered by the Senate.

As Congress considers legislation to further enhance U.S. food and feed safety laws, our organizations prefer the science- and risk-based approach generally taken in S. 510. We commend Senator Durbin and other co-sponsors for the open, transparent process used to develop a bipartisan bill. Several of the undersigned organizations have formally endorsed S. 510, while others believe the science- and risk-based principles it embodies provide a solid basis on which to build a more prevention-based approach to food and feed safety.

In particular, we commend the inclusion in S. 510 of provisions that:

- properly limit proposed safety standards to raw fruits and vegetables that may merit additional focus, and require any such standards to be developed through notice-and-comment rulemaking;
- include a streamlined re-registration process for facilities whose required information is unchanged, and provide for biannual, rather than annual, facility registration;
- incorporate an appropriate risk-based threshold for Food and Drug Administration (FDA) access to records at facilities, as well as a requirement that FDA requests for records be in writing;
- appropriately vest solely in the Secretary of Health and Human Services or Commissioner of Food and Drugs – and does not delegate – the authority to order significant enforcement or administrative actions;
- require that any standards for hazard analysis and preventive controls be flexible and be developed through notice-and-comment rulemaking (not through FDA guidance documents), be product-based (rather than facility-based) and not require application of specific technologies, practices or critical controls to individual facilities;
- require FDA to evaluate and, if necessary, revise its food/feed safety regulations and strategies to reflect the dynamic process of producing, handling, manufacturing and distributing raw and processed agricultural commodities, ingredients, feed and food;

- direct FDA, in cooperation with the Centers for Disease Control, to enhance its capacity and technology to more closely track and attribute the actual sources of foodborne illnesses in a more timely manner, thereby reducing the potential to misidentify the sources of contamination;

- preserve current law with respect to the scope of the Reportable Food Registry, which must have a chance to operate, be improved upon and be evaluated for its potential to enhance further FDA's product-tracing capabilities and response time; and

- allow firms to voluntarily recall adulterated products before any government-mandated recall.

In the attached Appendix 1 to this letter, we do suggest recommended refinements to S. 510 that we believe would improve the bill and make it even more science- and risk-based. In summary, we believe the following sections of S. 510 warrant further attention and work:

- Further clarify FDA's records-access authority, including the addition of confidentiality safeguards to protect against inappropriate disclosure of hazard analyses, preventive controls, food/feed safety plans and other proprietary information utilized by individual producers or facilities.

- Adopt more science-based thresholds in provisions addressing hazard analysis.

- Incorporate into existing provisions flexibility for FDA to consider warehouses storing grains, oilseeds and other similarly handled low-risk raw agricultural commodities when determining whether to exempt or modify requirements for hazard analysis, preventive controls and written food safety plans.

- Clarify that any performance standards adopted by FDA, which are intended for required implementation by regulated entities, be promulgated through notice-and-comment rulemaking.

- We generally oppose new fees, especially registration and reinspection fees.

- Clarify provisions on product-testing and subsequent reporting of test results to FDA.

- Enhance provisions on mandatory risk-based inspections, including providing necessary flexibility to FDA to alter the mandated inspection frequency for domestic and foreign facilities not designated as high-risk.

- Incorporate provisions from H.R. 2749 that grant an express exemption from S. 510 for farms, food, livestock and poultry intended for slaughter, for state-inspected meat and poultry processors, and for facilities regulated by the U.S. Department of Agriculture under the Federal Meat Inspection Act, Poultry Products Inspection Act or Egg Products Inspection Act.

- Add provisions creating an indemnification program to compensate individual producers and facilities for monetary losses incurred as a result of erroneous administrative actions or inactions related to food/feed safety by federal agencies that result in disruptions in the production, marketing and distribution of food or feed (including agricultural commodities).

- Amend current provisions that authorize FDA to administratively detain products to retain – not replace – the existing Bioterrorism Act threshold.

- Modify sections concerning intentional contamination and food defense to provide flexibility for facilities to address these requirements separately and distinct from hazard analysis, preventive controls and food safety plans, as the risks and processes used to develop such plans are fundamentally different.

- Require FDA to consider the existence of food-defense and facility-security plans already implemented by industry when evaluating further enhancements to protect against intentional contamination.

- Reexamine the specified timelines and deadlines for implementing various provisions to ensure they are achievable, and that both FDA and affected domestic and foreign facilities and parties have sufficient capacity and capability to comply without disrupting the domestic and import food system.

- Insert a provision into sections related to inspections and certifications of food imports to affirm that any such requirements be consistent with U.S. obligations under international agreements.

In the attached Appendix 2, we highlight significant objections to H.R. 2749, each of which we expressed during our organizations' extensive interaction with the House during its deliberations on this legislation. These concerns include: 1) facility registration fees; 2) the threshold for suspending facility registration; 3) records-access provisions; 4) inappropriate delegation of authority to FDA district offices; 5) unachievable and prohibitively costly product-tracing requirements; 6) inappropriate authority for FDA to regulate through guidance documents; 7) comparatively low thresholds under which FDA would be granted expansive authority to order product recalls andcease-distribution orders restricting the movement of food from a state or region within a state; 8) new quarantine authority ; 9) country-of-origin labeling, since it is not a food-safety issue; 10) unachievable guarantees that adulterated products will never enter commerce; and 11) imposition of excessive civil penalties, including hefty fines, for even unintentional violations that do not pose a risk to human or animal health.

We urge the Senate to reject any attempts to incorporate these provisions during consideration of S. 510.

While each of our groups may have additional specific issues with S. 510 and H.R. 2749, we have attempted to limit our concerns to those provisions on which we all agree.

We pledge and look forward to working constructively and closely with you during consideration of S. 510, and would be happy to meet with you at any time to share the perspectives of the broad agricultural production and agribusiness sector.

Sincerely,

American Beekeeping Federation

American Farm Bureau Federation

American Feed Industry Association

American Malting Barley Association

American Sheep Industry Association

American Soybean Association

American Sugar Alliance

National Association of Wheat Growers

National Barley Growers Association

National Corn Growers Association

National Cotton Council

National Cotton Ginners Association

National Council of Farmer Cooperatives

National Grain and Feed Association

National Livestock Producers Association

National Milk Producers Federation

National Oilseed Processors Association

National Renderers Association

North American Millers' Association

Pet Food Institute

United Egg Association

United Egg Producers

US Canola Association

US Rice Producers Association

USA Rice Federation

Western Pistachio Association

Cc: Sens. Durbin, Lincoln, and Chambliss

Appendix 1 – Suggested Refinements to S. 510

1. **Section 101 (p. 4):**

   - Clarify that FDA access to records applies to those records "directly" relating to the article of food when FDA determines there is reasonable probability that use or exposure to the food will cause serious adverse health consequences or death to humans or animals.

   - Add confidentiality safeguards prohibiting inappropriate or unauthorized disclosure of such records accessed by FDA, and providing indemnification for adversely affected individuals and facilities for economic losses associated with such disclosure.

2. **Section 103 (Sec. 418(b), p. 10):** In this section on hazard analysis and risk-based preventive controls, recommend deleting reference to "intentional contamination" and addressing such contamination later in the bill's food-defense section, as the processes are fundamentally different. *[Note: Suggest a similar change in Section 105 concerning standards for produce safety, p. 22]*.

3. **Section 103 (Sec. 418(c), p. 11-12):** In section on preventive controls, recommend:

   - Replacing references to "significantly minimizing or preventing" hazards with language from H.R. 2749 stating that preventive controls are to be sufficient to "prevent, eliminate or reduce (hazards) to acceptable levels."

   - Replacing term "ensure" with "provide assurance" in Section 103(f) on verification of preventive controls, since "ensure" implies ironclad "guarantees" that may be impossible to achieve. Further, this change would be consistent with other appropriate uses of the phrase "provide assurance" throughout S. 510.

4. **Section 103 (Sec. 418(h) (p. 12):** Suggest adding confidentiality-protection language to provisions that provide FDA with access to facility food safety plans, given the proprietary nature of these plans.

5. **Section 103 (Sec, 418(l), p. 14-15):** Add "warehouses storing grains, oilseeds and other similarly handled raw agricultural commodities" to this provision, which already authorizes FDA to exempt or modify requirements for hazard analysis, preventive controls and written food safety plans for facilities solely engaged in animal feed manufacturing and storage of packaged foods.

6. **Section 103 (Sec. 418(m)(3)(C), p. 16):** In this section defining the types of procedures, practices and processes encompassed in preventive controls, clarify that environmental monitoring programs are appropriate "in processes where a food is exposed to a potential contaminant in the environment."

7. **Section 103 (Sec. 418, p. 17):** In this section on establishing minimum science-based regulatory standards, suggest adding the word "domestic" prior to "international" when referencing the types of existing standards FDA is to consider when proposing such regulations.

8. **Section 104 (p. 19):** In this section on performance standards, recommend adding clarifying language stating that any standards that facilities are required to implement be promulgated through notice-and-comment rulemaking, not through issuance of action levels or guidance by FDA.

9. **Section 107 (p. 32):** We generally oppose new fees, especially registration and reinspection fees. Further, we urge that a non-delegation provision be added to another appropriate section of S. 510, to expressly limit to the FDA Commissioner or FDA Center Directors the authority to order reinspections of facilities.

10. **Section 110 (p. 45-46):** In this section on food defense and building domestic capacity, recommend including a reference requiring FDA to consider existing industry practices and programs for conducting vulnerability assessments and enhancing facility security.

11. **Section 201 (p. 63-68):** In this section on risk-based inspections, recommend:

    - Replacing the word "rigor" with "effectiveness" *[in Sec. 421(a)(4) and (b)(4)]* when referring to a facility's hazard analysis and risk-based preventive controls as a factor in allocating inspection resources.

    - Providing flexibility for FDA to modify mandated inspection frequency for non-high-risk domestic and foreign facilities, based upon the agency's evaluation of type(s) of food stored, manufactured, processed, or packed by the facility or sector; compliance history of facility or sector; whether importer certified; and other relevant factors.

12. **Section 202 (p. 70-71):** Recommend reviewing this section, which currently appears to require that only federal laboratories or non-federal laboratories accredited by FDA be used for testing food articles that are imported; subject to an import alert; or subject to mandatory testing required by statute, implementing regulations or FDA. Further, this section appears to mandate that all test results for articles of food – regardless of the outcome of the test or whether the product is high- or low-risk – be reported to FDA. If so, this raises concern that this provision may discourage testing of imports and violate U.S. trade obligations because a similar requirement is not imposed upon domestic articles of food. It is imperative to preserve international trade of food and agricultural products, which is essential to the profitability of U.S. agriculture and is one of the sole positive contributors to the U.S. balance of trade. Also concern that sufficient laboratory capacity may not be available, particularly since private-sector samples currently are not allowed to be tested by FDA laboratories.

13. **Sections 206 and 207 (pgs. 82-87):**

    - Recommend adding provisions creating an indemnification program to compensate individual producers and facilities for monetary losses incurred as a result of erroneous administrative actions or inactions by federal agencies related to food/feed safety that result in disruptions in the production, marketing and distribution of food (encompasses agricultural commodities).

    - Oppose reducing current Bioterrorism Act threshold to grant FDA authority to order administrative detentions of food based on a "belief" that the product is adulterated or misbranded. Instead, recommend retaining the current Bioterrorism Act threshold requiring that FDA have "credible evidence or information" indicating that a food product is adulterated and "presents a threat of serious adverse health consequences or death to humans or animals."

14. **Sections 303 (pgs. 96-99), 307 (pgs. 102-103) and 309 (pgs. 116-117):** Recommend incorporating into the appropriate sections related to inspections and certifications of food imports a provision affirming that any such requirements be consistent with U.S. obligations under international agreements.

15. **Section 308(c)(5)(C) (p. 113):** Recommend referencing each of the conflict-of-interest provisions contained in FDA's guidance *(as incorporated into H.R. 2749).*

16. **Incorporate USDA exemption language from H.R. 2749:** Recommend incorporating the provisions found in Section 5 of H.R. 2749 to clarify that farms, food, livestock and poultry intended for slaughter, state-inspected meat and poultry processors, and facilities regulated by USDA under Federal Meat Inspection Act, Poultry Products Inspection Act or Egg Products Inspection Act are expressly exempt from S. 510. USDA has been on the front lines of food safety for more than a century, and it is important to clarify that new food/feed safety legislation does not diminish, undermine or duplicate USDA's existing authorities.

17. **Reexamine Timelines and Deadlines:** Recommend that careful consideration be given to the timetable for implementing various provisions in S. 510 to ensure they are achievable, and that both FDA and affected domestic and foreign facilities and parties have sufficient capacity and capability to comply without disrupting the production, marketing and distribution of food.

Question

1. **Section 106 (p. 25-27):** We seek clarification over what appears to be an inconsistency in this food-defense section. It requires FDA to promulgate regulations within 24 months after enactment for high-risk food(s) determined to have "clear vulnerabilities" for intentional contamination. But this same section appears to circumvent this requirement by requiring FDA to issue guidance within one year after enactment "requiring" facilities to implement mitigation strategies or measures to protect against intentional adulteration – prior to issuance of a standard and regardless

of whether the facility handles “high-risk” food(s) that have “clear vulnerabilities” to intentional contamination. Further, we object to any use of FDA guidance documents to impose standards, which would undermine the value of the guidance-document process and circumvent notice-and-comment rulemaking.

Appendix 2 – Major Concerns in H.R. 2749

Each of the concerns articulated herein were expressed during our organizations' extensive involvement during House consideration of H.R. 2749. Several of the concerns represent irresolvable differences we have with the approach taken in the House-passed measure. In other cases, we were led to believe some of our concerns would be resolved prior to House floor passage, but regrettably, they were not.

In particular, we wish to draw the following issues to your attention:

- **User Fees:** H.R. 2749 would impose several fees to help fund the agency's mission, but provides no basis to justify the level of user fees that would be mandated. We strongly oppose facility registration fees, believing that FDA's food and feed safety activities provide a public benefit that should be financed through appropriations. As such, we find particularly objectionable the flat $500-per-facility annual fee that H.R. 2749 would imposed on all domestic and foreign facilities required to register with FDA. While H.R. 2749 would cap such fees at $175,000 per company, this "one-size-fits-all" fee also raises questions of equity for smaller businesses and facilities on which FDA expends negligible resources related to food or feed safety. Further, funds generated by the facility registration and other fees would be directed into FDA's general revenues rather than to a dedicated account to pay for FDA's food/feed safety functions. The bill contains no constraints on FDA expenditures for food safety activities and, in fact, considers items like "functions performed by advisory committees" to be included in food safety activities to be paid for via these fees.
- **Suspension of Facility Registration:** We object to H.R. 2749's threshold that would empower FDA to suspend the registration of facilities – in effect, shutting them down – based upon a belief that their activities "could result in serious adverse health consequences or death to humans or animals." We prefer the threshold established in S. 510, under which FDA would be required to demonstrate that a product has a "reasonable probability" of causing serious adverse health consequences or death to humans or animals. We also urge that this authority be limited to issues that directly affect food or feed safety. In that regard, H.R. 2749's provision that would give FDA the authority to cancel facility registrations if fees are not paid in a timely manner is objectionable.

- **FDA Access to Records:** H.R. 2749 dramatically expands FDA's access to facility records and expressly encompasses some farms in the records-access requirement. The inspector would merely need to present appropriate credentials and would not need to have any indication that a food/feed safety issue may exist as a precondition to accessing or photocopying records. In fact, the bill would expressly delete the Bioterrorism Act limitation on records-access that requires FDA to first have a "reasonable belief" that a product is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The bill also authorizes FDA to promulgate regulations mandating the types of records required and requiring that records be kept in a standardized electronic format and be retained for up to three years. We believe it is important that any such regulations promulgated under this legislation not be burdensome or allow FDA to penalize firms for "paper" violations that have no bearing on food or feed safety.

We recognize the importance of FDA having access to commercial facility records that pertain to the safe storage, handling, manufacture and distribution of products. However, FDA should have access only to records that directly bear upon product safety. It is important to include these qualifiers to prevent unwarranted and unreasonable "fishing expeditions" by the agency. It also is imperative that the bill provide confidentiality protections against unauthorized disclosure by FDA of proprietary or confidential business information to which the agency gains access when reviewing the contents of written food/feed safety plans and other records, as well as to inappropriate release in response to Freedom of Information Act requests. Confidential business information, such as the specifics of a company's food safety or quality assurance plans, manufacturing processes or methods and product formulas must be protected. This is not a hypothetical concern, as there have been incidents in which FDA inspectors have disclosed highly proprietary commercial facility business information to which they had access through records. Further, since H.R. 2749 also would provide FDA access to records on-farm, it is extremely important that confidentiality of farming operations be preserved, including items such as farm location, commodities produced, farming practices, and financial data. If FDA discloses confidential information, affected entities should be indemnified for any economic losses incurred as a result.

- **Delegation of Authority:** We strongly object to provisions in H.R. 2749 that would delegate to the FDA District Office level the authority to mandate product-specific preventive controls, mandate recalls and issue subpoenas. FDA District Offices have been known to issue and implement inconsistent and varying interpretations of even existing FDA regulations and policies. We believe that S. 510's provisions that retain authority for such monumental decisions at the FDA Commissioner level is more appropriate.

- **Product-Tracing:** While it would require FDA to undertake pilot programs and rulemaking prior to implementing more stringent product-tracing requirements, H.R. 2749 presupposes the outcome by requiring the agency – regardless of the results of its review – to implement a product-tracing system under which it can identify within two business days "each person who grows, produces, manufactures, processes, packs, transports, holds (stores) or sells" an article of food. While we share the goal of prompt traceback of food- or feed-safety incidents that pose a danger to human or animal health, we believe it is inappropriate and unwise for legislation to presuppose an outcome. This provision should be changed to eliminate the two-business day requirement and also require FDA to exempt a food, facility, or farm from being covered under the bill's traceability provisions if the agency determines that such a tracing system is infeasible, or the impracticalities or costs outweigh the commensurate public health benefit.

- **Requiring Facilities to Implement Preventive Controls Established by FDA through Guidance:** H.R. 2749 contains an objectionable provision that would require facilities to implement any preventive controls established by FDA through guidance. This is a totally inappropriate granting of authority, and would undermine the value of the guidance document process. Such a requirement should be limited to FDA regulations promulgated through public notice-and-comment rulemaking and cost-benefit analysis.

- **FDA Administrative-Detention, Cease-Distribution and Quarantine Authorities:** We strongly oppose the administrative-detention provisions in H.R. 2749 that would undermine the Bioterrorism Act threshold, which currently requires that FDA first have credible evidence or information indicating a product is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. H.R. 2749 would lower that threshold to require only that FDA have "reason to believe" a product is "adulterated, misbranded or otherwise in violation…." Current law, extensively negotiated during enactment of the Bioterrorism Act, should remain in place.

  We also strongly oppose provisions in H.R. 2749 granting FDA broad quarantine authority to restrict the movement of food from a state or a region within a state. We believe appropriate and judicious use of cease-distribution authority, if granted to FDA, would provide a much more targeted approach to preventing further movement of adulterated products that pose a risk of causing serious adverse health consequences or death to humans or animals. Further, if "cease-distribution" authority is retained in the bill, FDA should be required to demonstrate there is a reasonable probability, based upon scientific risk assessment, that the product in question will cause serious adverse health consequences or death to humans or animals.

  In addition, given the heightened emphasis on government accountability, the bill also should mandate that FDA indemnify affected growers and facilities that sustain economic damage resulting from erroneous FDA recall and quarantine orders issued under these sections.

- **Country-of-Origin Labeling:** H.R. 2749 would require all non-processed food products (which would encompass raw agricultural commodities, like grains and oilseeds) to identify the country-of-origin of the product until reaching the point of final processing, at which time the processed product could declare the country in which final processing occurs. This labeling also would apply to products of U.S. origin. Ostensibly, this would require recordkeeping, labeling and identity-preserved storage, handling and shipping by facilities importing raw agricultural commodities, which may change hands several times before reaching a final processor (or being exported in raw form). We strongly object to this provision. Country-of-origin labeling is not a food or feed safety issue. This is particularly true given the provisions in H.R. 2749 and S. 510 that require foreign facilities and suppliers exporting products to the United States to meet the same food/feed safety standards as U.S. facilities. Its implementation would be onerous and extremely costly to business and consumers alike. Further, it invariably would trigger trade retaliation against U.S. agricultural and food exports, and violate U.S. international trade commitments.

- **Requiring Facilities to Guarantee Adulterated Products Do Not Enter Commerce:** H.R. 2749 contains a troubling provision that states that if a facility has not fully implemented preventive controls or subsequently finds a deficiency in one or more controls and undertakes corrective actions, it must guarantee that no adulterated products enter commerce. This is an unreasonable standard to impose on facilities, which may experience accidental contamination despite implementation of best practices.

- **Civil Monetary Penalties:** We oppose H.R. 2749's provisions that would impose hefty civil monetary penalties on individuals, even for minor or unintentional violations that do not pose a food or feed safety risk to humans or animals.