

June 15, 2009

The Honorable Henry Waxman
Chairman Energy and Commerce Committee
United States House of Representatives
2204 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Waxman:

The following group of agricultural and agri-business associations would like to share our concerns regarding H.R. 2749, the food safety bill passed by the House Energy and Commerce Committee's Health Subcommittee last week. As drafted, this legislation would give the Food and Drug Administration broad new powers to regulate the entire spectrum of the agricultural and food system – from production agriculture to the final retail establishment -- in many cases without appropriate thresholds or accountability. We strongly urge that these deficiencies be corrected during full committee markup.

-- **Suspension of Facility Registration:** The bill empowers FDA to suspend the registration of facilities for violations that could result in serious adverse health consequences or death to humans or animals. Allowing FDA to shut down a business (by suspending a facility's registration) based on a supposition that its products could result in serious adverse effects is unacceptable. We suggest that FDA's facility-suspension authority be limited to "violations that FDA has a reasonable belief, based on a scientific risk assessment, present serious adverse health consequences or death to humans or animals". We also urge that this authority be limited to issues that directly affect food safety. In that regard, the bill's provision that would give FDA the authority to cancel facility registrations fees if not paid in a timely manner should be stricken.

-- **Authorizing FDA to Mandate Facility-Specific Product-Safety Standards:** We adamantly oppose the bill's provisions that would authorize FDA to establish (by either regulation or guidance) facility-specific preventive controls or elements of a food safety plan. This would be both unwise and counterproductive. Prevention and control systems resulting from a hazard analysis, by their very nature, are not "cookie-cutter" approaches suited to government mandates or dictums. They are unique to individual facilities, and facilities must be provided flexibility to tailor such programs in order for them to be effective. These sections are made even more troublesome by the bill's provisions that would delegate the authority to issue such directives to the FDA District Office Director level; those offices frequently issue and implement inconsistent and varying interpretations of even existing FDA regulations and policies. We also believe it is wholly inappropriate in these, and other, sections of the bill to allow FDA to regulate through guidance documents, which would destroy the protections afforded by notice-and-comment rulemaking.

-- **User Fees:** The bill requires FDA to impose several fees to help fund the agency's mission, but provides no basis to justify the level of user fees. Funds generated from the user fees are 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 constraint 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. The bill must be amended to require justification of the food/feed safety funding needs of the agency. In addition, the specific agency activities to be financed via fees must be clarified. We also believe a flat facility registration fee applicable to all types and sizes of facilities poses questions of equity, particularly for small businesses that consume a negligible share of FDA resources.

-- **Standards for Raw Commodities:** The bill requires FDA to implement regulations setting standards for safe growing, harvesting and storage of raw agricultural commodities, including on farm regulation if required to minimize the risk of serious adverse health consequences or death to humans or animals. It specifically references naturally occurring hazards, such as mycotoxins in corn. The bill also specifically cites manure, water quality, employee hygiene, sanitation, animal controls and temperature controls that FDA determines to be "reasonably necessary." The bill language also is overly broad and could be misconstrued to apply to environmental safety, which is not the purview of FDA. This provision should be changed to authorize rather than require FDA to set standards. Further, such standards, if promulgated, should be commodity-specific and should be limited to those that FDA determines, based on scientific risk-assessment and risk-management principles, are necessary to minimize the risk of serious adverse health consequences or death to humans or animals and necessary to protect public health.

-- **FDA Access to Records, Including On-Farm:** The bill dramatically expands FDA's access to facility records and expressly encompasses 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 which 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 recognize the importance of FDA access to commercial facility records that pertain to the safe storage, handling, manufacture and distribution of products. However, FDA should only have access 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 is also imperative that the bill provide for 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. 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 this bill 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.

-- **Product-Tracing:** The contemplated product-tracing system in the bill far exceeds the Bioterrorism Act's requirement that facilities maintain records sufficient to identify the immediate previous source of the agricultural products and ingredients they receive and the next subsequent recipient to which they ship – the so-called “one-step-forward/one-step back” requirement. The bill mandates that FDA issue regulations establishing a tracing system that enables it to identify within two business days each person who grows, produces, manufactures, processes, packs, transports, stores or sells agricultural commodities, food, feed or feed ingredients. This provision should be changed to 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.

-- **FDA Recall, Cease-Distribution and Quarantine Authorities:** The Bioterrorism Act requires FDA to detain a product if FDA has credible evidence or information indicating a product is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. This bill would lower that threshold that requires that FDA only have a “reason to believe” that a product is adulterated, misbranded or otherwise in violation of the bill. This should be revised to allow affected firms to voluntarily recall products before FDA issues a mandatory recall. If a “cease distribution” or quarantine provision is retained in the bill, it must require that FDA have 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. 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:** The bill requires all non-processed food products (which would encompass raw agricultural commodities, like grains and oilseeds) to identify the country-of-origin of the product. This labeling also would apply to products of U.S. origin. This section must be removed from the bill. Country-of-origin labeling is not a food or feed safety issue. This is particularly true given the bill's other requirements that foreign facilities and suppliers exporting products to the United States meet the same food/feed safety standards as domestic facilities. Its implementation would be onerous and extremely costly to business and consumers alike, particularly for products containing numerous ingredients from numerous countries.

While each of our groups may have additional specific concerns with other sections of the bill, we have attempted to limit our concerns to the eight major provisions on which we all agree, and strongly urge that the bill be amended to address these serious deficiencies during full committee markup. We would be happy to meet with you at any time to discuss these concerns.

Sincerely,

American Farm Bureau Federation
American Feed Industry Association
American Soybean Association
American Sugar Alliance
Corn Refiners Association
National Association of Wheat Growers
National Barley Growers Association
National Chicken Council
National Corn Growers Association
National Grain and Feed Association
National Milk Producers Federation
National Oilseed Processors Association
National Pork Producers Association
National Sunflower Association
National Turkey Federation
North American Millers' Association
Pet Food Institute
USA Dry Pea & Lentil Council
USA Rice Federation
US Canola Association

Cc: Collin Peterson
Frank Lucas