R-CALF USA's Proposed Analysis of the Food Safety Enhancement Act of 2009 (H.R. 2749)

Prepared August 17, 2009

1. **The Food Safety Enhancement Act of 2009 (H.R. 2749 or "the Act") purports to exempt livestock, farms and ranches that raise livestock, meat from livestock, beef packing and processing plants, and beef sold at retail pursuant to the following sections:**

    a. Sec. 4: The Act does not alter existing jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services.
    b. Sec. 5: The Act exempts food that is under USDA jurisdiction, e.g., meat from cattle, hogs, sheep, and poultry, which would include beef sold at retail.
    c. Sec. 5: The Act expressly exempts livestock and poultry intended to be presented for slaughter and it expressly exempts a cow, sheep, or goat used for milk production.
    d. Sec. 101: The Act exempts farms from the definition of "facility."
    e. Sec. 5: The Act exempts facilities that are regulated by USDA, which would include meatpacking plants and meat processing plants.
    f. Sec. 5: The Act exempts farms that raise animals for food if that food is regulated by USDA, which would include cattle, hogs, sheep and poultry.

    Discussion: The July 30, 2009 Congressional Record at H9157 states that "Livestock and poultry are exempt from the bill," and "USDA regulated farms, facilities, and products are not subject to the bill. It [the bill] allows farms to be exempt from the traceability requirements." Thus it appears the intent of Congress is to exempt the entire cattle and beef production chain from the Act.

    Concern: R-CALF USA is concerned that the livestock exemption may be insufficient to exempt all cattle. For example, because the language that exempts livestock (Item c above) exempts livestock "that are intended to be presented for slaughter," it could be interpreted that breeding bulls and cows are not exempt because they are primarily intended for production, even though they would eventually be slaughtered at the end of their production lives. It is acknowledged that Items c and f above, when read together, demonstrate Congress' intent to exempt livestock and livestock farms.

    Recommendation: R-CALF USA should seek to strengthen the livestock exemption (Item c above) to ensure that livestock and farms that raise livestock are exempt from the Act.

2. **Section 101 establishes an annual, federal registration program and registration fee program for facilities that manufactures, processes, packs, or holds food. Section 102 requires such facilities to develop a food safety plan and to conduct a hazard analysis, implement preventive controls, and maintain records for such activities, as well as develop a food defense plan. Section 104 subjects such facilities to food production and food safety standards. Section 105 subjects such facilities to inspection. Section 106 requires such facilities to disclose their records. And, Section 107 imposes traceability requirements on such facilities.**

Discussion: Most, but not all, of the requirements listed above apply only to facilities and not farms (as discussed below, certain farms that grow produce are subject to Sections 104, 106, and 107). However, there is no distinction between a corporate, industrialized facility and a family-owned facility, nor is there a relaxation of requirements for small- to mid-sized facilities. These requirements would impose significant costs, in terms of financial, time, and labor, on all facilities regardless of whether they are of high-risk or low-risk for food contamination. The exception would be that facilities and produce farms targeted by the Act that operate wholly within a state, and do not engage in interstate commerce, likely would be excluded from the Act's jurisdiction and subject instead to the food safety requirements of their respective state.

Concern: Based on R-CALF USA's belief that the increased incidences of food safety problems is attributable to the increased industrialization of the entire food production system and corresponding decrease of family farms, ranches and smaller food processing facilities, the costs and regulatory burden imposed by these requirements could be a barrier to start-up for new industry entrants and could force many smaller facilities operating at the margin out of business. If these possible outcomes were to occur, they would exacerbate food safety problems because it would facilitate even more industrialization of the food supply chain.

Recommendation: Inasmuch as this Act could set a precedent for future efforts to regulate livestock, livestock farms, and livestock facilities, R-CALF USA should suggest a method of achieving a scale-appropriate demarcation of jurisdiction to ensure the Act targets only the most likely sources of food safety problems – large industrialized farms and facilities.

3. **Section 103 authorizes FDA to establish performance standards to identify the most significant food-borne contaminants and the most significant resulting hazards. Section 104 expressly authorizes both FDA and USDA to establish both production and processing standards for farms that raise fruits, vegetables, nuts and fungi if the FDA determines such standards are necessary to minimize serious health consequences or death. FDA is given discretion to establish standards that *may*, for example, restrict a farmer's use of manure and other inputs and dictate both animal control and employee hygiene when growing such raw commodities. Section 106 grants FDA authority to access records on farms that raise such commodities.**

   Discussion: Farmers that grow fruits, vegetables, nuts and fungi are subjected to heightened federal oversight regardless of whether they are corporate, industrialized farming operations or family owned operations, or whether they are a small, moderate, or large farming operation. In addition, because the Act introduces the term "produced" in the section without defining this term, the Act may inadvertently subject more farms (except for livestock farms and ranches) to the requirement than what Congress intended.

   Concern: If Congress were to use this Act as a model for addressing food safety problems associated with ongoing meat recalls by imposing similar production standards on U.S. cattle producers, practices that have been employed in the U.S. cattle industry for over a century could become subject to federal restrictions. For example, a restriction against comingling cattle with wildlife would be both untenable and devastating to the U.S. cattle industry.

Recommendation: Inasmuch as this Act could set a precedent for future efforts to regulate livestock, livestock farms, and livestock facilities, R-CALF USA should suggest a method of achieving a scale-appropriate demarcation of jurisdiction to ensure that the Act targets only the most likely sources of food safety problems – large industrialized farms and facilities.

4. Section 107 authorizes FDA to establish a tracing system for food starting at the farm.

Discussion: The farms and food covered by this requirement for a tracing system does not include farms that raise livestock or meat from livestock; nor does it include farms that grow produce (fruits, vegetables, nuts and fungi) that is sold directly to a consumer, restaurant or grocery store, provided such farms keep records for at least 6 months regarding the sales of such produce; but, the Act would include farms that raise and sell fruits, vegetables, nuts and fungi to all other outlets. In addition, farms that grow and sell grains, legumes, grass and hay, for example, do not appear to be subject to the imposition of a tracing system, though the exemption for such farms is somewhat ambiguous due to the Act's inclusion of the term "produces," which is not defined in the Act.

Concern: The imposition of a tracing requirement under this Act applicable to certain farms, without regard to whether those farms are corporate, industrialized farms or family owned farms, could establish a troublesome precedent for future congressional food safety reforms that would target the U.S. cattle industry. In other words, if Congress establishes the criterion for requiring food tracing based solely on the type of commodity produced by a farm (as it does here for growers of fruits, vegetables, nuts and fungi) and applies this criterion to beef, then beef recalls caused by unsanitary conditions at industrialized meatpacking plants could result in subjecting the entire beef supply chain, including cattle, to tracing requirements. This would be an inappropriate solution to food safety problems that originate after livestock leave the farm or ranch. It is acknowledged that the raw commodities subject to tracing under the Act are fundamentally different than beef in that they are consumed in the same form as when they left the farm – they are consumed in their raw form. Beef, on the other hand, is not consumed in the same form as when it leaves the farm and it additionally is cooked before consumption.

Recommendation: R-CALF USA should ensure that farms that grow raw livestock feed (e.g., grain, legumes, grass and hay) are exempt from this traceability provision despite the potentially ambiguous use of the term "produces." Also, and inasmuch as this Act could set a precedent for future efforts to regulate livestock, livestock farms, and livestock facilities, R-CALF USA should suggest a method of achieving a scale-appropriate demarcation of jurisdiction to ensure that the Act targets only those farms and facilities that are the likely source of food safety problems – large industrialized farms and facilities.

5. Section 108 of the Act authorizes FDA to assess fees to a regulated entity that commits a violation of the Act and undergoes additional inspection by FDA for such a violation.

Discussion: This fee assessment would directly affect farms that raise fruits, vegetables, nuts or fungi, but it is uncertain whether other non-livestock farms would be affected.

Recommendation: R-CALF USA should ensure that farms that grow raw livestock feed (e.g., grain, legumes, grass and hay) are not inadvertently included under the Act's jurisdiction under this is section.

6. **Section 112 adds farms to the definition of parties responsible for reporting a food article that could cause harm to human or animal health.**

   Discussion: It appears that all non-livestock farms, whether they grow produce or grain, would be subjected to this new provision.

   Recommendation: R-CALF USA should ensure that farms that grow raw livestock feed (e.g., grain, legumes, grass and hay) are not inadvertently included under the Act's jurisdiction under this is section.

7. **Section 202 includes under the definition of a misbranded product the failure to label both processed food and unprocessed food with a country-of-origin label (COOL).**

   Discussion: For processed foods, this COOL label would only identify the country in which the last processing occurs, meaning it essentially adopts for domestic products the current international rule of origin applied to imported products. For unprocessed foods, the COOL label would have to meet the same criteria under the new U.S. mandatory COOL law.

   Concern: R-CALF USA is concerned that if Congress codifies in this Act the international rule of origin for processed foods – in which the country where the product was last substantially transformed is the country of origin, future efforts to provide more accurate information to consumers, such as a listing of the country of origin of ingredients contained in a processed food items, could be thwarted.

   Recommendation: Inasmuch as this Act could set a precedent for future efforts to regulate livestock, livestock farms, and livestock facilities, and due to the large volume of beef products that are currently exempt under the COOL law because they are considered processed, R-CALF USA should object to the Act's provision that allows processed food to be labeled with the name of the country where the last processing occurred. Such a provision would mask the foreign origins of large volumes of product and create confusion in the marketplace where processed food and unprocessed food would then have differing standards for determining their origins.

8. **Section 207 prohibits farms from delaying, limiting or refusing a FDA inspection for an adulterated food.**

   Discussion: Again, regulated farms appear to be those that grow fruits, vegetables, nuts or fungi; but it is unclear whether this provision would apply to other non-livestock farms such as those that produce grain and other similar commodities.

Recommendation: R-CALF USA should ensure that farms that grow raw livestock feed (e.g., grain, legumes, grass and hay) are not inadvertently included under the Act's jurisdiction under this is section.

9. **Section 102 encourages FDA to incorporate international standards when it promulgates rules to establish science-based standards for regulated facilities that are required to conduct a hazard analysis. Section 109 requires FDA to comport to international standards when requiring certification and verification of certification by importers. Section 112 authorizes FDA to provide information that is exempt from discloser to any foreign government agency or with international organizations having the responsibility to facilitate global or regional harmonization of standards or to promote and coordinate public health efforts. Section 206 encourages FDA to use the International Trade Data System for establishing unique identification numbers for facilities, importers and custom brokers.**

   Discussion: Federal agencies have demonstrated a propensity to deviate from international standards when they conflict with the self-interests of industrialized meatpackers. For example, in its 2005 rulemaking to reopen the U.S. border to live Canadian cattle following Canada's initial outbreaks of bovine spongiform encephalopathy (BSE or mad cow disease), USDA knowingly exempted Canada from the international standard requiring a BSE-affected country to have an effective feed ban in place for a period of eight years – the duration established by the OIE for determining the effectiveness of a feed ban.[1] USDA decided that just five years was a sufficient duration for Canada's feed ban.[2] However, it was soon revealed that Canada's five-year-old feed ban had been ineffective in halting the spread of BSE in that country.[3] As a result of this deviation from the international standard, USDA exposed the U.S. to an unnecessary and avoidable risk of BSE by prematurely allowing Canadian cattle that had been exposed to the BSE agent to enter the United States.[4]

   On the other hand, USDA's adoption of international standards to justify the relaxation of U.S. standards has resulted in the long-term erosion of consumer confidence in U.S. beef and a consequential loss of access to international markets. For example, USDA purported to follow international standards when it established lenient mitigation measures to allow the importation of Canadian beef and cattle, except with respect to the duration of Canada's feed ban.[5] However, U.S. export markets were practicing far more stringent mitigations for

[1] *See* 70 Federal Register, 470, col. 2 (USDA stated in its final rule: "We, therefore, concluded that a feed ban of less than 8 years' duration was appropriate for Canada. Canada, in fact, meets all OIE guidelines for a minimal-risk region, except for the duration of its feed ban.").
[2] *See id*., at 474, col. 2.
[3] *See* BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, available at http://www.cdc.gov/ncidod/dvrd/bse/index.htm. (The CDC stated that 11 of the 17 BSE cases detected in Canadian-born cattle "were known to have been born after the implementation of the 1997 Canadian feed ban; ten of these eleven were born after March 1, 1999," which is the birth date after which Canadian cattle are eligible for export to the United States.).
[4] *See Ibid*.
[5] *See* 70 Federal Register, 470, col. 2; *see also* 72 Federal Register, 53341, col. 1 (USDA claims its subsequent rule to allow the importation of Canadian cattle born after March 1, 1999 is consistent with OIE guidelines.).

countries with BSE than what the international standards recommend.[6] As a result of adhering to the lesser, international standards when importing beef and cattle from Canada, the U.S. remains unable to restore consumer confidence in U.S. beef in many important export markets and beef exports have suffered annual losses since 2004, ranging from $3.1 billion in 2004 to $2.5 billion in 2007.[7]

Concern: R-CALF USA believes it is fundamentally wrong for Congress to abrogate its responsibility to establish standards necessary to protect the health, safety and welfare of the citizens of the United States by adopting, by reference, international standards in statute. Such action unnecessarily erodes the sovereignty of the United States by diminishing and downplaying the United States' sovereign right to establish standards that may differ from international standards. By definition, international standards are not based on the unique risks and hazards of a particular country. Thus, international standards could be woefully inadequate for countries with an inherently high risk for food-borne contamination and completely unnecessary for countries with an inherently low risk for such contamination.

Even under international agreements countries have retained the right to maintain higher standards if the sovereign country finds international standards to be an "ineffective or inappropriate means for the fulfillment of the legitimate objectives."[8] In addition, sovereign countries are free to go beyond the internationally accepted standards if there is a scientific justification for the stronger standards or a risk assessment to support their choice.[9] R-CALF USA is concerned that references to international standards in the Act, and particularly the statutory directive recommending that FDA issue guidance and regulations consistent with international standards, to the extent such standards are practicable and appropriate, would reduce the likelihood that FDA would conduct a comprehensive risk and hazard analysis to determine the necessary level of protection needed for U.S. citizens that consume food available in the United States. Instead, such a statutory directive encourages the adoption of international standards, which would be presumed adequate, without the requisite due diligence by the agency. Thus, such references and directive would unnecessarily impede Congress', the federal agency's and the state's ability to establish appropriate standards to meet the specific goals and objectives of the citizens of each state and the United States.

Recommendation: Inasmuch as this Act could set a precedent for future efforts to regulate livestock, livestock farms, and livestock facilities, R-CALF USA should object to the inclusion in the Act of references to international standards, including any direct or indirect statutory recommendation that consistency with international standards be achieved. Instead, R-CALF USA should urge Congress to direct FDA and USDA to conduct a scientific assessment of the risks and hazards associated with the consumption of food in the United States, both from domestic and imported sources, and establish mitigation measures

[6] *See* Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at xvii (Even today the countries of Japan, South Korea, and Mexico refuse to accept beef from cattle over 30 months of age when slaughtered, with Japan requiring beef to be derived from cattle under 21 months of age, and both Japan and Mexico refuse to import any ground beef from the U.S., regardless of the age of the animal.).
[7] *See id*., at 12-1 (estimates based on ITC model simulations).
[8] World Trade Organization Technical Barriers to Trade Agreement. Article 2.4.
[9] *See* World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3.3.

commensurate with the specific, and perhaps unique, risks identified in that assessment. American citizens deserve an open and transparent government, one that affords them the opportunity to participate in the development of regulations to which they must comply and that define their respective industries. This can only be accomplished if citizens are given the opportunity to provide critical input on government risk and hazard assessments, the assumptions used therein, and on mitigation measures the government believes is justified by those risk and hazard assessments. The presumption that international standards are science-based and appropriate for the U.S., because they have international government-to-government support, strips away the right of U.S. citizens to meaningfully participate in the governance process in our free society and should be flatly rejected by Congress.