

Food/Feed Safety Legislation – Status and Ongoing Efforts

(Dec. 28, 2009)

Status:

- House bill (H.R. 2749) approved July 29 by 283-142 vote.
- Senate bill (S. 510) approved by Senate Health, Education, Labor and Pensions Committee on Nov. 18 by voice vote. Awaiting Senate floor consideration, most likely in first quarter of 2010 (after health care bill).

Major Common Elements of Both Bills:

- Cover all facilities registered with FDA under Bioterrorism Act (domestic and foreign; food, grain, grain processing, feed, feed ingredient, etc.).
- Generally science- and risk-based.
- Major Requirements: 1) more frequent registration of facilities with FDA; 2) conduct hazard analysis; 3) develop procedures to control hazards to acceptable levels; 4) develop written food/feed safety plans; 5) significantly expanded FDA access to company food/feed safety records; 6) product tracing; and 7) mandatory recall authority for FDA if voluntary recalls not conducted.

Important Advantages of Senate Bill Vs. House Bill:

- Senate bill much less prescriptive, more science- and risk-based. Also omits the following onerous provisions found in the House-passed bill:
 - A one-size-fits-all \$500 per year fee on all facilities registered with FDA under the Bioterrorism Act, with a cap of \$175,000 per company.

- Lower current Bioterrorism Act risk threshold allowing expansive FDA access to records.
- Delegate authority to FDA district offices to issue mandatory recalls, mandate product-specific preventive controls and issue subpoenas.
- Mandate FDA implement a product-tracing system and regulations that allow it to determine the origin of a product-contamination incident within two business days – much more stringent than the current Bioterrorism Act requirement.
- Expansive FDA quarantine authority (in addition to cease-distribution authority) to stop movement and impound products in states and regions based on suspicion of food/feed safety problem.
- Lower legal threshold under which FDA would be allowed to suspend a facility's registration, in essence shutting down its operations.
- Authorize FDA to require facilities to implement preventive controls through guidance documents, thereby short-circuiting the regulatory process.
- Impose country-of-origin labeling requirements on all imported raw and processed agricultural commodities.
- Require facilities to guarantee that adulterated products do not enter commerce if they find deficiencies in preventive controls.
- Create hefty civil monetary penalties, even for minor or unintentional violations that do not pose a danger to human or animal health.

NGFA Achievements in Senate Bill:

The NGFA was successful in incorporating into the version of the bill approved by the Senate committee the following significant changes:

- **Exemption/Modifications for Grain-Handling Facilities:** In a significant change, a provision was added that **authorizes FDA to exempt from or modify the bill’s hazard analysis, preventive controls and written food safety plan requirements as they apply to grain elevators and other warehouses that store raw agricultural commodities (except fruits and vegetables).** The Senate bill **already applied this NGFA-supported flexibility for facilities manufacturing animal feed and feed ingredients.** This provision is important so grain elevators, feed mills and feed ingredient manufacturers are **not** subject to requirements in the bill that are irrelevant to their operations, such as having procedures in place to ensure the sanitation of food-contact surfaces, allergen controls, radiological controls and drug residues. If retained, this provision would give the NGFA significant leverage to urge that any FDA regulations be practical and achievable for raw grain and oilseed handlers, as well as feed and feed ingredient manufacturers.

- **Compliance with Trade Agreements:** An NGFA-drafted new section that states that implementation of the bill shall be consistent with the World Trade Organization’s rules, as well as “any other treaty or international agreement” entered into by the United States. This is an important safeguard, given that several provisions of the bill apply to the safety of imported products and create a system under which FDA would be authorized to accredit (and conversely, revoke the accreditation of) foreign governments and independent third parties to certify the safety of imported products. But the NGFA will continue to work to correct provisions of the bill that may create potential trade retaliation against U.S. exporters.

- **Appeal of FDA Suspensions of Facility Registrations:** The Senate bill, like the House version, authorizes FDA to suspend a facility’s registration – in effect, shutting down its operations for food or feed safety problems. But the NGFA-drafted provision contains a higher threshold FDA would be required to meet: A requirement that it first demonstrate that the products being manufactured, processed, packed or stored at the facility has a “**reasonable probability**” of causing serious adverse health consequences or death to humans or animals – a significantly higher threshold than the House-passed bill. Under another provision authored and supported by the NGFA, the Senate bill would allow the facility to avail itself of a hearing to appeal a facility registration suspension later than two business days after FDA’s suspension action if it needs additional time to compile information or evidence to challenge FDA’s suspension action as unwarranted.