



National Grain and Feed Association

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Waxman-Dingell-Pallone-Stupak-DeGette-Sutton

Food/Feed Safety Bill Discussion Draft

...Detailed Summary...

Prepared by National Grain and Feed Association

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This summarizes the major provisions of the discussion draft food/feed safety bill released on May 26 by House Energy and Commerce Committee Chairman Henry Waxman, D-Calif., Chairman Emeritus John Dingell, D-Mich., and committee members Frank Pallone, D-N.J., Bart Stupak, D-Mich., Diana DeGette, D-Colo., and Betty Sutton, D-Ohio.

Importantly, all references to “food” in the bill adopt the definition in the Federal Food, Drug and Cosmetic Act – “articles used for food or drink for man or other animals, chewing gum and articles used for components of any such article.” This broad definition encompasses raw grains and oilseeds, animal feed, feed ingredients and pet food, processed agricultural products (e.g., corn and soybean oil and meal), etc.

1. **Registration of Domestic, Foreign Facilities and Commercial Importers** (*pages 3-9; 89-93*): All facilities registered under the Bioterrorism Act of 2002 (including foreign facilities shipping products to the United States) would be required to reregister annually. Management would be required to include: 1) the name, address and emergency contact information for the facility; 2) the primary purpose and business activity (including the dates of operation if a seasonal business like some country elevators); 3) all trade names associated with the facility’s food-related products; 4) contact information for any U.S. distribution agent used by the facility; 5) the name, address and emergency contact information for the U.S. agent of any foreign facility shipping products to the United States; and 6) the unique facility identification number assigned by the Food and Drug Administration (FDA). Changes to the information would be required to be submitted to FDA by the facility within 30 days, unless otherwise specified by FDA.

FDA would be empowered to suspend the registrations of facilities – in effect, shutting them down – for violations that “could result in serious adverse health consequences or

death to humans or animals.” [Emphasis added.] Any products shipped by facilities whose registrations have been suspended – or which are required to register, and don’t – would be deemed to be misbranded under the Federal Food, Drug and Cosmetic Act. There is no requirement that FDA offer a streamlined short form for facilities to reregister if there have been no changes in the required information.

The bill also would require importers, customs brokers and filers to register with the agency. As a condition of their registration, importers would be required to implement “good importer practices,” including verifying the good manufacturing practices and preventive controls of their suppliers.

2. **User Fees** (*pages 9-17; 44-45; 87-89; 93-96*): The bill would require FDA to impose the following fees:

- \$1,000 annual facility registration fee for **all domestic and foreign facilities** required to register with FDA under the Bioterrorism Act, starting in fiscal year 2010 (which begins Oct. 1, 2009) and ending in fiscal year 2015 (which begins Oct. 1, 2014). There are estimates that this facility registration fee alone would generate \$375 million in additional funds annually for FDA.
- An unspecified annual registration fee for importers, customs brokers or filers. Thus, for imported products, both the foreign facility and the importer would pay separate fees.
- Fees would be required to be adjusted annually for inflation, based upon the greater of the change in the urban Consumer Price Index; change in the government’s GS pay schedule; or change in the cost of the salary and benefits for full-time FDA employees for five of preceding six years.
- Separate fees to compensate FDA for the actual costs of: 1) reinspecting facilities that fail FDA inspections (*the bill does not specify that the FDA commissioner would need to authorize reinspections*); 2) conducting product recalls; and 3) issuing export certificates for FDA-regulated products.

The bill provides no basis to justify the level of user fees that would be assessed. Funds generated from the user fees would be funneled into FDA’s general revenues, not to a dedicated account to pay for food/feed safety functions performed by the agency. The bill contains no constraints on FDA expenditures for food safety activities. It specifically considers the following costs to be associated with FDA’s food-safety activities: 1) salaries and benefits for FDA officials and employees; 2) the use of contractors; 3) functions performed by advisory committees; 4) laboratory capacity; 5) management of information and technology resources; 6) facility leasing, maintenance and repairs; and 7) fee-collection activities.

3. **Hazard Analysis and Preventive Controls** (*pages 17-23; 27-28*): The bill would require all U.S. and foreign facilities required to register with FDA under the Bioterrorism Act to conduct an analysis to identify biological, chemical, physical and radiological hazards, natural toxins, pesticides, drug residues, allergens, unapproved food/feed additives and other potential hazards – both unintentionally and intentionally introduced – that could adversely affect human or animal health. Facilities would be required to conduct such a hazard analysis at least every two years.

Establishments then would be required to “identify, implement and validate effective preventive controls” for hazards “reasonably likely to occur” to “prevent, eliminate or reduce (them) to acceptable levels,” and to conduct follow-up monitoring to determine the effectiveness of the controls, including through use of environmental and product-testing, “as appropriate.” The preventive controls would be required to be those practices, procedures or processes that a “person knowledgeable” about the safe manufacturing, processing, packing, transporting or storage of the product would use, and which are “consistent with current scientific understanding.” The bill specifically references current good manufacturing practices as being one such set of procedures. The bill defines “reasonably likely to occur” to mean what a “prudent person” involved in the business would do based upon “experience, illness data, scientific reports or other information.” Facilities would be required to revise their preventive controls if there is a change that “could” affect the hazard analysis, or if FDA determines a change is needed to protect public health.

The bill also would authorize FDA – by regulation or guidance – to identify specific hazards “reasonably likely to occur” in different types of facilities or products. Further, it would require facilities to implement any preventive controls identified by FDA through either regulation or guidance. This would convolute the FDA guidance-document process – under which FDA provides recommendations, advice and its reasoning, but under which neither the industry nor the agency are bound. It also would allow the agency to short-circuit the regulatory process, imposing *defacto* regulatory requirements without the transparency and rigor required by rulemaking, such as responding to public comments and conducting cost-benefit analyses.

The bill’s “corrective actions” and “verification” sections (page 20) contain the extremely troubling use of the term “**ensure**” that could create huge legal liability risks and obligations for facilities – and a presumption of guilt – in the event their preventive controls fall short. Here are three specific examples:

- Facilities, when establishing and implementing preventive controls, would be required to “**ensure**” that if such controls are not fully implemented or are ineffective, that no product enters commerce and that “appropriate action” is taken to reduce the likelihood of a recurrence.
- Facilities would be required to “**ensure**” that preventive controls have “been validated as adequate” to control the identified hazards.

- Contradicting the bill’s earlier statement that environmental and product testing should be done by facilities “as appropriate,” this section states that facility owners, operators or agents “**shall ensure**” that preventive controls have been validated as adequate and effective, including through the use of environmental and product testing.

Records of the hazard analysis and preventive controls (including monitoring, verification and corrective actions) would be required to be maintained for two years, although the bill would authorize FDA by rulemaking to increase the record-retention requirement to three years, and require that records be maintained in a standardized electronic format (see page 37).

FDA would be required at least every two years to review data to identify the most significant food-borne contaminants and most significant resulting hazards, and would be required to issue updated standards – again either through regulation or guidance.

This section of the bill would take effect 18 months after enactment, except that “small” and “very small” businesses – as determined by FDA – would have two years or three years, respectively. For facilities not in compliance, any products in interstate commerce would be deemed to be misbranded.

- 4. Written Food Safety Plans (pages 23-28):** The bill would require facilities to implement a written food safety plan that includes: 1) a hazard analysis; 2) a description of preventive controls; 3) procedures for monitoring, verifying and taking corrective actions related to the controls; 4) and descriptions of the facility’s procedures for recordkeeping, product-tracing, recall and ingredient supply chain safety. FDA would be authorized – again through regulation or guidance – to establish “science-based standards” governing these activities, although it would be required to consider the impact on small business. Facilities that fail to develop written food safety plans would be deemed to have misbranded products if shipping in interstate commerce. Unlike previous drafts, the bill would not expressly authorize FDA to review facilities’ food safety plans; but that likely is not necessary for the agency given the expansive records-access granted in the bill (see item #7).

This section would take effect 18 months after enactment, except that “small” and “very small” businesses – as determined by FDA – would have two or three years, respectively, to comply.

- 5. Safety Standards for Raw Ag Commodities (pages 29-32):** The bill would require FDA within three years to develop and implement final regulations setting “minimum standards” for safe growing, harvesting...and holding (storage)” of raw ag commodities (*e.g., including on farm*) if required to minimize the risk of “serious adverse health consequences or death to humans or animals.” It specifically references naturally occurring hazards (*e.g., mycotoxins*). The bill also specifically cites “manure, water quality and employee hygiene, sanitation and animal control and temperature controls”

that FDA determines to be “reasonably necessary.” It does direct that FDA provide a “reasonable period of time for compliance.”

6. **Mandated Inspection Schedule** (*pages 32-36*): Within 18 months after enactment, the bill would require FDA to conduct inspections of all facilities registered under the Bioterrorism Act. Domestic facilities would be required to be inspected by federal, state or local agencies recognized by FDA. Foreign facilities exporting products to the United States would be required to be inspected on the same schedule by an agency or representative of the foreign country, as recognized by FDA. The bill would create three classes of facilities, with a specific inspection frequency mandated for each. High-risk facilities (category 1) would be required to be inspected “at least” every six to 18 months. Low-risk facilities (category 2) would be required to be inspected “at least” every 18 months to three years. Warehouses that merely hold food or feed (category 3) would be required to be inspected “at least” every three to four years. FDA could deviate from this inspection schedule only if it needs the resources to respond to foodborne illness outbreaks or food recalls.
7. **FDA Access to Records** (*pages 36-39; 96*): The draft bill would dramatically expand FDA’s access to facility records. It states that FDA can access and copy “**all** records...relating to the production, manufacture, processing, packing, transporting, distribution, receipt, holding (storage), or importation” of food, feed or agricultural products that could bear on whether the product is adulterated, misbranded or otherwise violative. The bill also would expressly encompass farms and restaurants 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 current Bioterrorism Act limitation on records-access, which currently 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.”

FDA would have similar authority to access of importers, customs brokers and filers importing food, feed, feed ingredients and other agricultural products into the United States.

8. **Product Tracing** (*pages 39-43*): The bill would dramatically expand the current Bioterrorism Act’s product-tracing requirement that facilities maintain records sufficient to identify the immediate previous source of the agricultural products and ingredients they receive, and next subsequent recipient to which they ship – the so-called “one-step-forward/one-step back” requirement. Instead, the draft bill would mandate that FDA require facilities that produce (including farms that don’t sell products directly to final consumers or restaurants), manufacture, process, pack, transport or store agricultural commodities, food, feed or feed ingredients have a record – in a standardized format – of the complete history of the origin and previous distribution (pedigree) of any such products, as well as the subsequent distribution history of the finished products that it receives, stores, handles or manufactures. The bill also would require facilities to purchase interoperable product tracing systems and to maintain records in a standardized

electronic format so they could be accessed by FDA, and presumably by others in the food/feed chain. Further, the bill would mandate that FDA, if it deems appropriate, require the establishment of additional information – including lot numbers, which the Bioterrorism Act does not require.

The bill attempts to “soften” these onerous requirements by stipulating that FDA, before issuing regulations implementing such product tracing, first identify appropriate technologies, convene public meetings and conduct a pilot program. It also would authorize FDA to exempt specific foods from this tracing system if “not necessary to protect public health.”

9. **Certification for Imports** (*pages 45-53*): Within three years after enactment, the bill would require FDA to implement a risk-based approach for certifying imported products. Unlike previous drafts, the bill no longer would restrict imports to specific ports of entry or require certification of all imports. But it would require FDA to make a determination as to whether requiring certification of imported products by a foreign government or other recognized body would be appropriate, given the health risk associated with the product, the foreign country or region involved, or adequacy of government controls in those foreign countries. FDA would be authorized to reach agreements with foreign countries providing for such certification. Certification could be done by an agency or representative of the foreign government or an individual or entity determined to be qualified by FDA. The bill contains extensive conflict-of-interest protections pulled from FDA’s most recent guidance document, including one suggested to FDA by the NGFA that certifying entities be independent from trade associations whose member companies operate facilities being certified.

Importantly, the bill does not authorize FDA to accredit third-parties for inspections of domestic facilities.

10. **Laboratory Accreditation** (*pages 53-56*): The bill would require FDA to establish a program to recognize laboratory accreditation bodies and to accept test results only from duly accredited labs. It also authorizes FDA to require laboratories to send test results to FDA.
11. **Recall, Administrative Detention and Quarantine Authority** (*pages 57-63; 78-80*): Facilities would be required “as soon as practicable” to notify FDA if a shipment introduced in interstate commerce is adulterated or misbranded to an extent that it poses a “reasonable probability” that it “will” cause serious adverse health consequences or death to humans or animals. The bill authorizes the secretary to request companies to initiate a voluntary recall, but also provides new authority enabling FDA to order facilities to cease distribution immediately if the agency has “reason to believe” that the product(s) “may cause adverse health consequences or death to humans or animals” – a relatively low threshold. [*Emphasis added.*] If FDA issues such an order, facilities would have 24 hours to request an informal hearing to appeal the order. But there is no obligation for FDA to grant such a hearing, and distribution would be required to cease regardless of whether an informal hearing is requested or granted.

The way the bill is structured, FDA would be authorized to implement a mandatory recall after issuing the order to cease distribution. But the bill also would authorize FDA to issue an “emergency recall order” if it has a “reasonable belief” that a product “presents a threat of serious adverse health consequences or death to humans or animals.” The facility that is subject to such an emergency recall order would have 24 hours to appeal; but, again, FDA would not be obligated to grant an informal hearing.

The bill also would reduce the threshold for FDA to detain a product. Specifically, the bill would delete the current Bioterrorism Act threshold, which requires FDA to have “credible evidence or information indicating” the product is adulterated and “presents a threat of serious adverse health consequences or death to humans or animals.” That stipulation would be replaced by a new standard that requires that FDA only have a “reason to believe” that a product “is adulterated, misbranded or otherwise in violation” of the bill. The new standard would take effect within 180 days after enactment.

Finally, the bill would give FDA new authority to quarantine products within “any geographical area” if it has “credible evidence” that the product “presents a threat of serious adverse health consequences or death to humans or animals.”

- 12. Reportable Food Registry (pages 63-70):** The bill would expand the persons required to submit notices to the reportable food registry (for products that rise to the danger of a Class I recall) to include farms, restaurants and retail food establishments. The bill also would require entities that ultimately report a product through the registry to also report any analytical test results pursuant to such products. This section also contains authority for FDA to share “any information” that is exempt from disclosure with states, foreign governments, international organizations and the public, if necessary to protect public health.
- 13. Food Import Program (pages 70-71):** The bill incorporates the Grocery Manufacturers Association-supported concept of authorizing FDA to expedite imports of ingredients or products if the importer verifies that each facility involved in producing, manufacturing, processing, packaging and storing the product complies with U.S. product safety requirements, and that “appropriate” safety and security controls are implemented “throughout” the supply chain for such products.
- 14. Ranking Food Categories Based on Hazards to Human Health (pages 73-75):** The bill would require FDA to assess the frequency and sources of human food-borne illnesses in the United States, and authorize the agency to rank food categories based upon their hazards to human health. The bill suggests that such rankings should compare the safety of “commercial” production, harvesting and processing systems versus small-scale, subsistence farming, as well as domestic versus foreign production systems. It also recognizes contamination associated with consumers’ food-handling practices, and would require a “national public education program” on food safety, including consumer education.

- 15. Research (pages 76-78):** The bill would require FDA to conduct research on a variety of food-safety matters, including: sanitation and food safety practices used in food processing; developing efficient, rapid methods for detecting contaminants; determining the sources of contamination; identifying common and emerging zoonotic diseases; methods for destroying pathogens; and analyzing antibiotic resistance and developing new methods for reducing the transfer of such resistance to humans. Unlike a previous draft, this version would not ban the subtherapeutic use of seven classes of antibiotics in food-producing animals.
- 16. Criminal and Civil Penalties (pages 81-84):** The bill would increase criminal penalties to up to 10 years imprisonment for those found to “knowingly violate” certain provisions of the “prohibited acts” (Section 301) of the Federal Food, Drug and Cosmetic Act – specifically the provisions governing adulteration, misbranding, labeling and dietary supplements. The bill also proposes a “one-size-fits-all” civil penalty structure, in which any violation of Section 301, even for unintentional violations, would be subject to fines of \$100,000 per individual and \$500,000 for companies for each violation. There would be no cap on total fines that could be levied for a single inspection involving multiple violations. This would enable FDA to generate extensive funds by having inspectors issue citations for violations, including those that do not pose risks to human or animal health (*e.g., a labeling violation*).
- 17. GRAS Program (pages 85-86):** The bill would require FDA to post on its website documentation it receives in support of generally recognized as safe (GRAS) notifications.
- 18. Country-of-Origin Labeling (pages 86-87):** The bill would require all non-processed food products (which would encompass raw ag commodities, like grains and oilseeds) to identify the country-of-origin of the product. Further, the website of the “original packer” of the food would need to identify the country of origin. For processed products (which would encompass feed, feed ingredients and pet food), the label would be required to identify the country in which the final processing occurs, while the website of the manufacturer would be required to identify the country(ies) of origin for every ingredient contained in the finished product. This labeling also ostensibly would apply to products of U.S. origin.
- 19. Inspections of Foreign Establishments (pages 102-104):** The bill would prohibit foreign establishments, including farms, from delaying, limiting or refusing to permit an inspection. It also would require FDA to establish a “dedicated corps of inspectors” to inspect foreign food, drug, medical device and cosmetic facilities and establishments sufficient to achieve the inspection frequency mandated in the bill.
- 20. New Subpoena Powers for FDA (pages 105-110):** The bill would grant FDA new subpoena powers to order domestic or foreign establishments to appear to provide testimony at hearings, investigations or other proceedings conducted by the agency.