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New Food/Feed Safety Law – Impacts on Grain Elevators, Feed Mills, Processors, Millers and Exporters

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It's been called the most important revision of the nation's food and feed safety laws since the Great Depression, when Congress enacted the federal Food, Drug and Cosmetic Act in 1938.

Back then, the reforms – which replaced the Pure Food and Drug Act of 1906 – were spurred by a drug-poisoning incident – known as the elixir sulfanilamide event – that killed more than 100 people. But this time around, the impetus for congressional action was several high-profile food contamination incidents, including peanut butter contaminated with *Salmonella* typhimurium and several incidents of foodborne illnesses associated with consumption of eggs, jalapeno peppers, spinach and other leafy greens.

On balance, the new law – signed by President Obama on Jan. 4 and dubbed the "FDA Food Safety Modernization Act" – takes a science- and risk-based approach to food and feed safety. Notable from a regulatory perspective, it also mandates that the Food and Drug Administration (FDA) and regulated commercial facilities take a prevention-based approach to food and feed safety.

But make no mistake. The new law significantly expands FDA's authorities and regulatory reach, and will result in several significant new regulatory requirements for the wide swath of the food industry, including facilities in the grain, animal feed and feed ingredient, grain processing, milling, pet food, biofuels *(for distillers dried grains used as feed ingredients)* and export sectors.

As an aside, despite the high-profile food safety outbreaks that generated unstoppable momentum for the new law, the United States continues to have one of the – if not **the** – safest and most abundant food and feed supplies the world has ever known. That was borne out in a couple of recent reports issued by the U.S. Centers for Disease Control (CDC), a branch of the same parent federal department (the U.S. Department of Health and Human Services) that houses FDA.

- In a report released in the fall of 2010, the CDC reported that the number of reported food-borne outbreaks declined 8 percent in 2007 (the most recent year for which final data were available). Further, the number of human illnesses associated with those outbreaks had declined 15 percent compared to the previous year.

- In a subsequent posting on its website in December, the CDC released preliminary 2009 data that showed a continuation of this improving trend. Compared to the 1996-98 period, the agency found that rates of infection in 2009 from foodborne pathogens were lower for *Shigella (the Shiga toxin that produces E coli.)* (55 percent decrease); *Yersinia* (53 percent decrease); STEC O157 (41 percent decrease); *Campylobacter* (30 percent decrease); *Listeria* (26 percent decrease); and *Salmonella* (10 percent decrease). Rates were higher for *Vibrio* (85 percent increase).

This article provides an overview of the most significant provisions of the new law that apply to NGFA-member companies, what they will require and some preliminarily projected time frames for implementation.

Food/Feed Safety Law – Key Requirements for Facilities At-A-Glance

- Develop, Implement Written Food/Feed Safety Plan
  - Analyze "known or reasonably foreseeable" hazards that could cause products to be adulterated, misbranded (both unintentional and intentionally introduced hazards, including by terrorist acts)
  - Implement risk-based, reasonably appropriate" controls to prevent, minimize hazards
  - Monitor effectiveness of controls, including through product testing; implement corrective actions; maintain records for two years documenting monitoring, corrective actions taken
  - Reanalyze hazards, preventive controls at least every three years; sooner if significant changes in facility activities, processes occur that creates "reasonable potential" for new or increased hazards
- Develop, Implement Written Food/Feed Defense Plan (for high-risk products only)
- Update facility registration with FDA between Oct. 1 and Dec. 31 every-other-even-numbered year, starting in 2012
- Provide increased access to existing records to FDA if agency provides written notice it has "reasonable belief" products pose threat of serious adverse health consequences or death to humans or animals
- Develop, implement foreign supplier verification program if importing food (including feed ingredients) for consumption by humans, animals in United States
- Pay fees to FDA if reinspected, subject to mandatory recall, utilizing FDA export certificates or participating in Voluntary Qualified Importer Program

Facilities Covered by the New Food/Feed Safety Law

The new law applies to all facilities required to register with FDA under the Bioterrorism Act of 2002. Under the Bioterrorism Act, that registration requirement applies to facilities – both domestic and foreign – that manufacture, process, pack, or hold (store) food.

Importantly, the term "food" is as defined in the federal Food, Drug and Cosmetic Act, which covers products intended for consumption by humans or animals in the United States. It also applies to such products regardless of whether they are shipped in interstate or intrastate commerce.

Thus, under this broad umbrella, the law applies, among others, to:

- grain elevators;
- feed and feed ingredient and pet food manufacturers;
- grain processors, including corn and flour milling operations, soybean processors and others;
- biofuels producers manufacturing coproducts like distillers dried grains for use as feed ingredients; and
- exporters of grains, feed and feed ingredients, and processed commodities.

Most Significant Requirements for Affected Facilities

By far the most significant section of the new law for most covered facilities will be the requirements to perform the following tasks:

- **Hazard Analysis:** Conduct and develop a written analysis of **hazards** that are "known or reasonably foreseeable" that may exist in their operations. This is to include biological, chemical and physical hazards, natural toxins (e.g., mycotoxins), pesticides, drug residues, decomposition and unapproved additives. While focused primarily on unintentional contamination incidents, the law also specifically requires that facilities evaluate hazards that may be "intentionally introduced, including by acts of terrorism."

- **Preventive Controls:** Implement **controls** that the facility develops to prevent or minimize identified hazards *(intentionally or unintentionally introduced)* so that the product is not adulterated or misbranded under the federal Food, Drug and Cosmetic Act. Importantly, the law defines preventive controls as "risk-based and reasonably appropriate" measures "consistent with current scientific understanding" that a person "knowledgeable about the safe" manufacturing, processing, packing or storage of products would use to "significantly minimize or prevent" such hazards. Further, the law specifically recognizes current good manufacturing practices (CGMPs) as one of several acceptable methods for meeting the preventive control requirements.

  In addition, the owner, operator or agent in charge of the facility will be required to monitor and verify the adequacy and effectiveness of those controls, including through product and environmental testing. In addition, facility management will be required to implement procedures for correcting controls that either are not implemented or found to be ineffective, and take steps to prevent resulting products that may have been adulterated or misbranded from entering commerce. Finally, facility management will be required to maintain records for at least two years documenting monitoring of the preventive controls they implement, instances of nonconformance and corrective actions taken, and the results of testing done as part of such monitoring.

- **Written Food/Feed Safety Plan:** Develop and implement a **written food/feed safety plan** that documents and describes the procedures used by the facility to comply with the aforementioned hazard analysis and preventive control requirements. FDA inspectors will be authorized to access and review the facility's food/feed safety plan and records associated with the implementation and monitoring of preventive controls, with appropriate confidentiality protections.

- **Food/Feed Defense Regulations:** While the law requires facilities to analyze "known or reasonably foreseeable hazards" that could be intentionally introduced, including by acts of terrorism, the law limits FDA's issuance of regulations for mitigating such hazards to **"high-risk" products** – determined by FDA after conducting vulnerability assessments . The focus is on products with a short shelf life or susceptibility to intentional contamination, or that are in bulk or batch form prior to packaging to final consumers. Given vulnerability assessments that already have been conducted of the grain and feed manufacturing sectors, it is questionable such regulations will be imposed on these industry sectors by FDA.

- **Reanalyze Hazards and Preventive Controls:** Facility managers will be required to **reanalyze hazards and preventive controls**, as well as update their written food/feed safety plans if needed, at least every three years or sooner if a significant change is made in activities or processes used at the facility that creates a "reasonable potential" for a new hazard or a significant increase in a previously identified hazard.

- **Special Flexibility for Raw Commodity Storage (e.g., Grain Elevators), Animal Feed, Pet Food:** Very importantly, the law contains a provision that the NGFA helped draft that specifically authorizes – but does not require – FDA **to exempt or modify the requirements for hazard analysis, preventive controls and written food/feed safety plans for facilities "solely engaged" in the production of animal food (including pet food) and the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing**. This important language encompasses elevators and other commercial facilities storing raw grains and oilseeds. Among other things, this language is designed to preclude FDA from implementing unreasonable requirements (such as allergen controls or sanitation standards) that are inappropriate for raw commodities and animal feed.

- **Implementation:** The law requires FDA within 18 months of enactment (on or about July 2012) to develop and implement minimum standards (regulations) to implement these aforementioned requirements. However, there is expected to be a phase-in period before the regulations are enforced.

Other Key Requirements: The new law also contains the following requirements for facilities:

- **Renewing Facility Registrations:** The law mandates that domestic and foreign facilities required under the Bioterrorism Act to register with FDA renew and update

those registrations every two years. This requirement is designed to rectify the problem that FDA has experienced with facilities not correcting or updating their registration information, despite the requirement to do so under the Bioterrorism Act. The registration renewals will be required between Oct. 1 and Dec. 31 of even-numbered years, starting in 2012. Importantly, the law includes an NGFA-drafted provision that requires FDA to provide an abbreviated registration process (such as a short form) for facilities that have not had any changes to the required information. It also states that FDA cannot require registration to be done electronically until five years after enactment (on or about Jan. 4, 2016); this will be a change from FDA's current requirement that facilities registering under the Bioterrorism Act do so exclusively through electronic means.

- **Safety Standards for Produce:** The only product-safety standard that FDA specifically is required to issue under the new law is for produce, such as fruits, vegetables and leafy greens (lettuce, spinach, etc.). This requirement may affect some ingredient suppliers to the feed industry (such as citrus pulp, etc.). The agency is required to issue proposed regulations within a year (by January 2012), with a final rule to be issued a year thereafter (by January 2013).

Inspection Frequency for Domestic Facilities

FDA is required to inspect "high-risk" domestic facilities within five years of enactment and every three years thereafter. In determining which facilities are "high risk," FDA is to consider: 1) the known safety risks of the product(s) being manufactured, processed, packed or stored at the facility; 2) the facility's compliance history, including previous food recalls or linkage to foodborne illness outbreaks; 3) the "rigor and effectiveness" of the facility's hazard analysis and risk-based preventive controls; and 4) other relevant criteria.

All other domestic facilities not classified by FDA as "high risk" are required to be inspected within seven years of enactment and every five years thereafter. It is anticipated that virtually all grain elevators, feed mills and feed ingredient manufacturers will not be classified as high risk.

The law sets a goal of FDA hiring 1,000 additional field personnel, principally inspectors, by fiscal year 2014. But the agency's ability to achieve that hiring goal and the mandated inspection frequencies will depend greatly on whether Congress appropriates sufficient funding, as this represents the bulk of the estimated cost of the bill ($1.4 billion cost over five years). It also is likely that FDA will seek to leverage its inspection resources by entering into agreements with state regulatory officials to conduct inspections on its behalf. In that respect, FDA already has a model – its utilization of state feed inspectors to conduct certain compliance inspections on its behalf.

New, Increased Authorities for FDA

The new law grants several new powers to FDA, including the following:

- **Authority to Set Contaminant-Specific Standards:** The law requires FDA, in coordination with the U.S. Department of Agriculture, to evaluate every two years relevant health data, new science and assorted other studies and information to determine whether it is appropriate to set contaminant-specific and science-based regulations or guidance documents, including but not limited to guidance documents regarding action levels for various contaminants. If issued by FDA, the law requires that such regulations or guidance be specific to products or product classes, but not be facility-specific. **Importantly, the law includes a provision the NGFA helped draft that requires FDA, where appropriate, to differentiate between animal feed (including pet food) and human food when issuing any such regulations or guidance**.

- **Suspension of Facility Registration:** The law authorizes FDA to suspend a facility's registration – in essence, shutting it down – if it determines there is a "reasonable probability" that its products could "cause serious adverse health consequences or death" to humans or animals. If this threshold is met, FDA would have the authority to suspend the registration of: 1) the facility that created, caused or otherwise was responsible for the adulteration; or 2) any facility that packed, received or stored such products and knew of, or had reason to know, that it was handling such a product. Importantly, in another provision the NGFA helped draft, a suspension could be ordered only by the FDA commissioner – not by an individual inspector or FDA district or regional office. Further, the law requires FDA to provide the affected facility with an opportunity for an informal hearing to contest the suspension order not later than two business days after it is issued, unless the facility and FDA mutually agree to an extension. The law also authorizes the affected facility to submit a corrective action plan to FDA to resolve the reason for the suspension, and requires the agency to consider such a plan generally within 14 days after it is submitted.

This facility suspension provision takes effect within 180 days after enactment (on or about July 4) unless FDA issues regulations prior to that time.

- **Records Access:** FDA is authorized to access existing facility records *if* it has "reasonable belief" that a product presents a threat of serious adverse health consequences or death to humans or animals *and* the agency "reasonably believes" other products are "similarly" affected. Importantly, FDA's access is limited to records relating to the manufacture, processing, packing, distribution, receipt, storage or import of products that meet these aforementioned criteria and danger threshold. FDA also is required to provide written notice before accessing such records. This provision is effective immediately.

- **Enhanced Product-Tracing:** FDA is required within nine months to conduct one or more pilot programs exploring ways to improve tracking/tracing of food, which is focused primarily on packaged food and raw fruits/vegetables. The pilots are to be completed by July 2012. The agency is required to issue proposed regulations within two years after enactment (by January 2013) establishing additional recordkeeping requirements for product-tracing solely for "high-risk" foods, which FDA would be required to designate within one year after enactment (by January 2012) based upon the product's history and severity of foodborne illness outbreaks. The law further requires that any future recordkeeping be reasonable, scale-appropriate, cost-effective, practical and demonstrably beneficial to public health.

  Importantly, the law prohibits FDA from imposing recordkeeping requirements that would limit the commingling of raw agricultural commodities (except raw fruits, vegetables), a provision that the NGFA assisted in authoring. Further, it states that facilities handling such raw commodies on a commingled basis are subject to the existing Bioterrorism Act requirement to maintain records sufficient to identify the immediate previous surce and immediate subsequent recipient of the product(s). It is anticipated that the law's potential enhanced product-tracing and recordkeeping requirements will have a negligible impact on grains, oilseeds and most feed and feed ingredients, given the requirement that it be applied to "high-risk" products.

- **Mandatory Recalls:** Effective immediately, FDA for the first time is authorized to issue mandatory recalls if it determines there is a "reasonable probability" that an article of food (other than infant formula) is adulterated or misbranded, and that use of, or exposure to, the product would cause serious adverse health consequences or death to humans or animals. Such action would require the concurrence of the FDA commissioner, and could not be delegated to a lower-ranking official. Failure to comply with a mandatory recall order would trigger a civil money penalty of up to $50,000 per individual and $250,000 for any other involved entities, not to exceed $500,000 for all related violations.

  Importantly, FDA first would be required to give the facility the opportunity to voluntarily cease distribution and recall the product within a time frame and in a manner prescribed by the agency, as currently occurs. If a company declines to conduct a voluntary recall, FDA is authorized to issue a cease-distribution order and direct that the firm notify subsequent receivers of the product and initiate a mandatory recall. The firm subject to the mandatory recall order would be given the opportunity for an informal hearing within two calendar days with FDA to contest the agency's findings. FDA has said based upon previous experience with voluntary recalls, it anticipates using the mandatory recall authority very sparingly.

- **Administrative Detention:** FDA is authorized to administratively detain a product when it has "reason to believe" that it is adulterated or misbranded. This is a lower standard than the current Bioterrorism Act threshold that requires FDA first to have "credible evidence or information" indicating that the product "presents a threat of (causing) serious adverse health consequences or death to humans or animals." The agency is required within 120 days (by May 2011) to issue an interim final rule to implement this provision. Regardless, the law requires that this provision take effect within 180 days after enactment (July 2011).

- **Fees:** FDA is required to assess fees to: 1) compensate the agency for the actual cost of reinspecting facilities that fail an original inspection *(total cap of $25 million annually)*; 2) compensate for the actual cost of conducting mandatory recalls *(capped at $20 million annually)*; 3) implement a so-called Voluntary Qualified Importer Program *(discussed in next section)* that provides for expedited entry of imports from trusted suppliers; and 4) compensate for the actual cost of issuing export certificates for food and animal feed/ingredients *(capped at $175 per certificate)*. These fees likely will take effect starting later this year.

- **Sanitary Transportation of Food/Feed:** FDA is required within 18 months after enactment (by July 2012) to implement regulations governing the use and cleanliness of conveyances used to transport food, commodities, feed and feed ingredients, and other products. This provision is designed to again reiterate Congress's mandate that FDA implement a law first passed in 1990. FDA rulemaking on this already is underway, and proposed regulations could be issued later this year. The impact could be significant, depending upon whether the agency recognizes appropriate clean-out measures rather than expressly banning certain types of conveyances based upon previously hauled products, and puts responsibility on carriers to provide appropriately clean equipment.

Impacts on Importers of Ingredients

In an effort to enhance the safety of imported food, feed and feed ingredients, the new law is intended to apply the same product-safety standards to foreign facilities exporting products intended for use in the United States. The following are among the most important requirements applying to importers and foreign facilities:

- **Foreign Supplier Verification Program:** The new law requires importers to develop a risk-based program to verify that imported products: 1) offer the "same level of public health protection" as U.S. standards *(through "reasonably appropriate risk-based preventive controls")*; 2) are not adulterated or misbranded; and 3) do not contain undeclared allergens. Specifically, the law requires importers to engage in various foreign supplier verification activities, which "may" include monitoring shipment records, lot-by-lot certification by an accredited third party, annual on-site inspections of foreign suppliers, checking the hazard analyses and preventive controls implemented by foreign suppliers, and conducting periodic sampling and testing of imported shipments. Importers are required to maintain records for two years of foreign supplier product-safety verification activities they undertake. FDA is to issue regulations and guidance within one year of enactment (January 2012) specifying the content of importers' foreign supplier verification programs, with such regulations taking effect a year thereafter (January 2013). FDA is required to consider risk-based differences in imported products when establishing such rules.

- **Voluntary Qualified Importer Program:** The law establishes a Voluntary Qualified Importer Program designed to expedite imports from trusted suppliers. To qualify, the importer is required to submit an application to FDA and the foreign facility is required to undergo a third-party inspection. Other eligibility considerations include: 1) the nature of the food; 2) the risk of intentional adulteration of the product; 3) the compliance history of the foreign supplier; 4) the exporting country's capacity to ensure compliance of the facility with U.S. standards; and 5) the recordkeeping, testing, facility inspections and audits, traceability capabilities and sourcing practices of the importer. Imported products from participating facilities are required to be accompanied by a certificate from: 1) the agency or government of the originating foreign country; 2) from an accredited third party; or 3) some other assurance FDA deems appropriate that attests to its safety. FDA is required within 18 months of enactment (July 2012) to issue guidance regarding the program.

- **Inspections of "High-Risk" Foreign Facilities:** The law requires FDA to inspect 600 "high-risk" foreign facilities during the first year after enactment, and to double that number every year for each of next five years. Participation of a foreign supplier in the Voluntary Qualified Importer Program will be one of the factors FDA uses to determine which foreign facilities are inspected. Again, FDA's ability to achieve this objective will depend greatly on whether Congress appropriates the funds needed to hire additional FDA inspectors. The law also authorizes FDA to enter into agreements with foreign countries to facilitate inspection of "high-risk" facilities registered under the Bioterrorism Act.

- **Establishment of FDA Offices in Foreign Countries:** FDA is required to establish offices in foreign countries – in consultation with U.S. Departments of State and Homeland Security, and U.S. Trade Representative's Office – to facilitate inspections of foreign facilities and support foreign government food safety capacity building. The law does not specify which countries or the number of offices. It does mandate that FDA report to Congress on the implementation of this provision by Oct. 1, 2011. FDA, under its own initiative and authority, already has established such offices in a number of foreign countries, including China and India.

- **Compliance with International Trade Agreements:** FDA is required to implement the entire law in a manner consistent with the World Trade Organization and all other treaties and international agreements to which the United States is a party – a provision that the NGFA drafted. But implementation will require close monitoring to avert trade disputes and retaliatory counter-measures being imposed upon U.S. exporters.

Conclusion

The specific requirements implementing the new law will be developed by FDA in what are expected to be dozens of rulemakings over the course of the next two-plus years.

The NGFA already offers several tools that the industry can use to begin preparing. The association's ***Model Feed Quality Assurance Program***, developed in 1994 and updated periodically, has relevance to many of the requirements likely to be applied to commercial feed mills and ingredient suppliers. And the NGFA's ***Facility Risk-Assessment and Security Guide***, updated in September 2009, offers a fill-in-the-blank template for meeting the law's food-defense requirements.

The NGFA will be updating these and developing additional compliance guidance for NGFA members as FDA's rulemakings unfold.