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ALERT

Comprehensive Food Safety Bill Enacted

January 5, 2011

After complex legislative maneuvering, Congress passed, and on January 4, 2011, President Obama signed, the *FDA Food Safety Modernization Act*, H.R. 2751, which represents the most significant overhaul of the regulatory scheme for food safety in 70 years. The new law will impose significant new burdens on manufacturers, processors and packers of human and animal foods and gives the Food and Drug Administration (FDA) substantial new enforcement powers designed to further enhance the nation's food safety. Many aspects of the new law remain to be implemented by further FDA regulations, and questions remain whether FDA will receive adequate funding to fully implement its new powers, but the practical impact of the law on the food industry will be immediate and significant. Among the law's major provisions, some of the key changes industry can expect include:

Hazard analyses, preventative controls, corrective actions and verification of compliance. The law imposes significant new obligations on manufacturers, packers and other registered food facilities by requiring each facility to evaluate and develop a written analysis of "known or reasonably foreseeable hazards" that could affect food at the facility. Potential hazards that must be evaluated include biological, chemical, physical, radiological and naturally occurring hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens and unapproved food and color additives.

Based on the hazard analysis, facilities must implement "preventative controls" that will "significantly minimize or prevent" such hazards and assure that food is not misbranded or adulterated. Preventative controls may include sanitation procedures, training, environmental monitoring programs, food allergen control programs, recall plans,

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Good Manufacturing Practices (GMPs) and supplier verification activities. A "reanalysis" is required whenever a significant change occurs that creates a "reasonable potential for a new hazard or a significant increase in a previously identified hazard" *or* every three years, whichever is earlier. Reanalysis must be conducted prior to any change being implemented. Each facility must monitor the effectiveness of its controls and maintain records of such monitoring. Facilities are also required to establish prospective corrective action procedures to be followed in the event that the preventive controls are not properly implemented or are found to be ineffective in minimizing food safety risks.

These requirements come with two important enforcement hooks. First, failure to conduct a hazard analysis and employ preventative controls is a prohibited act under the Food, Drug and Cosmetic Act (FDCA), and violators may be subject to civil or criminal enforcement action. Second, the owner, operator or agent in charge of each food facility must sign a substantive verification not merely stating that the facility has implemented the required procedures, but that: (1) the preventive controls are in fact "adequate" and "are effectively and significantly minimizing or preventing the occurrence of identified hazards[;]" (2) the owner, operator or agent "is making appropriate decisions about corrective actions[;]" and (3) there is "documented, periodic reanalysis of the plan...to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility and new and emerging threats."

- The potential liability implications of this verification requirement are significant. First, if FDA were to find a facility's analysis and corrective action plans to be inadequate, the person signing the verification, and potentially the company, could be subject to prosecution for making a false statement to the government under 18 U.S.C. § 1001. Second, the verification could be a damaging piece of evidence in a personal injury lawsuit or a lawsuit by a commercial customer who purchased food from the facility and suffered economic damages where the food has to be recalled or destroyed.

Exemptions: The law provides limited exceptions from these provisions for seafood, juice, low-acid canned foods, certain raw agricultural commodities (other than fruits and vegetables) and dietary supplements. Other specific food safety programs already apply to or are being further developed for such categories of food. In addition, the law provides "modified requirements" for "qualified facilities," specifically, "very small businesses" (to be defined by regulations) and businesses whose annual monetary value of food sold is less than $500,000. The exemption for such qualified facilities is limited and arguably illusory, because such a facility must either document that it has identified potential hazards, is implementing and monitoring preventative controls and is in compliance with all state and local laws, or alternatively, must "prominently and conspicuously" notify customers via the product labeling (if otherwise required) or at the point of sale, of "the name and business address of the facility where the food was manufactured or processed." Moreover, the FDA may withdraw the exemption for a qualified facility "[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility."

- **Animal food facilities, certain agricultural commodities, and packaged food storage facilities.** As written, the law's hazard analysis related requirements apply to all human and animal foods not expressly exempted (as described above), but the law gives the FDA discretion to issue regulations to "exempt or modify the requirements for compliance under this section with respect to facilities that are

solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment."

- **No preemption of state laws.** Notably, the law provides that "[n]othing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law." In other words, compliance with the new law's risk prevention requirements will not automatically shield a company from liability under state law in the event a food causes injury to a consumer, although such compliance may provide evidence that the company was not negligent in connection with any such injuries.

Effective Date. The hazard analysis, preventative controls and compliance verification requirements become effective 18 months after enactment (*i.e.*, July 2012), but given the breadth of the new requirements, companies should promptly begin developing the systems and processes necessary for compliance.

Summary suspension of food registration. The Act gives FDA the power to immediately suspend the registration of a food facility if the agency believes that any food associated with the facility "has a reasonable probability of causing serious adverse health consequences or death to humans or animals." This power extends against any facility that "created, caused, or was otherwise responsible for such reasonable probability," as well as to any facility that "packed, received, or held such food" if the registrant "knew of, or had reason to know of, such reasonable probability." The effect of such a suspension is that the facility may not import, export, or distribute any food unless and until the suspension is lifted. This suspension power becomes operative 180 days after enactment of the law, or earlier if FDA issues regulations to implement these new authorities.

- Under this very broad standard, large-scale food facilities such as distributors, warehouses and repackers that handle items from numerous manufacturers or suppliers could find their entire operation shut down due to a contaminated food received from a single source, merely because FDA believes the registrant "knew" or "had reason to know" that the food at issue could cause adverse health consequences. FDA must promulgate regulations to implement these food registration suspension provisions; regulated industry should pressure FDA to clearly define key terms such as "knew" and "had reason to know."
- Although FDA must grant the registrant an informal hearing within two business days of a suspension order, even if the registration is promptly reinstated (which is not guaranteed), the intervening suspension period could have a devastating impact on a company's operations, revenue and reputation, especially for companies dealing with perishable foods that must make it to market within days or even hours of being received.

The summary suspension authority will become effective on "the earlier of...the date on which the Secretary issues regulations [implementing this authority] or...180 days after the date of enactment" (July 2011).

FDA must implement standards for produce safety. Within a year of enactment, FDA must promulgate proposed regulations establishing standards for "safe production and harvesting" of fruits and vegetables that are raw agricultural commodities. Under the regulation, the agency must establish science-based minimum standards that will minimize the risk of serious adverse health consequences or death from raw agricultural commodities. Such standards may relate to soil amendments (*i.e.,* non-fertilizer substances intended to change the composition of soil), hygiene, packaging, temperature controls, animals in the growing area and water. Standards should address practices "reasonably necessary" to "prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards," including both intentionally and unintentionally introduced hazards. The agency must prioritize its implementation of these regulations based on known risks of particular products, including history (and severity) of foodborne illness outbreaks.

Variances may be requested, but the requester must demonstrate that granting the variance will not make the product more likely to be adulterated and that the variance protects the public health to the same degree as the regulations adopted under this section. Farms that sell the majority of their products to "qualified end-users" may be exempt from these regulations. "Qualified end-users" are limited to consumers and retail food establishments and restaurants within 275 miles of, or in the same state as, the farm producing the product. Failure to comply with such regulations will be a prohibited act under the FDCA.

Regulations for the prevention of intentional adulteration. The law requires the FDA to develop regulations and Guidance in collaboration with the Department of Homeland Security (DHS) and the Department of Agriculture "to protect against the intentional adulteration of food.... for which there is a high risk of intentional contamination." These regulations will likely require companies to develop risk assessments and mitigation strategies to protect against intentional food tampering (*e.g.*, terrorist attacks via the food supply).

FDA will have the authority to mandate food recalls. To date, FDA has only had the authority to request a food recall. By and large, industry has complied with these requests. However, under the new bill, FDA will have the authority to order a recall and collect any costs associated with the order from the targeted facility. If the agency determines that there is a "reasonable probability" that a product is adulterated or misbranded, and using or being exposed to the product will cause serious adverse health consequences or death, the agency may request that the responsible party cease distribution of and recall the product. If the responsible party fails or refuses to cease distribution and recall the product within the time allowed by the agency (if a time period is prescribed), the agency may order the responsible party to cease distribution and notify distributors that they must cease distribution of the product. The agency must provide an informal hearing to any party subject to an order to cease distribution within "two days" of the order. After the informal hearing, the agency may uphold, withdraw or amend its prior order to demand a recall of the product. Failure to comply with recall orders may result in civil penalties and is a prohibited act under the FDCA. The mandatory recall authority is effective immediately.

- As with the FDA's new power to summarily suspend a facility's registration (see above), FDA must grant the registrant an informal hearing within two days of the order to cease distribution. However, given the investigative facts that would be developed prior to an FDA-mandated recall, it will be very unlikely that the agency would rescind its decision after such a hearing.

- Much has been made regarding the new mandatory recall authority, but in practice FDA is unlikely to use this authority very often. Under current law, FDA already has tremendous power to persuade companies to recall suspect food, and given the liability risks where a problem is suspected, most companies already take a proactive approach to recalls, especially where FDA makes a request for voluntary action by a company.

FDA will have expanded access to facility records. The law allows the Secretary to inspect records of manufacturers, processors, packers, distributors, receivers, holders and importers if there is a "reasonable probability" that a food "has a reasonable probability" to cause "serious adverse health consequences or death to humans or animals." This expanded inspection power extends to "all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation" of a suspect food. This power applies to all entities in the supply and distribution chain, even if the entity is not suspected as the cause of the potential safety risk. Moreover, the power applies with respect to other food "likely to be affected in a similar manner." Farms and restaurants are exempt from this requirement. This authority becomes effective immediately.

FDA will have more authority over imported foods, foreign facilities and foreign suppliers. FDA's increased international enforcement powers under the new law will result in more burdens and liability risks for foreign food suppliers who wish to participate in the U.S. market. Like domestic facilities, importers, *i.e.*, U.S. owners, consignees, or agents, must conduct "verification activities" to ensure that foreign suppliers are performing hazard analyses and risk-based prevention controls, that imported food is not misbranded or adulterated, and that suppliers are complying with any applicable produce safety standards. Foreign supplier verification activities may include monitoring shipment records, lot-by-lot certification of compliance, annual on-site inspections, checking hazard analysis and risk-based preventative control plan, and periodically testing and sampling shipments. It will be a prohibited act to import food if the importer does not have in place a foreign supplier verification program that complies with the requirements of the new law.

Effective Date. The foreign supplier verification requirements become effective two years after enactment (January 2013). Companies should, however, begin discussions with key foreign suppliers as soon as possible to ensure that any necessary changes can be made by suppliers well in advance of when the requirements take effect.

Import certifications may be required by the FDA for imported foods. Criteria to be used in determining whether to require an import certification include the known safety risks associated with a particular food, or the country, territory or region of origin of the food. Certification requirements may also be based on a finding by FDA that the country, territory, or region of origin has inadequate food safety programs, systems and standards necessary to ensure the safety of a particular food. Certifications must be issued by an agency or representative of the foreign government or by a third-party auditor accredited by an accreditation body deemed acceptable to FDA.

- Refused Admission of Imported Foods. Imported food may be refused admission to the United States if the food is not accompanied by a required certification of compliance. Moreover, an imported food will

be refused admission if the foreign manufacturer or supplier has refused to allow FDA inspection of its facility(ies) within 24 hours of a request to conduct such an inspection.

- Firms importing food from overseas or retailing imported food bought from wholesalers will be well advised to include contractual terms requiring foreign supplier compliance and providing for indemnification by the supplier for foods detained due to supplier non-compliance.

FDA must establish a program providing expedited review for food importers who voluntarily agree to participate in a qualified importer program. To participate, an importer must be certified as in compliance with the FDCA. FDA may require some food items to be certified prior to admission in the U.S. "based on public health considerations, including risks associated with the food or its place of origin."

Furthermore, FDA may review foreign food safety regimes and conduct on-site audits to determine if a country's food supply meets U.S. food safety standards. FDA may inspect foreign food facilities that are registered with the agency, and Congress has instructed the agency to set up foreign offices to assist with such inspections.

FDA will expand its track and trace programs and recordkeeping requirements. FDA must implement pilot projects with the food industry to determine effective track and trace programs. This pilot program should enable FDA to implement a track and trace program that will identify recipients of food, mitigate foodborne illness outbreaks and address threats of serious adverse health consequences or death.

FDA must also promulgate new recordkeeping requirements for facilities that manufacture, process, pack or hold food the agency determines to be "high-risk." High risk foods may include those the agency determines are known to have safety risks, have a high potential for microbiological or chemical contamination, have a high likelihood of being contaminated in the manufacturing process, have a high likelihood that, when consumed, will result in a foodborne illness and the likelihood or severity, including health and economic impacts, of a foodborne illness attributed to a particular food. Both expanded track and trace programs and recordkeeping requirements will impose additional burdens on regulated industry and additional liability if appropriate actions are not taken. Failure to comply with any new recordkeeping requirements will be a prohibited act.

FDA will have expanded authority to issue administrative detentions. While FDA has previously had the authority to administratively detain allegedly unsafe food that is found during an inspection, examination, or investigation under the FDCA, the standard for detaining products has been lowered. Whereas, previously, FDA could only detain a product if it had "credible evidence or information indicating" that the product presented a threat of serious adverse health consequences or death, now FDA may detain a product if it has "reason to believe" the product is adulterated or misbranded. This authority takes effect 180 days after enactment (July 2011).

FDA will have expanded authority under its reportable food registry. Currently, responsible parties must report foods which they believe have a "reasonable probability" to cause serious adverse health consequences or death (reportable food). Under the new law, FDA has the authority to request additional

"consumer-oriented information" about the reportable food from the responsible party, including contact information for the responsible party and specific product identifiers (*e.g.*, SKUs, UPC numbers, and/or batch and lot numbers). In addition, grocery stores with fifteen or more locations, that have sold "reportable foods" must notify consumers by posting a one-page summary of the reportable food registry from FDA's website in a prominent place in each store (to be determined by regulation). Failure to comply with this notification requirement is a prohibited act. This authority appears to be immediately effective, but arguably temporary, as the law states that FDA "may require" such information "not more than 18 months after the date of enactment."

Protection for "whistleblower" employees. The new law grants employees who allege violations of any of the above provisions protection from retaliation by their employers. Any employee who provides information to his or her employer or the government, testifies for the government, or otherwise assists the government in a proceeding relating to violations by his employer cannot be discharged or otherwise discriminated against based on that activity. In addition, an employer may not take adverse action against an employee who refused to perform a task because he "reasonably believed" the task would be a violation of law.

- Dealing with purported "whistleblowers" is always a challenge in any regulated industry. With statutory protection for whistleblower activities, employees may be more motivated to report non-compliance by their employers. The best defense against such activities is to implement a strong compliance program that includes taking all employee concerns and allegations seriously and documenting both the allegation and the company's follow up investigation. However, it is also true that poor-performing employees may allege regulatory violations in order to seek whistleblower protection against being terminated for their poor performance. Regularly documenting employee performance and the investigation of any allegations of non-compliance is critical in this context.

The employee whistleblower protections become effective immediately.

"User Fees." The new law grants FDA the authority to impose fees for re-inspections (where a facility failed an initial inspection), failure to comply with recall orders, and on facilities participating in the voluntary qualified importer program. Where a facility did not comply with a recall order, the agency may recoup the entire cost of implementing the recall, which could potentially impose huge additional costs on industry.

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As noted above, the more burdensome direct requirements of the law have delayed effective dates, which gives regulated companies some lead time to develop appropriate compliance programs. However, despite the delayed effect of the hazard analysis, preventative controls, corrective actions, and verification requirements, given the complexity and level of detail required for compliance, regulated food companies need to start immediately to plan for compliance with the new law. And, given the many aspects of the law for which FDA must implement regulations, companies should take all available opportunities to submit comments in response to proposed regulations to ensure that the regulations strike a fair and reasonable balance between the safety goals of the new law, and the practical considerations of how businesses can

comply with the rules.

Members of Wiley Rein's FDA Practice have extensive experience working with clients on food registration, recording keeping compliance, recalls, importation and FDA enforcement matters and are available to advise clients on compliance with the extensive new requirements of the law.