

Trade & Customs - USA

New food safety bill has consequences for importers

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On January 4 2011 President Obama signed into law HR 2751, the much-anticipated Food and Drug Administration (FDA) Food Safety Modernisation Act, bringing about the biggest reform of US food safety regulation in decades. The new law has significant consequences for importers of food items, which should prepare for increased federal government oversight of food imports.

Background

The safety of imported food became the subject of national and congressional attention in 2001, when the September 11 terrorist attacks and the mailing of letters containing anthrax raised concerns about bioterrorism. Congress responded by passing the Bioterrorism Act of 2002. The act required facilities handling food for consumption in the United States to register with the FDA, the part of the Department of Health and Human Services responsible for regulating food safety, and required importers to notify the FDA of shipments of food into the United States.

Between 2007 and 2010, food safety was back at the forefront of national attention due to a spate of high-profile contamination incidents involving pet food, baby formula, peanut butter, peppers and eggs. However, the FDA's authority to deal with such incidents was limited – for example, the FDA could not order mandatory recalls.

Congress passed the FDA Food Safety Modernisation Act in December 2010 with bipartisan support, paving the way for sweeping changes to the regulatory system. The act enhances the FDA's authority and institutes new requirements for FDA-regulated facilities. In recognition of the increasing importance of imported food in the US market, the act calls for new regulations and programmes to ensure the safety of imported foods.

Need for foreign supplier verification programmes

The act requires importers to verify that imported food is as safe as food produced in the United States. The Department of Health and Human Services will have one year to promulgate regulations for the programme, which will be implemented within two years.

Regulations will require each importer to have a programme to ensure that food produced outside the United States is subject to procedures that provide the same level of public health protection as is required of producers in the United States. Importers of non-produce food items will be obligated to evaluate hazards that could affect food manufactured, processed, packed or held by an exporting facility and to implement controls to minimise or prevent the occurrence of such hazards. Suggested verification activities include monitoring records for shipments, lot-by-lot certification, annual on-site inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers and periodically testing and sampling shipments. Importers of produce items will need to ensure compliance with regulations to be issued by the Department of Health and Human Services, in consultation with the Department of Homeland Security, setting forth science-based minimum standards for the safe production and harvesting of those types of fruits and vegetable. Foreign governments may request a variance from these requirements to account for different growing conditions in that country. All importers' programmes must verify that food is not

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adulterated or misbranded.

Importers will be required to maintain records related to their foreign supplier verification programme for no less than two years and to make the records available to the Department of Health and Human Services on request. Imports of food will be prohibited if the importer does not have in place a programme that is compliant with the act. To prevent port shopping, the act requires that the Department of Health and Human Services notify the Department of Homeland Security of any time that food is refused admittance into the United States so that the commissioner of US Customs and Border Protection can prevent admission of that food through another port. Small quantities of food for research purposes or personal consumption will be exempt from the requirements.

Certification

Importers may be required to certify that food imports comply with relevant provisions of the act. The bill charges the Department of Health and Human Services with making a risk-based determination of when and what type of certification or other assurances will be required. The risk-based determination will consider what food safety programmes, systems and standards exist in the place of origin of the food. Possible forms of certification include shipment-specific certification or a listing of certified facilities that manufacture, process, pack or hold the imported food.

According to the act, foreign government representatives designated by the Department of Health and Human Services or accredited third-party auditors will provide the certifications. The Department of Health and Human Services will create a body to accredit third-party auditors, who will conduct regulatory audits and other activities necessary to establish compliance with the relevant sections of the act.

Expediting review through voluntary qualified importer programme

Importers will be able to apply to participate in a voluntary qualified importer programme to facilitate the clearance of food imports. The Department of Health and Human Services, in consultation with the Department of Homeland Security, will establish a process for issuing facility certifications to accompany food offered for import by participating importers. The Department of Health and Human Services will determine whether an importer may participate by considering the risk of the food to be imported, based on factors such as the compliance history of foreign suppliers and the regulatory system of the country of export. Participating importers must pay an annual fee to cover the administrative costs of the programme, and continued participation will be reevaluated every three years.

Inspection of imports and foreign food facilities

To improve the safety of imported food further, the act calls for the identification and inspection of food at ports of entry. The Department of Health and Human Services, in consultation with the Department of Homeland Security, will allocate resources to inspect any article of food imported into the United States according to the known safety risks of that article.

The act also calls for the inspection of foreign food facilities, suppliers and food types. If a foreign food facility denies inspection, or the government of a foreign country refuses to permit the entry of inspectors, imports of food from that facility will be refused admission into the United States.

Importers and US agents of foreign facilities may need to pay fees if a re-inspection is determined to be necessary (where an initial inspection identified a material non-compliance). Importers may also need to pay a fee if the FDA issues a recall order with which an importer does not comply.

Benefits of standards harmonisation and capacity building efforts

The act calls on the Department of Health and Human Services, in consultation with other US government agencies, to develop a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and food industries. Aspects of the plan could ultimately reduce the regulatory burdens. For example, the plan will include recommendations on whether and how to harmonise requirements under the Codex Alimentarius. The plan will also include provisions for the multilateral acceptance of laboratory methods and testing and detection techniques and for mutual recognition of inspection reports.

Comment

The FDA Food Safety Modernisation Act institutes sweeping new changes to the way in which food safety is regulated in the United States. Funding for the act, estimated at \$1.4 billion over five years, still has to be approved. However, the Department of Health and Human Services and the FDA are moving forward with implementation based on existing resources and with the assumption that the necessary additional funding

ultimately will be provided.

Importers may be affected by certification and foreign supplier verification requirements, and by inspections of imports and foreign food facilities. To ensure compliance with the new law and future regulations, importers may want to review and update existing policies and procedures, and consider applying for the voluntary qualified importer programme.

For further information on this topic please contact [Richard M Belanger](#) or [Brenda Jacobs](#) at [Sidley Austin LLP](#) by telephone (+1 202 736 8000), fax (+1 202 736 8711) or email (rbelanger@sidley.com or bjacobs@sidley.com).

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