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Important Dates for the Food Safety Modernization Act

The **FDA Food Safety Modernization Act** (the Act) was signed into law by President Obama on January 4, 2011. The date of signing affects the timing of enforcement for various requirements. Registrar Corp has analyzed the FDA Food Safety Modernization Act to provide industry with the following timeline of anticipated events:

Changes Effective Immediately

- FDA is granted new power to enter food facilities (except farms and restaurants) and **inspect and copy records**. This power may be exercised if FDA believes that there is a reasonable probability that the use or exposure to an article of food will cause serious adverse health consequences to humans or animals.
- FDA may begin the process of establishing and setting **reinspection fees**. FDA must specify in the Federal Register the time and manner in which assessed fees will be collected, and must set fees in accordance with a procedure that will take time to gointo effect.
- FDA may issue **export certificates** for food, and may charge fees for such certificates.

On or before Monday, April 4, 2011:

- FDA's web site will be updated to include a search engine that is consumer friendly. The website will provide a means by which an individual may locate relevant information regarding each article of food subject to a recall and the status of the recall.
- The Comptroller General will submit a report to Congress concerning State and local recall authority, as well as any mandatory recall authority by federal agencies other than FDA. The report will identify the agencies with the authority to require the mandatory recall of food, and evaluate frequency, effectiveness, and appropriateness. In addition, the report will include consideration of any new or existing mechanisms available to compensate persons for general and specific recall-related costs when a recall is subsequently determined by the relevant authority to have been an error.

On or before Wednesday, May 4, 2011:

- FDA will issue interim final rules concerning **Administrative Detention of Food**.
- FDA will issue new interim final rules concerning **Prior Notice** of Imported Food Shipments.

No later than July 3, 2011:

- FDA empowered to **suspend food facility registration**
- FDA may suspend registration (effectively closing) of any facility that:

  - created, caused or wasresponsible for food having a reasonable probability of having adverse health consequences for humans or animals, or

  - knew or had reason to know of such reasonable probability, and packed, received or held such food
- No person shall import or export food from a suspended facility, or otherwise introduce such food into commerce in the USA.
- FDA may extend the suspension of registration until it determines that adequate grounds do not exist to continue the suspension.
- FDA may require "corrective action plans" from suspended facilities.
- FDA will issue a small entity compliance guide within 180 days of issuing the interim regulations concerning facility registration.
- FDA and USDA will issue contaminant-specific and science based guidance documents regarding action levels, tolerances or regulation, based on studies to be conducted at least every two years.
- FDA will update the Fish and Fisheries Products HACCP Guidance to take into account advances in technology that have occurred since the previous publication.
- FDA will publish a guidance that clarifies when a dietary supplement ingredient is a **new dietary ingredient**, when the manufacturer or distributor of a dietary ingredient or dietary supplement must document the safety of new dietary ingredients, and appropriate methods for establishing the identify of a new dietary ingredient.
- FDA will report on the progress made in implementing a national food emergency response laboratory network. This report will be prepared in coordination with USDA, DHS, and State, local, and tribal governments, and it will be publicly available on the FDA Web site.
- FDA and USDA will establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance.
- FDA will establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia, to make recommendations to the Secretary regarding designations of the Centers of Excellence.
- FDA will develop and implement a strategy to better **identify smuggled food** and prevent entry of such food into the United States. This plan will be developed in coordination with DHS.

On or before October 1, 2011:

- FDA will establish pilot projects (in coordination with industry) to evaluate methods of effectively identifying recipients of food so as to prevent or mitigate a foodborne illness outbreak. The pilot projects will also address credible threats of serious adverse health consequences as a result of such food being adulterated or misbranded.

On or before October 4, 2011:

- FDA will publish a notice of proposed rulemaking in the Federal Register to promulgate regulations that further define farms and exemptions applicable to farms. Specifically, the regulations will address:

  - activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, and

  - activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.

On or before January 4, 2012:

- FDA will issue new rules for **produce safety**. The rules will be staggered to give priority to specific fruits and vegetables based on known risks and history of incidents. FDA is required to coordinate with the USDA, Department of Homeland Security, and state agriculture authorities, and must hold a minimum of 3 public meetings in diverse geographical areas of the U.S. to obtain public input.
- FDA will issue guidance documents for producers and importers of fruits and vegetables, and will hold at least 3 public educational meetings in diverse geographical areas. Within 180 days after regulations are issued, FDA will publish an additional small entity compliance guide.

Important Dates for the Food Safety Modernization Act, Continued

- FDA will issue guidance documents concerning protection against intentional adulteration of food.
- FDA will prepare and publish a National Agriculture and Food Defense Strategy. The strategy will be presented to Congress and available on the websites of the FDA and USDA. The plan will be revised at least every four years. An annual evaluation of each program shall be conducted to deter mine the effectiveness in achieving legislated intent, purposes, and objectives.
- FDA will conduct a study regarding the need for, and challenges associated with, development and implementation of a program that would require a **unique identification number for each food facility** and each broker that imports food into the United States. The study will include an evaluation of the costs associated with development and implementation of such a system, and make recommendations about what new authorities, if any, would be necessary to develop and implement such a system. A report of this study must be submitted to Congress by this date.
- FDA will develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs. The guidelines will be developed in consultation with the Department of Education and will be available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.
- FDA will designate high-risk foods for which **additional record-keeping requirements** are appropriate and necessary to protect public health.
- FDA will complete a review of State and local capacities, and needs for enhancement. The review may include a survey with respect to staffing levels and available expertise to perform food safety functions; laboratory capacity to support surveillance, inspection, outbreak response, and enforcement activities; and information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level.
- FDA will designate 5 Integrated Food Safety Centers of Excellence to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. These centers shall be headquartered at selected State health departments
- FDA will develop additional instructions for grocery stores in announcing recalls. It will develop and publish a list of acceptable conspicuous locations and manners that shall include posting the notification near the register, providing the location of the reportable food, providing targeted recall information, and other such prominent and conspicuous locations and manners utilized by grocery stores to provide notice of such recalls to consumers.
- FDA will promulgate regulations to provide for the content of the **foreign supplier verification program**.
- FDA will issue guidance to assist importers in developing foreign supplier verification programs.
- FDA will develop a comprehensive plan to extend the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.
- FDA will establish a system for the recognition of accreditation bodies that accredit third-party auditors.

On or before July 4, 2012:

- FDA will issue **HACCP Regulations** for all products except seafood and juice (which are already subject to HACCP regulations).
- FDA will report to Congress on the results of a study of the food-processing sector mandated by the statute. The study is to determine:

  - the distribution of food production by size and type of operation, including the monetary values of food sold,

  - the proportion of food produced by each type and size of operation,

  - the number and types of food facilities co-located on farms, segregated by commodity and by manufacturing or processing activity, and

  - the incidence of foodborne illness originating from each size and type of operation, and assessments of risk of foodborne illness associated with commingling, processing, transporting and storing food and raw agricultural commodities.
- FDA will issue regulations to protect against intentional adulteration of food. Farms will be exempt, except those that produce milk.
- FDA will report to Congress on the findings of the pilot projects with recommendations for improving the **tracking and tracing of food**.
- The reportable food registry may be enhanced. FDA may require a responsible party to submit to the Secretary consumer-oriented information regarding reportable food, including a description of the article of food, product identification codes such as UPC, SKU, lot or batch numbers, and contact information for the responsible party.
- FDA, in consultation with DHS, shall establish a **qualified importer program**. The program will provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such a program. It will also establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such a program.
- FDA will develop model standards, including requirements for regulatory audit reports. Each recognized accreditation body must ensure that third-party auditors and audit agents of such auditors meet such standards.
- FDA will promulgate regulations concerning **third party auditors**, standards, accreditation, and against conflicts of interest between an ac credited third-party auditor and the eligible entity to be certified by such auditor or audited by such audit agent. The regulations must include requiring that audits performed under this Section be unannounced, a structure to decrease the potential conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors, and appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor.

On or before, January 4, 2013:

- FDA will submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food, and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities. The report will be prepared in consultation with DHS and USDA.
- FDA will establish a program for the testing of food by **accredited laboratories**, and establish a publicly available registry of accreditation bodies and laboratories accredited by a recognized accreditation body.
- FDA will publish a notice of proposed rulemaking to establish record keeping requirements for facilities that manufacture, process, pack, or hold foods that the FDA designates as high-risk foods.
- FDA will submit a report on the use of recall authority and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.
- FDA will submit a report that describes the effectiveness of the Centers of Excellence and provides legislative recommendations or describes additional resources required by the Centers of Excellence.

On or before July 4, 2013:

- Only Federal laboratories or non-Federal laboratories that have been ac credited for the appropriate sampling or analytical testing methodology or methodologies may conduct **food testing**. Accreditation must be by a recognized accreditation body on the registry, which is established by the Secretary.

On or before January 4, 2016:

- FDA may eliminate paper food facility registration, and may require that facility registration be submitted in electronic format.

The above timeline is subject to change.
If you have specific questions or concerns about implementation of the FDA Food Safety Modernization Act, please contact Registrar Corp in the U.S. or contact any of Registrar Corp's Regional Offices around the world.