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## **What Does The New FDA Food Safety Modernization Act Mean To Us?**

The president just signed the new “**FDA Food Safety Modernization Act**”, so what does that mean to us?

The new bill will emphasize food-safety regulation, with increased FDA enforcement power, increased fees, broader recordkeeping demands and greater control of food imports.

Here are some key points of the new changes in the regulations:

### **Must register every two years**

The FDA is now requiring domestic and foreign facilities to register every two years. Companies will be required to share their food-safety plans with FDA upon request. Food from an unregistered foreign company will not be imported into the United States. All companies will be required to develop food defense plans aimed at preventing intentional contamination for food determined to be high-risk.

### **Increase FDA inspections**

The schedule frequency of FDA inspections for each food facility would be based on risk profiles that are based on such factors as the type of food, and the facility’s history of food recalls. Domestic food companies will now be inspected at least once every 5 years.

### **New FDA authority—**

The FDA will now have mandatory recall authority. They also now have the power to detain food that they believe is dangerous or adulterated. Most recalls will still continue to be voluntary.

The FDA is also required to contact the press with complete recall information and an image of the recalled food. This information shall be posted on the FDA website and the recall information should be updated with any new developments for the public to see.

Food companies that do not comply will be subject to civil fines. If the FDA feels that food from a food company can cause serious adverse health problems or death then the FDA can suspend their registration. When a food company has their registration suspended they must cease operations.



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## **Food Safety plans (HACCP)**

The legislation requires food manufacturers and processors to develop and document food safety plans that identify and prevent hazards at each facility ( HACCP plans). These companies also need to verify the safety of their entire process by developing and implementing a preventative control plan. These written plans with documentation must be made promptly available to the FDA upon request. This includes:

- Identification and evaluation of known or foreseeable hazards
- Implementation of appropriate controls with verification
  - Sanitation procedures
  - Recall plan
  - Food allergen control program
  - Supplier verification activities
  - Environmental sample testing
- Monitoring of effectiveness
- Develop corrective action procedures for when controls are not effective
- Maintenance of records for 2 years.

## **Performance Standards**

Every 2 years, the FDA must review and evaluate relevant health data to determine most significant food borne contaminants and also issue contaminant-specific performance standards, which may include action levels. These standards will be developed based on known safety risks.

This bill mandates that specific standards be developed for fresh produce and for its safe production and harvesting.

## **Tighter controls over imports**

Major parts of the bill are now devoted to food imports, which account for an increasing share of the U.S. food consumption. The FDA will greatly increase their inspections of foreign facilities over the next 5 years.

- Importers will have to ensure that all food coming into the US meets FDA food-safety standards that are equivalent to U.S. standards.
- Importers will be required to perform foreign supplier verification and have tighter controls on all of their ingredients.
- The FDA will allow third party auditors and audit agents to issue written and electronic certifications to accompany each food shipment imports.
- They must also maintain records for 2 years and be available to the FDA upon request.



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Entry of imported food products into the U.S. may be expedited based on the facilities' compliance history. This new program is called the "Voluntary Qualified Importer Program".

## Third-party Auditors and Accreditation Standards

The FDA will develop a system where accredited third-party auditors and audit agents certify that foreign food entities meet the U.S. requirements. The third-party agents will provide an import certificate. This will both improve and expedite the movement of food through the U.S. import process.

The FDA will develop, evaluate and regulate the performance of third-party auditors and private labs. The FDA is also required to develop a system for recognizing accredited third-party auditors and private labs. With additional third-party auditors and private labs the import system will hopefully run quicker and better.

There is one important change to the system. If a third-party auditor or private lab finds a serious health risk to public health they are now required to notify the FDA immediately.

## Fees

The FDA will now impose some new fees or expenses that are related to re-inspection because of non-compliance. These fees are listed below.

- Annual fee for each domestic facility or U.S. agent for foreign that is subject to a re-inspection. Cost = 100% of FDA's re-inspection expenses
- Annual fee from the responsible party who fails to comply with a recall order. Cost= 100% of FDA's recall expenses
- Annual fee from each importer participating in the Voluntary Qualified Importer Program. Cost=100% of FDA's Administrative costs.
- Annual fee from each importer that is subject to a re-inspection. Cost = 100% of FDA's re-inspection expenses

## Record keeping Requirements

The FDA is gathering information and using this information to try to improve the effectiveness to trace and track food in the United States. They will also issue new regulations on recordkeeping requirements for all food manufacturers to strengthen record-keeping and food traceability systems. These new recordkeeping requirements will be based on:



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- Risk factors related to type of food
- Possibility of potential contamination
- History of foodborne illness

The FDA will subject high risk foods to increased recordkeeping requirements. The FDA will determine which foods are considered high risk and publish this list on their website.

The FDA will now have access to all records of a food company. Access to records will have to be provided by the company who manufactures, processes, packs, distributes, receives, holds, or imports the food. Food industry companies will be required to maintain all records for 2 years.

*The prior food laws mandated that the FDA had to have a reasonable belief of adulteration to access private records from a company.*

The FDA will be able to access the following documents:

- Food Safety plan
- HACCP plan
- Environmental testing reports
- Finished product testing reports
- Corrective action reports
- Supply chain information

If a food offered for import does not comply with the new recordkeeping requirements than the food can be refused entry by the FDA.

## **Additional Items of Importance**

- The new bill will provide “Whistleblower Protection” to employees working in the food industry.
- The FDA and the Department of Education are required to develop voluntary guidelines for state and local education agencies to plan for managing food allergies in schools.
- New regulations are in the works for Sanitary Transportation of Food.



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Deibel Laboratories will be glad to provide guidance for your additional needs to meet these new FDA demands. Watch the Deibel webpage for future projects to help you with your FDA or USDA/FSIS compliance needs. Contact [TechnicalServices@deibellabs.com](mailto:TechnicalServices@deibellabs.com) and we will be glad to help you.

With nine laboratories across North America, Deibel is large enough to handle all of your testing needs and still give you the service and dedication you deserve.

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