

FDA's Food Safety Modernization Act: An Overview

Dr. Paul Priyesh Vijayakumar, Ph.D., Dr. Melissa Newman, Ph.D.,
and Dr. Gregg Rentfrow, Ph.D.

What is Food Safety Modernization Act (FSMA)?

The Food Safety Modernization Act (FSMA) is a set of regulations signed into law by the President Obama on June 4, 2011. It was meant to strengthen the US food safety system by stressing three fundamental strategies: prevention, increased surveillance, and better response and recovery.



Image credit: <http://www.nasda.org/>

Why is FSMA needed?

Food can be contaminated with bacteria, chemicals, and other substances at any point, from growing, harvesting, processing, packaging, and shipping the food, to storing or preparing it to be eaten at restaurants or at home. Though federal agencies such as the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are responsible for regulations and food safety guidelines, everyone involved in the food chain, from farm-to-fork, is responsible for the safety of food.

The FDA is responsible for regulating 80% of the US food supply, while red meat, poultry, and processed egg products are regulated by the USDA. The FDA has worked closely with different federal, state, and local agencies to establish regulatory guidelines. Food safety

issues continue to be a problem. According to reports by the Centre for Disease Control and Protection (CDC), 48 million people suffer from foodborne illness or disease every year. Fresh produce, which the FDA defines as fruits and vegetables, have raised major concerns in recent years, with 131 foodborne illness outbreaks over a 14 year period (1996-2010), from 20 different products. These outbreaks made 14,350 people sick, sent 1,350 people to the hospital, and killed 34.

Farm-to-Fork

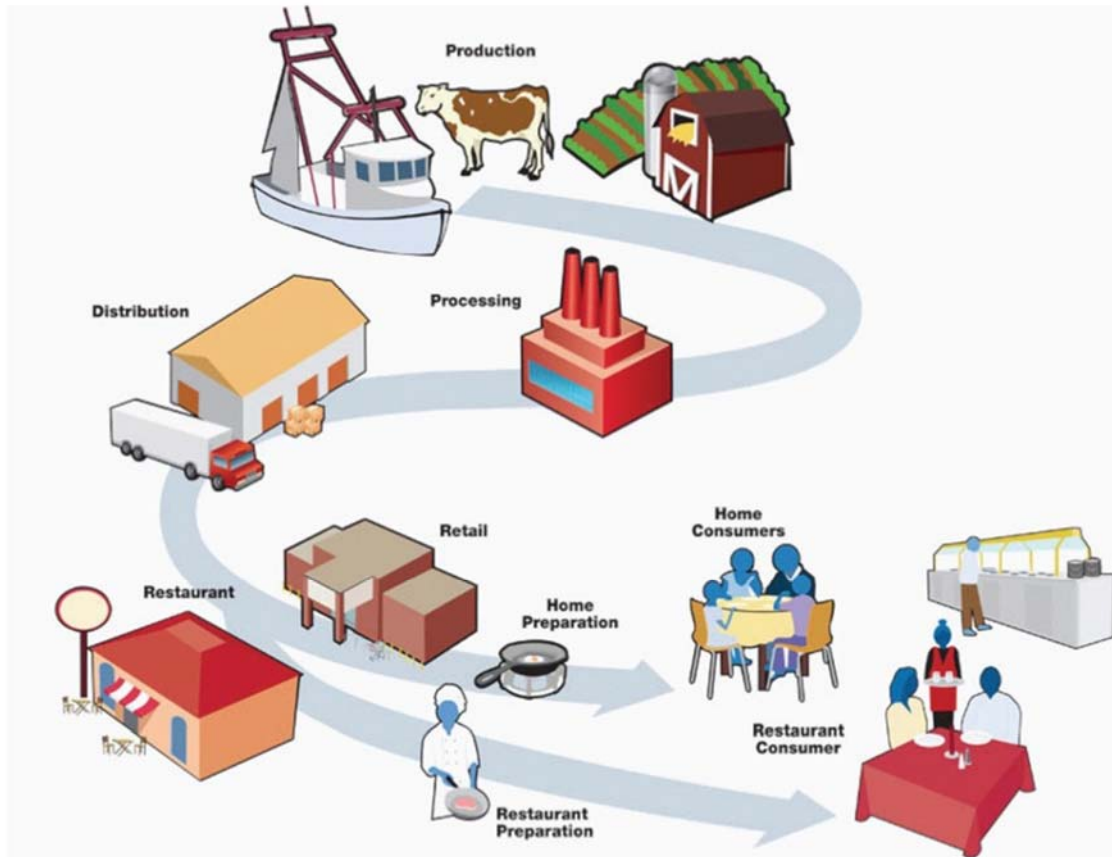


Image credit: <http://blogs.cdc.gov/>

Foodborne illness creates a significant health burden on society, but the FDA believes it can be prevented. The CDC estimates that if we could reduce foodborne illness outbreaks by 10%, we could protect 5% of the American population from sickness, hospitalization, or death due to foodborne illness. The Food Safety Modernization Act (FSMA) was introduced in an effort to upgrade the food safety system and prevent such foodborne illnesses through increased surveillance and monitoring.

What are the key elements of FSMA?

I. *PREVENTION*

In the spirit of Benjamin Franklin's proverb, "an ounce of prevention is worth a pound of cure," the goal of FSMA is to create a comprehensive plan that unites local and national agencies in efforts to prevent food safety outbreaks from happening, rather than just cleaning up the aftermath.

II. *SURVEILLANCE*

FSMA gives the FDA the power to inspect food and facilities more often if they are thought to be at a higher risk of contamination. This decision would be based on details like the nature of the food, increased food safety risks involved with handling certain food products, and the severity of the risk. For instance, the FDA will have the right to inspect an organization's food safety plans and how they are being carried out, and will be able to require that food testing be done at laboratories they approve, that have been approved through a program they created.

III. *RESPONSE AND RECOVERY*

These regulations grant the FDA the following powers to control the entry of contaminated food into the market place:

- Mandate a recall even if a business doesn't issue a voluntary recall
- Detain foods suspected to have violated the law
- Suspend registration if food from a facility is possibly hazardous
- Effectively track where US and foreign (imported) food comes from, through improved systems
- Order more detailed record keeping policies for facilities that hold, manufacture or process certain high risk foods (to be decided at the discretion of the secretary).

What areas of "Food" are covered under the proposed regulations?

The FSMA uses scientific methods to establish rules covering the following areas:

1. Produce Safety

2. Human Food
3. Preventive Controls for Animal Food
4. Foreign Supplier Verification Program
5. Accredited Third Party Certification
6. Sanitary Transportation of Human and Animal Food
7. Strategies to Protect Food Against Intentional Adulteration

What is the current status of FSMA?

While certain elements of the law, such as, mandatory recall authority went into effect on June 4, 2011, the day the President signed FSMA into law; other areas of FSMA are currently under the FDA’s rule making process, waiting to be put into effect on the following FDA timeline:

Proposed Rule	Tentative Publication of Final Rule
<ul style="list-style-type: none"> • Preventive Controls for Human and Animal Food 	August 2015
<ul style="list-style-type: none"> • Produce Safety and Imports 	October 2015
<ul style="list-style-type: none"> • Sanitary Transportation 	March 2016
<ul style="list-style-type: none"> • Intentional Adulteration 	May 2016

Does FSMA require registration with the FDA?

The proposed regulation states that if a food facility is registered with the FDA under section 415 of the Food, Drug, and Cosmetic Act (FD&C), the facility will need to renew its registration with the FDA. The requirements under section 415 of the FD&C Act remain unchanged, which means if a facility was not registered under the FD&C Act prior to FSMA, it is not required to register now.

For additional information on registration, visit the FDA’s website (www.fda.gov), or follow the link below.

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

Are there fees associated with FSMA?

FSMA does not require any fees for registration and initial inspection; however, the FDA has been invested with the authority to collect fees from some US-based and imported food facilities and for re-inspection of importers. A proposed rule states that the FDA will collect fees in the following situations:

- When a facility (domestic or imported) does not comply with a recall order.
- When it costs the FDA money to issue food export certifications, or they have to use an outside company's accreditation program.
- When the FDA has to re-inspect US and foreign import facilities after the first inspection found food safety issues.

For more up-to-date information on fees, visit the FDA's website (www.fda.gov), or follow the link below.

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm325614.htm>

Other important information on FSMA

Plain Language Guidance:

Within six months after the final rule is published, the FDA would publish a guide that would explain the hazard analysis and preventive controls in "plain language (layman's terms)," to help businesses comply.

Scope:

FSMA would also define the scope of each of the proposed rules. For instance, it would explain what type of facility is covered by the proposed "Preventive Controls for Human Food."

Timeline Information:

The final published FSMA ruling would lay out a more specific timeline for compliance. The proposed rules will go into effect 60 days after the final rule is published. Compliance dates would be staggered based on the size of the farm (annual produce sales) and business (annual food sales) for produce safety rule and preventive controls rule, respectively.

Exemptions:

The FDA would clearly define all exemptions under the FSMA guidelines in the final ruling. For example, the proposed rule says that some companies that meet special requirements could be exempt from parts of the law, and would instead be subjected to "modified control requirements." These organizations still have to follow the Current Good Manufacturing Practices (CGMP) requirements.

Selected Resources:

- FDA
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/>
- USDA
http://www.ers.usda.gov/amber-waves/2011-december/us-food-safety-policy.aspx#.UUI_9VdY3IU
- Food Safety
<http://www.foodsafety.gov/>
- CDC
<http://www.cdc.gov/>

Disclaimer:

This article is for information purposes only. It does not cover every detail of the new requirements, and may differ from the final FDA rules. For additional information please visit www.fda.gov/fsma, or the resources mentioned above.
