Human Food & Animal Food Industries
Prepare to Comply with
Food Safety Modernization Act

June 22, 2016

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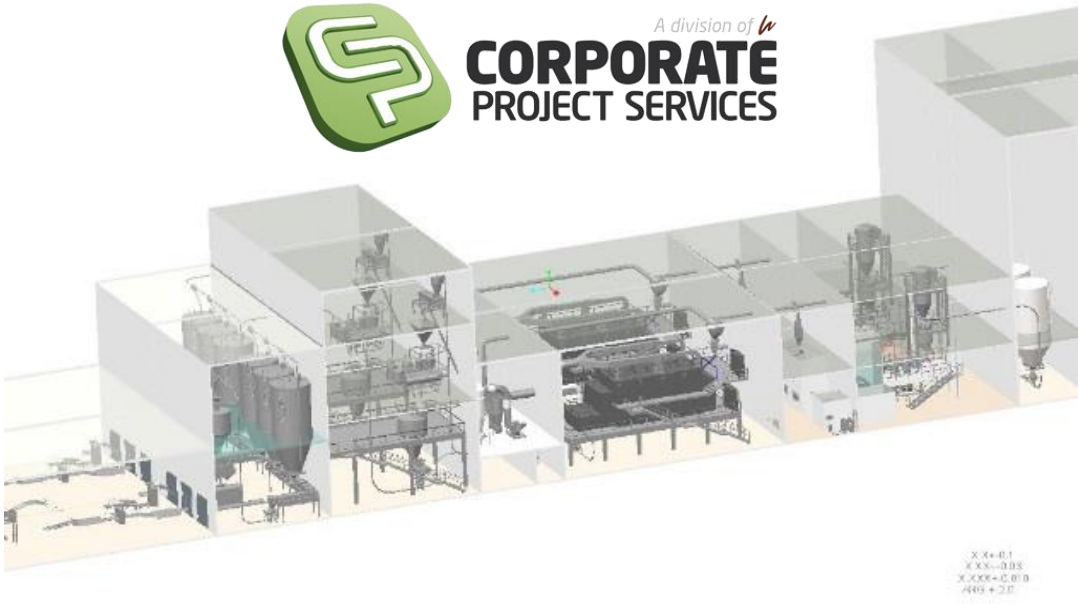
The Food Safety Modernization Act (FSMA) signed into law in January of 2011 places significant responsibility for food safety squarely on food producers, with requirements that were to come into force as finalized and funded. The dates by which those requirements take effect are finalized.

Many food processors and manufacturers throughout the human food and animal food industries have wisely been preparing their operations to meet these requirements, rather than waiting for them to come into full force. Others were waiting to see whether the requirements would indeed become law or would be once again delayed, or even canceled. Now the decision has been made, and the time for action has arrived.

This paper recommends actions that human food and animal food processors should now take to meet the full requirements of the FSMA law, including reviewing the effectiveness of their current processing systems, including equipment and facility layout, and the existing air flow patterns, as well as existing controls for the processing equipment, to assure the CCP's are identified and controlled, confirming their ability to provide the reporting data that FSMA requires.



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1. Introduction to FSMA

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. These requirements affect companies from food growers through processors and manufacturers to those that deliver food products to consumers.

FSMA gives broader powers to the Food and Drug Administration (FDA), shifting FDA's approach to food safety from responding to outbreaks of foodborne illnesses to preventing them from occurring. This will be accomplished by holding food production facilities accountable for implementing safe, effective and documentable measures to maintain food safety, including developing written procedures for eliminating and/or controlling potential hazards. This accountability will be enforced by an expanded inspection capability that FSMA gives to the FDA, along with the authority to issue mandatory recalls for food products it has reasonable belief of being unsafe. The new law also requires companies to maintain more thorough and accurate records of their operations and their hazard control activities.

FSMA is far more than new rules, though. It's about how FDA has fundamentally changed its approach to implementing food safety rules, including how it works with other governments and the food industry to achieve food safety success.

This paper addresses only those requirements affecting human food and animal food processors and manufacturers, briefly outlining the elements of the new law, then focuses on the direct effect they will have on food processing and manufacturing companies in terms of new procedures and new recordkeeping. It also recommends actions that food processors can take to meet the requirements governing verification of foreign supplier food safety programs and recommendations about inspection equipment and electronic data collection systems that can help you meet those requirements.

2. Basic Provisions of FSMA

FSMA alters FDA's approach to food safety from a system that responds to outbreaks to one that works to prevent them. This new approach holds food-processing companies accountable for controlling contamination and is a significant change in the food safety system. Food production facilities will have to evaluate the hazards in their operations and develop effective measures to prevent food contamination, supported by written documentation. Facilities will also be required to create a concrete plan for taking corrective action when it may become necessary.

FSMA requires each food production facility to Register with the FDA. Each registered facility is required to conduct a hazard analysis of its operation and develop and implement a written preventive controls plan to ensure that food is not adulterated, misbranded or incorrectly labeled. The written plan must include these elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping.

FSMA expands the FDA's ability to achieve greater oversight of the millions of food products coming into the United States annually from other countries, which constitutes an estimated 15 percent of the U.S. food supply, 60 percent of fresh fruits and vegetables and 80 percent of seafood. This includes overseeing the ingredients, flavorings, etc., imported by U.S. food processors.

More specifically, to increase import food safety, FSMA:

- Requires importers to perform supplier verification activities to ensure that imported food is safe;
- Authorizes the FDA to refuse admission to imported food if the foreign facility or country refuses to allow an FDA inspection;
- Authorizes the FDA to require certification, based on risk criteria, that the imported food is in compliance with U.S. food safety requirements;
- Provides an incentive for importers to take additional food safety measures by directing the FDA to establish a voluntary program through which imports may receive expedited review of their shipments if the importer has taken certain measures to assure the safety of the food.

Further, FSMA provisions offer Whistleblower Protection for those reporting failures to address food safety hazards to the FDA.

3. FSMA Requirements Affecting Food Production Facilities

Following are the primary requirements that FSMA imposes on food production facilities:

Registration

Food production facilities are required to register with the FDA and renew their registration biennially in even-numbered years. Recent FDA Registration Statistics indicates the number of registered food facilities globally has continued to grow at a significant pace. Registration is critical, since food from an unregistered facility may not be imported into the United States or be introduced into U.S. interstate or intrastate commerce.

Registered food facilities are required to conduct thorough hazard analyses of their operations and to develop and implement written preventive hazard controls plans. This analysis is to be updated every three years, and more often if a significant change is introduced into the company's production process. Registered food facilities must also maintain detailed records for at least two years, including

copies of their hazard analyses and preventive controls plans, related records, and additional records to assist the FDA in tracking and tracing high-risk foods.

Preventive Controls

The FDA's FSMA Preventive Controls for Human Food & Animal Food are now final, and compliance dates for some businesses will begin in September 2016.

Final rules require preventive controls based on hazard analysis, and describes those controls as being "similar" to the traditional HACCP system, and including controls that may be required at points other than the traditional Critical Control Points.

The preventive controls provisions apply to facilities that are required to register under FSMA. These controls require those facilities to:

- Create and maintain a written food safety plan that includes an analysis of hazards and risk-based preventive controls;
- Perform hazard analysis;
- Establish preventive controls for hazards that are reasonably likely to occur;
- Monitor controls performance through verification activities;
- Take corrective actions;
- Validate that controls are effective; and
- Maintain associated records.

Each human food and animal food processing facility must have a Preventive Controls Qualified Individual to oversee or conduct preparation of the food safety plan, validation of the preventive controls, review of records and analysis of the food safety plan. The Preventive Controls Qualified Individual must successfully complete training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or otherwise be qualified through job experience to develop and apply a food safety system.

Flexible requirements for preventive control management components provide that preventive control management components consider both the nature of the preventive control and its role in the facility's food safety system.

Product testing and environmental monitoring are listed as possible verification activities, but, like other preventive control management components in general, they are only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system.

For example, a raw material or other ingredient added to an RTE food after a pathogen "kill step" must be tested before use when the raw material or other ingredient has been associated with a pathogen and has not been treated to significantly minimize or prevent that pathogen (*e.g.*, spices added to snack chips, flavoring added to animal food, a food that has been previously involved in an outbreak of foodborne illness). Product testing would be required because it is appropriate to the facility (one making an RTE food), the food (spiced snack chips, flavored animal food), and the nature of the preventive control (there is no control applied to the spices added to the snack chips or the flavoring on animal food).

Inspections

Under FSMA, the FDA is required to identify high-risk facilities and to allocate resources to inspect registered facilities according to their risk profile, based on the following factors:

- The known safety risks to the food manufactured, processed, packed, or held at the facility;
- The facility's compliance history, including past recalls, outbreaks, and violations;
- The rigor and effectiveness of the facility's hazard analysis and preventive controls;
- Whether the facility or its products have been certified by an accredited third-party auditor;
- Whether the food manufactured, processed, packed, handled, prepared, treated, distributed, or stored at the facility meets the criteria for priority under FD&C Act section 801(h)(1).

Recordkeeping

The manner in which companies respond to an FDA records request and the type of documents that will have to be provided to the FDA in response to a records request remain unchanged. However, FSMA is expanding the FDA's former records access. The former records access related to a specific product that the FDA reasonably believes is adulterated; today, the records access includes records relating to any food product that the FDA deems is reasonably likely to be adulterated.

The owner, operator, or agent in charge of each facility is required to maintain a copy of its written preventive controls plan. Facilities must also maintain – for at least two years – their records of monitoring, instances of nonconformance that are material to food safety, corrective actions, verification and the efficacy of preventive controls and corrective actions. Such records must be made available to the FDA promptly upon oral or written request.

4. FSMA Final Rule Compliance Dates

Final Rule on Preventive Controls for Human Food

Compliance dates for businesses are staggered over several years after publication of the final rule which was published in September of 2015.

- **Very small businesses (averaging** less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): *Three years, except for records to support its status as a very small business (January 1, 2016).* **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): *Three years*

- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years

- **All other businesses:** *One year*

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** *Two years*

- **Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** *Two years or six months after the supplier is required to comply with the applicable rule, whichever is later*

- **Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** *18 months*

- **Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** *Six months after the supplier is required to comply with the applicable rule*

Congress has built into FSMA a powerful deterrent to discourage any food company from trying to avoid the FSMA preventive processes or otherwise allow unsafe food to enter the supply chain. FSMA encourages employees to report employers' unsafe food practices to the FDA. In addition, in February 2014, the Occupational Safety and Health Administration (OSHA) published interim final regulations that govern FSMA's whistleblower provisions, establishing systems and time frames for the filing, handling and investigation of, and ruling on, FSMA-related retaliation complaints.

Final Rule on Preventive Controls for Animal Food

Compliance dates for businesses are staggered over several years after publication of the final rule which was published in September of 2015.

- **Very small businesses (**a business averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale) *cGMP compliance date – 3 years; PC compliance date – 4 years, except for records to support its status as a very small business (January 1, 2017)*

- **Small businesses** (a business employing fewer than 500 full-time equivalent employees): *cGMP compliance date – 2 years; PC compliance date – 3 years*

- **Businesses other than small and very small:** *cGMP compliance date – 1 year; PC compliance date – 2 years*

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will be subject to CGMPs but not to preventive controls**: *six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.*

- **Receiving facility is not a small or very small business and its supplier will be subject to CGMPs but not to preventive controls**: *six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.*

- **Receiving facility is a small business and its supplier is subject to the preventive controls for animal food final rule**: *Three years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.*

- **Receiving facility is not a small or very small business and its supplier will be subject to the preventive controls for animal food final rule**: *Two years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.*

5. Complying with FSMA Requirements

Manufacturers are strongly advised to prepare to be able to meet FSMA requirements by performing the required risk assessments on their processing lines and creating the written documentation that FSMA demands. As a processor, you will be held accountable for putting into place reliable technical systems and controls that minimize your risks, such as integrating control and monitoring solutions into the processing equipment to assure appropriate temperatures are reached at the critical control point (CCP) of the process and to have real time records of these temperature profiles on file, to assure the water activity of finished product is within a food safe range to mitigate the risk of contaminated product, and to eliminate, where possible, the need for operators to physically handle product on the production floor.

Preventive Action

To begin the assessment required by FSMA, if your facility has not done so already, it should immediately begin to review its existing production procedures to identify current hazards, critical control points, auditing and documentation capabilities, and your existing hazard analysis plan. It should then correct existing hazardous conditions and create a written description of the assessment and the corrective actions taken. If your facility does not have an existing hazard analysis plan in place, it is critical to immediately create one, employing specialized consultants if necessary to ensure its thoroughness.

It is also important to conduct a thorough examination of your facility's records and recordkeeping procedures to ensure that they are ready for an FDA inspection. This should include examining how your production equipment and controls assist by keeping up-to-date records, including numbers of rejects, reworks, CCP temperature control profile at the extruder temperature control point, water activity of product exiting the dryer, etc. For example, in the past, it was often assumed the heat profile of the extrusion process provided effective pathogen control. Today, FSMA has shifted that emphasis towards compliance and documentation and requires scientific validation and verification of the process. An inspection system is a component of a complete foreign body prevention program, properly installed, validated and continuously monitored, and able not only to conduct inspection but also to keep records that will satisfy future FDA inspections.

You should also evaluate your facility's capabilities and recordkeeping regarding product tracing. Modern extrusion control programs should be designed to provide real time product tracing through the extruding, drying, coating and post cooling processing environment. Consultative experts can help you determine whether it is possible to trace both forward and backward each product movement and enhance that capability as necessary. This data will be critical in determining where in your supply chain adulteration may be likely to occur and taking necessary corrective action.

Certification

With FSMA's stringent requirements in mind, many manufacturers and suppliers are seeking certification from a globally-accepted food standard to reinforce their commitment to proactive prevention of contamination and assessment of their preventive systems.

The Global Food Safety Initiative (GFSI) was set up in 2000 as a non-profit foundation with the intention of ensuring worldwide consumer confidence in food safety and to provide retailers with a standard to follow whereby human food and animal food producers. GFSI benchmarks existing food standards against food safety criteria with the goal of standardizing certifications and eliminating multiple audits.

The four most widely used manufacturing certification schemes approved by GFSI focused on the processing of human food and animal food are:

- BRC Global Standard for Food Safety
- FSSC 22000
- IFS (International Featured Standard) Food
- SQF CODE

All GFSI-accepted standards must meet three main areas of certification requirements:

- Companies must demonstrate that they have a food safety management system;
- Companies must demonstrate current Good Manufacturing Practices (cGMP);
- Companies must demonstrate that they have conducted a Hazard Analysis and identified the Critical Control Points in line with HACCP principles.

Certification does not eliminate the likelihood of an FDA inspection, but it demonstrates a facility's commitment to the production of sale human food and animal food products. And, having this type of certification may be one of the determining factors in FDA's decision to initiate an inspection. In addition, recognized certification that proper manufacturing procedures are in place benefits both the company and its customers, and therefore also helps to enhance the manufacturer's brand reputation and profitability.

6. Supply Chain Requirements

One of the larger developments to come out of the new regulations is the requirement that manufacturers establish a supply chain verification program. Specifically, it requires that suppliers of raw materials to manufacturers adhere to the regulations as well and makes it the responsibility of the manufacturer (or "receiving facility") to ensure this is the case: "A receiving human food and animal food facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated….That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier". Supplier verification activities can be conducted by other entities earlier in the supply chain – but the receiving facility will still need to have documentation demonstrating the aforementioned activities were performed properly.

Another function of the supply chain requirement is to ensure that food products coming into the country have been produced under the new regulations. This is referred to as the Foreign Supplier Verification Program, or FSVP. In essence, the FSVP includes importers under the requirements of the supply chain program. The verification activities are slightly less comprehensive, but importers are required to possess enough documentation from their sources which "provide assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented".

Supplier verification activities can include on-site audits, sampling and testing of the raw material or ingredient, review of the supplier's food safety records and any other "appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or ingredient".

The supply chain program also keeps the FDA from having to directly pressure foreign suppliers to follow the regulations. Instead, it makes conducting business with a company that does not have a

food safety plan that follows the regulations unattractive. The receiving facility in that case would need to compensate for all food safety issues which could arise during the manufacturing or processing of the raw materials they are sent.

Like every other part of the FSMA regulations, the supply chain program requires arduous documentation. This includes records of the supply-chain verification activities taken at each supplier facility, and a complete record of every supplier facility with which the receiving facility works. The regulations recommend that suppliers negotiate which hazards will be controlled where in the production chain, including the sourcing of raw materials. Those negotiations and agreements must also be thoroughly documented.

International Manufacturers

As the supply chain program makes clear, the FDA expects international manufacturers to follow the regulations outlined in the regulations; specifically, the hazard analysis and food safety plan creation. The same rules apply to international manufacturers as apply to local manufacturers.

The responsibility for working out ways to demonstrate compliance with the regulations falls upon the importers, and not on the international manufacturers. If proper documentation of food safety processes is easily accessible, a supplier verification activity such as an on-site audit once a year will be sufficient to satisfy the requirements

7. Label-Specific Regulations

The regulations specifically state that part of the food safety plan must include controls to help ensure food "manufactured, processed, or held by the facility will not be misbranded". Food is considered to be misbranded if "it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless certain labeling requirements are met". The labeling requirements referred to are essentially an accurate declaration of ingredients, with allergens specifically highlighted or separated from the ingredient list.

It is important to note that "misbranding" does not mean the same thing as "mislabeling." A package with the correct label but a product that has been contaminated with an allergen would be considered misbranded in the same way that a product with the incorrect label applied would be considered as misbranded. When the regulations discuss "preventive controls" to address the hazard of misbranding, they are not specifically focusing on the label, but labeling does enter the equation. The packaging and labeling process is specifically called out as being a necessary part of the hazard evaluation.

FSMA requires regular verification that allergen controls are functioning as intended. Verification can range from testing employees' knowledge of the allergen control process to monitoring inspection equipment to ensure it is functioning properly. Any verification activities must be documented and kept in a form that is easily retrievable and presentable to the FDA should they ask for proof. Every manufacturer will need a procedure to prevent any possibility of mislabeling.

An interesting change to food labeling regulations is the additional requirement that manufacturers notify consumers when a facility does not control for a particular hazard. This information must appear on the label and include both information on the hazard in question and "the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities)". This information must appear on the food packaging label "prominently and conspicuously" (ibid). For products which may not have a label, the regulations

require the information to appear "prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales" (ibid).

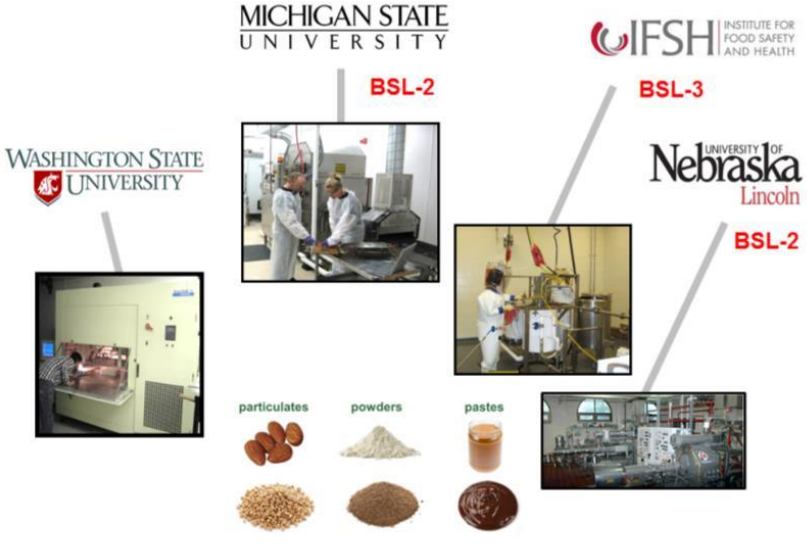
This regulation serves two purposes. It serves to warn consumers about the possible hazards of consuming a food not subject to the proper hazard controls. Secondly and more importantly, it encourages thoroughness in the food safety plan, as no manufacturer wants to advertise an uncontrolled hazard on their product label. Again, the final decision on how far to go in their food safety program is up to the manufacturer, but the FDA is clearly hoping manufacturers will choose to control for more hazards rather than make label design changes.

8. Low-Moisture Food Pasteurization Alliance

Salmonella has been implicated in outbreaks and/or recalls in numerous low-moisture foods and ingredients, including almonds, pistachios, peanut products, hazelnuts, pecans, pet food, cake batter mix, and other dry ingredients, including soy products, black pepper, and dried hydrolyzed vegetable protein (HVP). Hygiene and sanitation practices are insufficient to alone ensure product safety; therefore, processing interventions are an emerging imperative to reduce the risk of Salmonella in low-moisture products. FSMA Preventive Control rules mandate that the food industry implements and validates interventions to prevent or control identified hazards, such as Salmonella in low-moisture products. No single technology will provide a universal solution acceptable for all types of low-moisture products or processors.

From the FDA perspective, there is an entire category of currently-operating "legacy technologies" that were not designed as "kill steps" (e.g., roasting, baking, and drying), but which now must be validated for this purpose (including appropriate controls and monitoring systems). Although general guidance about controlling Salmonella in low-moisture products and validating thermal processes is available, prior reports do not address specific challenges associated with technology selection, technology improvement, or application of product- or process-specific inactivation data or models.

To address this need, the USDA-NIFA has awarded University of Michigan a five-year (2015-2020) multi-institutional research/training/education grant focused on low-moisture food pasteurization. The alliance involves the multi-institutional group shown in the chart below, together with an Industry Advisory Group (AIG), the FDA, IIT and IFSH.



Alliance Objectives

- Alliance objectives are to develop standardized protocols for evaluation/validation of low-moisture pasteurization technologies (e.g., mapping temperature distributions, quantifying process variability, and selecting/preparing/utilizing a non-pathogenic surrogate).
- Conduct an extensive battery of inoculated challenge studies with representative products treated by multiple process technologies (e.g., steam, radio-frequency, extrusion, drying, gas), including pilot-scale trials in multiple Biosafety Level-2(3) pilot plants, to quantify process characteristics (e.g., efficacy, variability) and to establish "safe harbors."
- Develop and evaluate improvements of key existing thermal processes previously designed to achieve quality outcomes, but not necessarily pasteurization outcomes (e.g., dryers, baking ovens, roasters), in order to enable implementation of low-cost food safety solutions, particularly for small and medium-sized processors.
- Develop, implement, and assess multiple outreach, training, and service resources aimed at technology developers, end-users, and validation professionals, including:

    ✓ A multi-criteria technology comparison tool.
    ✓ Sustainable professional training programs, including annual workshops, webinars, and FSMA standardized curriculum modules.
    ✓ A multi-location "Validation Center" that will provide long-term support (validations and on-site training) for equipment companies and processors of low-moisture foods.

- Develop, test, disseminate, and assess online, graduate-level learning modules focused on low-moisture food safety, pasteurization technologies, and process validation methodologies.

Validation Center

One of the purposes of this project is to provide long-term support (i.e., process validations and on-site training) for equipment companies and processors of low-moisture foods, via a multi-location "Validation Center" that enables easy access to the very significant, aggregated Biosafety Level-2(3) pilot processing capabilities among the project teams/institutions.

9. FDA Strategy for FSMA Training

The Produce Safety Alliance (PSA), Food Safety Preventive Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA), which are composed of representatives from FDA, USDA, state regulatory agencies, the food industry and academia, are developing training programs to help domestic and foreign food businesses, including small and very small farms and facilities, understand the requirements of the preventive controls regulations and final rules.

Crafting FSMA Alliance Curricula for Human Food and Animal Food

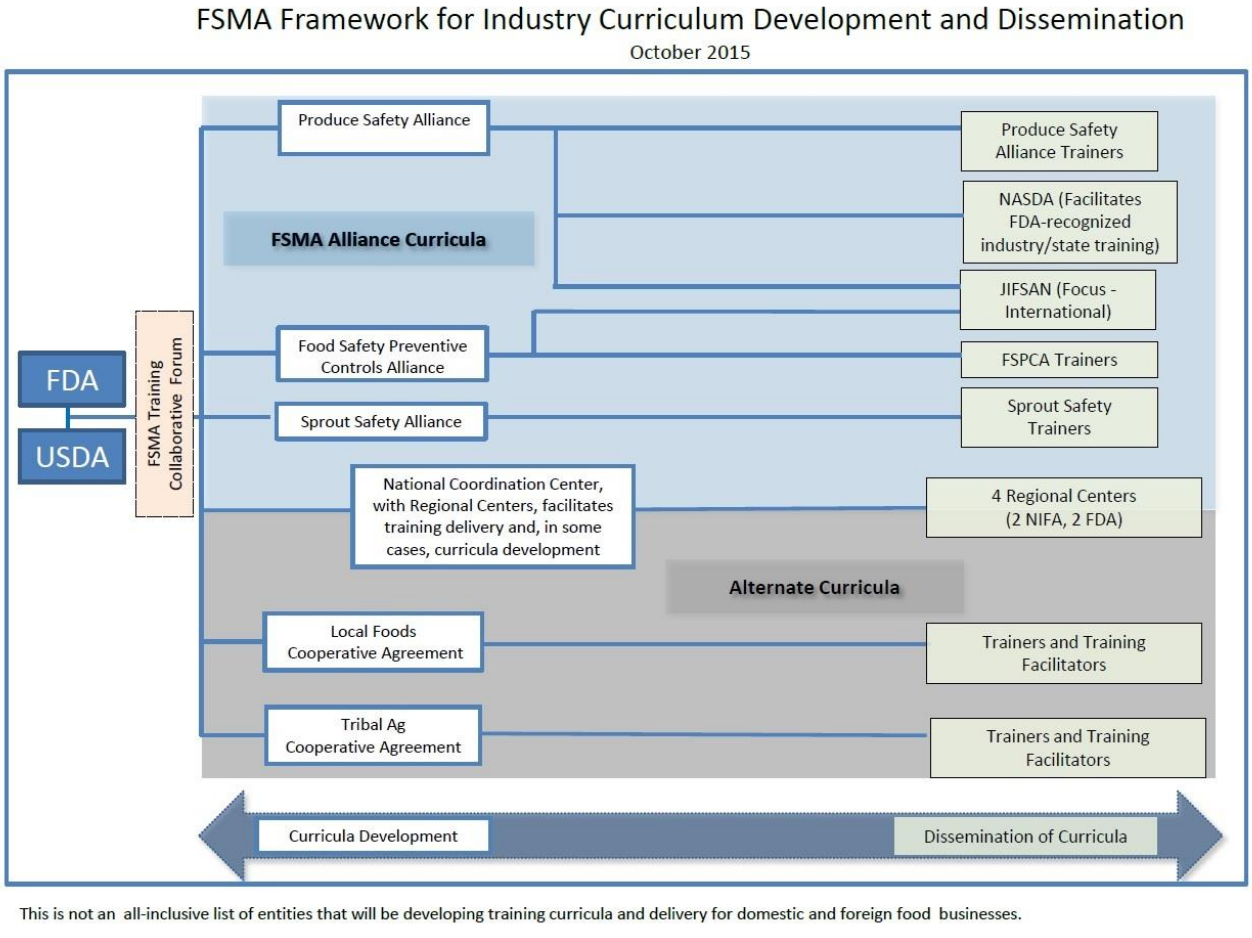
The role of the **Food Safety Preventive Controls Alliance (FSPCA)**, initiated in 2011 and coordinated by Illinois Institute of Technology's Institute for Food Safety and Health, is to develop a standardized training and education program and technical information network to help the domestic and foreign food industry, including certain mixed-type facilities on farms, comply with the requirements of the Preventive Controls rules for human food and animal food, as well as the rule on Foreign Supplier Verification Programs (FSVP). This work includes developing:

- Two separate standardized hazard analysis and preventive controls training courses and distance education modules—one for human food industry and regulatory personnel and another for animal food industry and regulatory personnel.
- A training curriculum that addresses:
  - Resources for and preliminary steps in developing a food safety plan,
  - Types of hazards, conducting a hazard analysis, preventive controls for hazards,
  - Monitoring preventive controls, verification and validation, and corrective actions/corrections, recordkeeping, and regulatory requirements.
- A website at http://www.iit.edu/ifsh/alliance/
- Two separate Train-the-Trainer courses for those interested in helping to train food facilities—one course for human food and another for animal food.
  - A module on the FSVP rule for processors who import foods, and a full FSVP course for non-processor importers. The Alliance is also encouraging all importers to take the complete Preventive Controls training.

The IIT/IFSH/FSPCA website provides the following link http://www.iit.edu/ifsh/alliance/upcoming_events/fspca_traineroftrainers.shtml that lists recognized FSPCA Trainers of Trainers for Human Food and animal food.

The alliance also provides a link on their website at http://www.iit.edu/ifsh/alliance/ to their FSPCA Lead Instructor listing.

FDA is working with public and private partners globally to ensure that training programs meet the needs of those who must comply with the new FSMA standards, no matter their size, nature or location. Following is a chart showing an overview noting the FDA and USDA's approach to curricula development.



10. Detention & Recall of Product and Suspension of Registration

Expanded Administrative Detention:

Today, the FDA is using its expanded authority to prevent the sale or distribution of potentially harmful foods, while the agency determines whether other actions are warranted.

Suspension of Registration:

FSMA authorizes the FDA to suspend the registration of a food facility, and its ability to legally distribute or sell food from the facility in the United States, if there is a reasonable probability that human food or animal food manufactured, processed, packed, received, or held by the facility presents a serious health hazard and certain other criteria are met.

Mandatory Recall:

Under certain circumstances, the FDA can order the recall of a potentially harmful food if the responsible party does not voluntarily cease distribution and recall the food after being provided with an opportunity to do so by the FDA.

11. Summary

The Food Safety Modernization Act is generally regarded as a positive change, both by food safety proponents who have lobbied for it for more than ten years, and by the food industry itself. They recognize not only the benefit it brings of avoiding food-borne illnesses and saving lives, but also of reducing the likelihood of the product recalls and liability lawsuits that have led to substantial unpredicted costs and loss of brand value in the past.

The new law will require both added effort and financial expense from food producers, but these should be viewed as investments leading to the reduction of potential costly losses due to unsafe foods entering the marketplace. The close review of production procedures and equipment for safety hazards required by FSMA also offers the opportunity for greater productivity, since systems are upgraded and streamlined as a result. Newer systems – both production and inspection systems – that may be installed as a result of the review will also introduce increased automation into production lines, further increasing productivity and reducing labor costs.

The sooner facilities begin the analysis and documentation process, the more confident they can be of meeting FSMA's requirements and avoiding potential costly inspections, recalls and liability lawsuits.

12. FDA Resources

- FDA Food Safety Modernization Act (FSMA)
- FSMA Public Law 111-535-January 4, 2011
- Registration of Food Facilities
- Inspection Classification Database Search
- FDA Inspection and Compliance
- FSMA Framework for Industry Curriculum Development and Dissemination
- FDA Investigations Operations Manual
- Food Safety Preventive Controls Alliance (FSPCA)
- Recall, Market Withdrawals, & Safety Alerts

13. FSMA Final Rules and Fact Sheets

- Accredited Third-Party Certification
- Accredited Third-Party Certification – Fact Sheet
- Foreign Supplier Verification Program
- Foreign Supplier Verification Program – Fact Sheet
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Mitigation Strategies to Protect Food Against Intentional Adulteration – Fact Sheet
- Preventive Controls for Human Food
- Preventive Controls for Human Food – Fact Sheet
- Preventive Controls for Animal Food
- Preventive Controls for Animal Food – Fact Sheet
- Produce Safety
- Produce Safety – Fact Sheet
- Sanitary Transportation of Human and Animal Food
- Sanitary Transportation of Human and Animal Food – Fact Sheet

14. Other Resources

- Global Food Safety Initiative (GFSI)
- OSHA Final Rule for Handling Retaliation Complaints (Whistleblower Protection)
- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Public Health Service Act (FHS Act)

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