

FDA's Strategy for FSMA Training: Who Will Provide Training for the Food Industry? Public and Private Partners Working Together

Executive Summary

The FDA Food Safety Modernization Act (FSMA) will transform the nation's food safety system into one that is based on the prevention of foodborne illnesses. It will be a system in which the food industry systematically puts in place measures proven effective in preventing contamination.

Keeping food safe to eat is paramount, no matter where it is produced, whether conventional or organic, whether the operation is small, medium or large, whether it's produce or processed foods.

The FDA has finalized the seven foundational rules that will implement FSMA. These include the two Preventive Controls rules for Human and Animal Food, the Produce Safety rule, and the Foreign Supplier Verification Programs (FSVP) rule. There will be extensive outreach to industry to help ensure that everyone who seeks to comply with these rules, whether legally required to or not, understands the new requirements.

Food industry training will be an important component of successful implementation. The Produce Safety Rule and the Preventive Controls rules all have training components, although they are not the same for each rule. There will be ample time for farmers and food producers to come into compliance with the FSMA rules. Compliance dates for the rules are staggered according to the size of the business and other factors.

While members of the food industry are ultimately responsible for getting the training they need to comply with the FSMA rules, the FDA recognizes the importance of its role in facilitating that training. For the agency, this means joining with public and private partners in state, federal, tribal and international governments, industry, and academia in the development and delivery of training.

One size doesn't fit all. The most important goal that the FDA expects of any training program is the outcome—that it advances knowledge among the food industry to meet FSMA requirements. There is more than one way to get there and there will be a variety of training options and delivery formats:

- The vision of FSMA training began in 2010-2012 with the creation of public-private Alliances funded primarily by the FDA as a resource for industry and to facilitate widespread understanding of the new standards to support compliance. Training through the Alliances will be available shortly after the rules have been finalized.

- Recognizing the great diversity among members of the food industry, the FDA is building on that investment by funding cooperative agreements that will develop training options for local food production systems and tribal operations.
- The FDA is partnering with the U.S. Department of Agriculture’s National Institute of Food and Agriculture (NIFA) to provide grants to fund a National Coordination Center (NCC) and four Regional Centers (RCs) to provide training opportunities for owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

FSMA training will encompass various members of the food industry, including domestic and foreign food producers and domestic importers. The FDA will work with partners around the world—including the Alliances, regulatory counterparts, and multinational organizations—to promote training to the global community of food suppliers. Participants will likely receive documentation of completion for any of the above mentioned training options.

The following is a description of the evolving training strategy. There is a glossary of frequently used terms and a listing of some of the FDA’s training partners at the end of this document.

Summary of the Major Components of the Training Strategy

The FDA is striving for transparency as this multi-faceted training plan for the food industry, outlined below, takes shape.

Crafting the FSMA Alliance Curricula

The Produce Safety Alliance (PSA), Food Safety Preventive Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA) 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 the Produce Safety rule. The Alliances are composed of representatives from the government, including FDA, USDA, and state regulatory agencies, the food industry, and academia.

The Alliances initially conducted extensive outreach to gain an understanding of training needs, including a consideration of food safety training available prior to FSMA. Since then, the Alliances have actively engaged over the past several years with hundreds of stakeholders—including food processors, the farming community, academia, cooperative extension, and regulators—to develop industry training curricula. Numerous working groups assessed course content needs, established learning objectives, and defined critical elements for the curricula. The Alliances also conducted pilot sessions with these partners to review training materials.

The curricula developed through the Alliances will focus on the FSMA rules and the foundational

reasons for the rules' existence to foster an understanding of both what is required and why it is required. They will be designed to be model curricula with training modules that can be added to meet unique needs.

The Alliances are working to ensure that training opportunities available to international food businesses are consistent with those being provided domestically. FSPCA—working with PSA, as well as representatives of importers and foreign governments, and others—has established an International Subcommittee to address the training, education and technical assistance needs of global stakeholders.

More on the individual Alliances:

- The most longstanding is the **Produce Safety Alliance (PSA)**, a partnership created between Cornell University, the U.S. Department of Agriculture (USDA) and FDA in 2010. PSA's role includes developing:
 - Standardized training and education curriculum to assist the domestic and foreign produce industry, including but not limited to small and very small farms, as well as regulatory personnel, with the implementation of FDA's Produce Safety rule.
 - A Train-the-Trainer (TTT) course to develop certified trainers and an interview process for developing certified lead trainers who are qualified to use the curriculum to train farms. The TTT course will include information on Good Agricultural Practices (GAPs), concepts of adult learning, and the forthcoming FSMA Produce Safety standards.
 - A website at www.producesafetyalliance.cornell.edu
 - A network of trainers to support the produce industry and the dissemination of produce safety trainings
- 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 developing 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 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 **Sprout Safety Alliance (SSA)**, initiated in 2012 and coordinated by Illinois Institute of Technology's Institute for Food Safety and Health, is serving as a network hub and resource for the sprout industry, and federal and state regulatory agencies. SSA is developing:
 - Training materials that will provide techniques to enhance the safe production of sprouts, and facilitate implementation of relevant requirements in the Produce Safety rule.
 - A Train-the-Trainer course for those interested in helping to train farms on safe sprout production.
 - A website at http://www.iit.edu/ifsh/sprout_safety/

The Alliance-developed materials will be publically available for use in training activities and as benchmarks for others developing equivalent curricula.

Alternate Training Options

The FDA will be issuing guidance that details the core criteria, learning objectives, and elements recommended for FSMA training programs.

The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) are developing model, standardized curricula that are intended to meet the needs of, and be used by, the majority of those affected by the FSMA rules.

By the same token, the FDA recognizes that traditional training activities may not work for all groups,

and there are certain instances in which alternate curricula and training delivery may be appropriate.

The FDA intends to fund the development of certain alternate training programs for specific target audiences through cooperative agreements, as discussed further below. The agency will work closely with the participants in those agreements and expects to recognize the training programs that are developed through these collaborations.

The agency intends that the standardized curricula being developed by the Alliances and the alternate curricula to be developed through cooperative agreements are the only ones that will be officially recognized by the FDA. The agency encourages those developing other training courses to work with the Alliances, the NCC and the RCs to ensure consistency and completeness of training. The agency plans to provide additional information regarding how such training programs will be evaluated.

Cooperative Agreements

FDA-funded cooperative agreements encompass a range of actions to support implementation of the FSMA rules.

- The agency has entered into a five-year cooperative agreement with the **National Association of State Departments of Agriculture (NASDA)** that brings together a range of state partners to collaboratively plan implementation of the Produce Safety rule.
 - Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation is actively participating in the development of these practices.
 - NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.
- To accommodate alternate approaches to FSMA readiness, the FDA plans to fund development of several specific training programs through cooperative agreements. The agency's goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA. These training programs would include providing an awareness of the underlying reasons for the new standards and would ensure that training addresses the unique needs of the target audiences.

Specifically, cooperative agreements are planned to support curricula development and dissemination among two such communities: local food producers, including those engaged in direct marketing (see glossary below for more information), and tribes.

- The agency plans to allocate Fiscal Year 2016 funds for the development of training curricula and delivery, in addition to education and outreach, with a focus on small and mid-

size businesses involved in local food production, including those that engage in sustainable and organic farming.

- The FDA anticipates funding a similar cooperative agreement for the development of training curricula and dissemination in tribal communities.
- The FDA will be involved in facilitating communications between the Alliances and the participants in the new cooperative agreements to maximize use of materials that are already developed, when appropriate.

Establishing the National Coordination and Regional Centers to Support Training Delivery

In January 2015, the FDA announced that it had joined with USDA’s National Institute of Food and Agriculture (NIFA) in a collaborative partnership to establish the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, as mandated in Section 209 of FSMA.

As mandated in FSMA, this competitive grant program will provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

Grants issued through this program will fund a **National Coordination Center (NCC)** and four **Regional Centers (RCs)**, which will be involved in both key components of training—primarily facilitating training delivery but also, in certain situations, facilitating curricula development targeted to specific audiences.

- FDA has awarded the **International Food Protection Training Institute** (<http://www.ifpti.org>) a grant of up to \$600,000 over three years to establish the NCC, which will lead coordination of curriculum development and delivery to those food businesses covered by the FSMA Section 209 mandate for implementation of FSMA.
- The NCC will coordinate and support the delivery of standardized and/or alternate training curricula through the RCs.
- The RCs will be charged with understanding and communicating the landscape of training opportunities available to target businesses in their region. They will identify any need to develop or tailor curricula to meet specific unmet regional needs and/or to target a specific audience. Training programs may differ to meet those needs. The NCC will facilitate communication between the RCs, the Alliances and other partnering groups about the development of such region- and/or audience-specific materials.

- The regional centers will be established with separate grant money in the Southern, Western, North Central and Northeast regions of the country. These centers will work with representatives from non-governmental and community-based organizations, as well as representatives from cooperative extension services, food hubs, local farm cooperatives and other entities that can address specific needs of the communities they serve.
- Those eligible to receive a grant to establish a regional center included federal, state, or local government agencies, state cooperative extension services, non-profit community-based or non-governmental organizations, institutions of higher education, tribal organizations and tribal stakeholders, or a collaboration of two or more eligible entities.

Work has already begun on the establishment of the regional centers. In October 2015, NIFA issued grants for the Southern and Western regional centers to the University of Florida and Oregon State University. In February 2016, the FDA issued grants for the North Central and Northeast centers to Iowa State University and the University of Vermont and State Agricultural College.

Delivering the Training

Communication between organizations involved in curriculum development and delivery will strengthen the delivery of training and will involve coordination between the Alliances, NCC, RCs, and other training providers. Other organizations have had key roles in the development and/or delivery of training, as well as training certificates.

- The three Alliances—**Produce Safety Alliance (PSA), Food Safety Preventive Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA)**—are developing Train-the-Trainer programs to ensure that lead trainers are familiar with, and prepared to deliver, the curricula and that they understand the requirements of the FSMA rules.
 - Lead trainers—selected based on their education, work experience and training experience—who complete Train-the-Trainer programs will, in turn, deliver training to industry through an established process in which a certificate of completion of the PSA, FSPCA or SSA training is issued to participants.
- The FDA intends that funding of organizations and tribes through **cooperative agreements** will finance both the development of training curricula and the delivery of that training.
 - Training delivery for industry—and possibly trainers—will be coordinated through the cooperative agreement and these organizations will interact with the NCC, RCs,

Alliances, Extension and other partners to increase awareness of recognized training programs.

- These programs may also provide a certificate of completion to food industry participants.
- An important partner in the delivery of the recognized training programs will be the well-established network of cooperative extension offices affiliated with land-grant universities. This key group will support training efforts based on both the standardized and alternate curricula recognized by FDA.
- Other key partners on training delivery include:
 - PSA's four **Regional Extension Associates**, which will deliver training curricula developed by PSA.
 - NASDA and other state regulatory stakeholder associations, including the **Association of Food and Drug Officials**, the **Association of Public Health Laboratories**, the **Association of American Feed Control Officials**, and the **Association of State and Territorial Health Officials**. These state stakeholder groups participate in the Alliances and will help facilitate FDA-recognized industry training, as well as the training of state regulators.
 - The **Joint Institute for Food Safety and Applied Nutrition (JIFSAN)** for international training programs. JIFSAN is a partnership between the FDA and the University of Maryland.
 - Other training entities, such as government agencies, cooperative extension, universities, trade associations, nonprofit and community-based organizations, and consultants, who will deliver both the standardized and alternate curricula recognized by FDA.
- The NCC will coordinate training delivery to food businesses covered by the FSMA Section 209 mandate through the RCs and will ensure the involvement of partners during the development of and dissemination of training.
 - The RCs will coordinate and facilitate the delivery of curricula.
 - The RCs may also coordinate with multiple training entities to deliver the curricula in the most effective way for a target audience.

FSMA Collaborative Training Forum

The FDA intends to establish an informal **FSMA Collaborative Training Forum**, co-chaired by the FDA and USDA, to provide an opportunity for dialogue between the agencies, centers, associations and

others involved in this training.

- It will be a chance for representatives of these groups to come together, share information about their programs, provide updates about the work, and discuss issues of common concern. The purpose is not to come to a consensus on issues but to have an open dialogue about them and, to the greatest extent possible, eliminate duplication and maximize the use of limited resources.
- Participants will represent the FDA, USDA, the Alliances, the NCC, JIFSAN, NASDA, and the organizations who have received cooperative agreements. Others may be invited to join where appropriate.
- It is anticipated that meetings will be held on a quarterly basis.

Conclusion

FDA is on a path to 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.

It will take time and effort to make this work, and to get it right. FDA is committed to making sure that everyone involved in the food supply chain knows what training and education resources are available, and how to gain access to them.

Glossary of Terms Often Used in FSMA Training Documents

- **Standardized training curriculum:** A structured program in which the training materials will be recognized by the FDA as meeting the training standards and requirements in the Produce Safety rule (as proposed) and the Preventive Controls rules. The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) are developing model, standardized curricula designed to meet the needs of, and be used by, the majority of stakeholders who must comply with the FSMA rules.
- **Alternate curriculum:** FDA-recognized training programs to be developed through cooperative agreements. The agreements currently planned will support curricula development and dissemination among local food producers and tribes. The agency plans to provide additional information regarding how training programs developed by other entities (including universities, trade associations, and non-profit organizations) will be evaluated.
- **Train-the-Trainer:** Programs offered to those interested in becoming trainers and providing training for others on the FSMA regulations. The lead trainers would be schooled in

foundational food safety principles, the applicable FSMA regulations, the content of the training curriculum and how to deliver it, conducting working group exercises (as appropriate), and the principles of adult education. These are being developed by the Alliances and may also be part of alternative training programs.

- **Training delivery:** The dissemination of training curricula. (The approach may vary as appropriate for the target audience.)
- **Regional needs:** Regions may have unique needs based on target audiences and the nature of their food operations. This could include environmental differences, cultural considerations, the type of product, and marketing strategies. Examples include dry-climate farming practices, organic products, and direct-marketing channels.
- **Cooperative agreements:** An FDA cooperative agreement is a grant funding mechanism that involves significant FDA participation during the performance of the work. These usually involve FDA-funded partnerships with entities in the public or private sector, or both, that are designed, in this case, to lay the groundwork for FSMA implementation.
- **Local food production:** Food marketing channels that focus on providing food to a community or region directly or through intermediated markets. The farms and food enterprises that utilize these market channels include diversified, sustainable, organic, and identity-preserved agricultural operations; owner-operated and family farms; beginning and socially disadvantaged farmers; value-added farm businesses and small-scale processors; and direct and intermediated supply chain participants.

Setting the Stage for FSMA Implementation

The following organizations working in partnership with FDA have important roles in providing training to the food industry in preparation for implementation of FSMA:

Produce Safety Alliance (PSA): This Alliance was created by FDA and USDA, in cooperation with Cornell University, to develop a standardized training and education program to increase produce safety knowledge and prepare the produce industry and associated groups for FSMA implementation.

Food Safety Preventive Controls Alliance (FSPCA): This Alliance was created by a grant from FDA to the Illinois Institute of Technology's Institute for Food Safety and Health, to develop a standardized training and education program that will help industry comply with the Preventive Controls rules for human and animal food for animals under FSMA.

Sprout Safety Alliance (SSA): This Alliance was created by FDA, in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, to develop a standardized training and education

program and help sprout producers identify and implement best practices in the safe production of sprouts and prepare for FSMA implementation.

National Institute of Food and Agriculture (NIFA): Part of the U.S. Department of Agriculture, NIFA is partnering with the FDA to provide grants to fund food safety training, education, extension, outreach, and technical assistance to owners and operators of farms; small food processors; and small fruit and vegetable merchant wholesalers.

National Coordination Center (NCC): This center, funded by the FDA, will lead the coordination of training delivery, outreach, education and technical assistance to reach small and medium-size farms, beginning and socially disadvantaged farmers, small processors, and small fruit and vegetable merchant wholesalers.

Regional Centers (RCs): These regional centers will work with the NCC to increase the understanding and adoption of established food safety standards, guidance, and protocols. They will identify region and audience-specific training, education, outreach and technical assistance needs and deliver training to food producers covered by the FSMA Section 209 mandate, in addition to ensuring the availability of informed trainers.

International Food Protection Training Institute (IFPTI): Established in 2009, IFPTI is a public-private partnership that addresses public health needs and collaborates with industry, federal, state and international governments, and other organizations. IFPTI, which builds training and certification systems for food safety professionals, has been awarded the contract to establish the NCC described above.

Cooperative Extension and Land-Grant Universities: More than 100 land-grant colleges and universities have extension programs through which they bring science-based information to agricultural producers and small business owners, among others. Members of the Cooperative Extension System will have key roles in the delivery of FSMA training.

Cooperative Agreement Partners: The recipients of FDA funding to support curricula training and delivery to local food producers, including sustainable and organic farms, and tribes.

National Association of State Departments of Agriculture (NASDA): This association of state officials is in partnership with the FDA to collaboratively plan implementation of the produce safety rule under FSMA. NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.

Additional Organizations: These state stakeholder organizations will also have roles in facilitating regulatory and industry training:

- **Association of Food and Drug Officials**, whose members include state and local officials involved in critical food safety issues;
- **Association of Public Health Laboratories**, which works to strengthen laboratories serving public health;
- **Association of American Feed Control Officials**, whose members include state, local and federal officials involved in the safety of animal feed, and
- **Association of State and Territorial Health Officials**, which represents public health agencies and professionals.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN): This partnership between the FDA and the University of Maryland strives to increase global knowledge of effective food safety practices.

FSMA Collaborative Training Forum: Co-chaired by the FDA and USDA, this forum will facilitate communication and coordination between the groups involved in FSMA training and give the groups an opportunity to share information about their programs and address common concerns. In addition to the two agencies, represented groups will include the Alliances, the NCC, JIFSAN, NASDA, and the organizations that have received cooperative agreements with FDA. Other stakeholder groups may also be included.