

Regulatory Alert: FDA Releases FSMA Training Strategy *Public-Private Alliances to Play Key Role*

October 9, 2015

On October 6, 2015, the U.S. Food and Drug Administration (FDA) published a [document](#) entitled “FDA’s Strategy for FSMA Training-Who Will Provide Training for the Food Industry? Public and Private Partners Working Together” which summarizes the major components of FDA’s training strategy pertaining to implementation of the Food Safety Modernization Act (FSMA). Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information. Lieberman PLLC assists firms in FSMA compliance and managing regulatory risks. Erik Lieberman is a member of the Food Safety Preventive Controls Alliance.

Background

On September 17, 2015, FDA published in the Federal Register the Final Preventive Controls Rules for Human¹ and Animal Food.² Compliance with the preventive controls requirements of the rules begins as early as September 2016. The Produce Safety, Foreign Supplier Verification Program and Accreditation of Third Party Auditor rules are required to be finalized by October 31, 2015. The Sanitary Food Transportation Act and Food Defense rules are required to be finalized by March 31, 2016 and May 31, 2016 respectively. FDA FSMA alliance partners are currently developing training curricula for the Preventive Controls for Human and Animal Food Rules, Foreign Supplier Verification Program Rule and Produce Safety Rule. Section 209 of FSMA directs FDA to coordinate with the U.S. Department of Agriculture (USDA) in advising producers and small processors on FSMA and assisting them in regulatory compliance. It also requires the Agency to enter into one or more memoranda of understanding or cooperative agreements with USDA to provide training and assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers among other things.

Key Points

Who is developing the curricula?

FDA has funded three alliances to develop model, standardized curricula that are intended to meet the needs of, and be used by, the majority of those affected by the FSMA rules. The alliances are for Produce Safety, Food Safety Preventive Controls, and Sprout Safety. The Food Safety Preventive Controls Alliance is developing curricula to help businesses comply with the Preventive Controls Rules and Foreign Supplier Verification Program Rule and to educate regulatory officials. The Produce Safety Alliance and Sprout Safety Alliance are developing curricula for the Produce Safety Rule.

¹ 80 Fed. Reg. 55908 (September 17, 2015)

² 80 Fed. Reg. 56170 (September 17, 2015)

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Will there be alternative training options?

Yes. FDA states that they recognize 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. However, the alternate curricula will be limited.

What will the alternative training options be?

FDA is supporting alternate training programs through the following cooperative agreements:

- National Association of State Departments of Agriculture (NASDA): FDA has entered into a five-year agreement with NASDA to develop a set of best practices for implementation of the Produce Safety Rule and help facilitate industry training and play a role in the delivery of training to state regulators.
- FDA plans to fund development of specific training programs through cooperative agreements for local food producers, including those engaged in direct marketing, and tribes.

Will FDA recognize any other training curricula?

No. FDA 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. FDA encourages those developing other training courses to work with the Alliances, FDA's National Coordination Center and its four Regional Centers to ensure consistency and completeness of training.

What are the National Coordination and Regional Centers?

In January 2015, 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. 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 as required under Section 209 of FSMA.

Grants issued through this program will fund a National Coordination Center (NCC) and four regional centers (RC).

FDA has awarded the International Food Protection Training Institute a grant of up to \$600,000 over three years to establish the NCC which will lead coordination of curriculum development and delivery of training materials.

The RCs will be established with separate grant money in the Southern, Western, North Central and Northeast regions of the country.

How will training be delivered?

The Food Safety Preventive Controls Alliance, Produce Safety Alliance and Sprout Safety Alliance 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 is issued to participants.

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.

FDA notes that an important partner in the delivery of recognized training programs will be the network of cooperative extension offices affiliated with land-grant universities.

Other key partners identified by FDA include:

- Produce Safety Alliance Regional Extension Associates
- National Association of State Departments of Agriculture
- Association of Food and Drug Officials
- Association of Public Health Laboratories
- Association of American Feed Control Officials
- Association of State and Territorial Health Officials
- Joint Institute for Food Safety and Applied Nutrition

The NCC will coordinate training delivery to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers through the RCs.

FSMA Collaborative Training Forum

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.

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