

Updated Q&A for FSMA posted at:

http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#admin_detention

For your convenience the new updates are pasted below:

Update of FDA FSMA Q&A - November 14, 2011

FS.7 Could you elaborate more on how you are looking to engage partners, particularly NGOs, within the regulated community to conduct compliance inspection and facilitate reporting to better leverage limited governmental resources and staff? **NEW**

A: As part of the integrated food safety system and the formation of a national work plan, FDA/ORA has formed a work group to look at how to engage partners. FDA/ORA also has a field management directive (FMD) that outlines improvements in communications between FDA and state agencies.

I.4.9 Has FDA considered using the GFSI (Global Food Safety Initiative) program as the (or one of a few) third party accreditation? **NEW**

A: As a general matter, we cannot answer this or any other question that relates to predecisional, internal agency deliberative processes. Moreover, the question is unclear as worded. What we can state publicly that FDA is currently developing regulations and model accreditation standards directed by FSMA section 307 on third-party accreditation. FSMA directs the agency to look to existing standards to avoid unnecessary duplication of costs and efforts. To the extent that the questioner is asking whether FDA will rely on GFSI benchmarked standards, we cannot answer the question at this time. To the extent that the question is asking whether GFSI will have a role in the third-party program, we can say that after the third-party rulemaking is final, the program will go into effect and accreditation bodies can begin to seek FDA recognition and likewise, third-party auditors (also known as certification bodies) can begin to seek accreditation from an accreditation body recognized by FDA. Direct accreditation of certification bodies may take place only under certain conditions and after the program has been in effect for two years.

I.4.10 Will third party auditors have the same authorities and tools of FDA when qualifying imported food companies for entry into the US? **NEW**

A: No. Accredited third-party certification bodies will not be commissioned by FDA nor will they otherwise be in the role of regulatory authority, acting on FDA's behalf. This is true regardless of whether the accredited certification body is, itself, government (i.e., public) entity.

IC.4.2 Is compensation available for those whose products are determined to have been recalled or detained without cause? **NEW**

A: There is nothing in FSMA that changes existing rules regarding such matters, such as, for example, the Federal Tort Claims Act.

P.11 What are the estimated costs of a new inspection system – new inspectors, new processing, additional labs and reporting to Congress? What will the cost impact be on the farmer and consumer? **NEW**

A: It is too soon to know what the costs will be; FDA anticipates there will be some initial costs with the implementation of two rules that FDA anticipates releasing soon, the preventive controls and produce regulations.

PT.1.4 Your priorities for FSMA did not list when you will run pilots on overarching food traceability systems. When will this be a priority? **NEW**

A: On September 7, FDA announced two product tracing pilot projects that will enhance the agency's

and industry's ability to trace products through the food supply. These two pilot projects, one for processed foods and one for produce, are being conducted through an existing contract with the Institute of Food Technologists (IFT). IFT will carry out the pilots at the direction of FDA, and the Agency will retain the ultimate decision making authority. IFT will obtain input from the industry sectors and consult with USDA, state agencies and consumer groups on proposed foods and/or ingredients and product tracing technologies. If North Carolina is interested in participating, please contact IFT (see Frequently Asked Questions section for Product Tracing on FSMA website for contact info). Prioritization is an important part of our implementation strategy. It is clear that we cannot meet all of the deadlines in the statute. We are focusing first on those with the greatest public health benefit, such as preventive controls, inspection and compliance, and the import provisions. Product tracing is a component of the Inspection and Compliance Team.

As new information becomes available on the pilots and prioritization, as well as other aspects of FSMA, FDA will update its website at <http://www.fda.gov/fsma>¹⁵. See below for more information on the Product Tracing Pilots.