ADPI Commentary
Volume II
Issue 2

FDA Fast Tracks Proposed FSMA Intentional Adulteration Regulations - Is Your Plant Ready? - January 2014

The US Food and Drug Administration is increasing the pace of publishing proposed regulations required by the 2011 Food Safety Modernization Act (FSMA). On December 20th, 2013, the FDA released the proposed 170 page regulation on Intentional Adulteration (IA), which once finalized sometime in mid-to-late 2014 will give larger dairy plants and those meeting certain criteria to have a formal, written enhanced IA/Food Defense program one year to comply.

Dairy plants exempt from the IA regulation include those generating less than $10 million in total annual sales. Other exempt facilities include warehousing unless they contain liquid storage tanks, distributors that keep food in original packaging on the food, plants that make only food for animals and plants that make alcoholic beverages. Farms may or may not be exempt depending on what they produce, if they process on-farm and if they produce raw milk or some other food (see table below).

A dairy plant's written IA program will need to focus on preventing acts of terrorism, actions by disgruntled employees, consumers and competitors as well as economically-motivated adulteration (example – melamine in infant formula). Dairy plants which are not exempt from the IA regulations (see table below) will have to have a written IA/Food Defense program that addresses the following:

- Restricting access to bulk liquid receiving, storage and handling, mixing, blending and similar operations
- Sealing of tankers and other vehicles delivering raw materials, ingredients and packaging
- Protections for secondary ingredient handling
- Identification of processing areas with the highest risk for IA
- "Open" processing points

The written IA program will have to identify mitigation strategies to reduce the likelihood of intentional contamination at all processing steps such as cameras, employee training, restricted access via locked doors, etc. The IA program will have to be supported by monitoring records, documented corrective actions and a verifi cation program to demonstrate that the plant's written IA program is being properly implemented. Another

requirement is that the plant must identify a "qualified individual" that has the responsibility to manage the IA/Food Defense program.

FDA has requested comment from the industry on the use of HACCP as the basis for determining where to concentrate IA efforts. If HACCP would be used, then the plant would be required to identify Threat Assessment Critical Control Points (TACCP) and build a written IA program around the 7 principles of HACCP, focusing on intentional contamination threats instead of food safety hazards. Comments are also being requested from the industry on whether dairy farms should be included in the IA final regulation as well as if on-farm processing, packaging or holding of foods or food ingredients (raw milk) should be exempt from the FDA FSMA Intentional Contamination Requirements.

An FDA-sponsored public meeting will be held on February 20, 2014 in College Park, MD to take verbal comments on the proposed International Adulteration (IA) proposed regulation. ADPI members interested in submitting comments can either contact ADPI CEO Dave Thomas or make written comments directly to FDA through its on-line Dockets Management system until March 31, 2014. The FDA will conduct additional outreach during the comment period, which may include additional public meetings. For more information, please contact Mr. Allen Sayler at asayler@cfsrs.com or via phone at 571-931-6763.

View FSMA Food Defense Proposed Regulation Fact Sheet
For ADPI Members - Click here to view CFSRS Summary of the Proposed International Contamination Regulation

Exemptions and Modified Requirements for Focused Mitigation Strategies to Protect Food against Intentional Adulteration*

Type of facility or operation	Exempt Status
A very small business (a business that has less than $10,000,000 in total annual sales of food, adjusted for inflation)	Exempt, but would be required to provide to FDA, upon request, documentation relied on to demonstrate that the business is very small.
The holding of food, except the holding of food in liquid storage tanks	Exempt
The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact	Exempt
Activities that fall within the definition of "farm"	Exempt
Manufacturing, processing, packing, or holding of food for animals	Exempt
Alcoholic beverages under certain conditions	Exempt

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