



New FDA Bioterrorism Regulations

As discussed in QAI's last two quarterly newsletters, there is proposed legislation that, when implemented, will impact the way business is conducted in the United States. The US Food and Drug Administration (FDA) plans to publish the final legislation in the *Federal Register* by October 12, 2003. For more information on the proposed regulations and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: www.fda.gov/oc/bioterrorism/bioact.html. FDA, 5630 Fishers Lane Room 1061, Rockville, MD USA 20852.

In keeping with our commitment to our valued clients, QAI will continue to update you on this matter as information becomes available. Should you have any questions, please contact Ellen P Holton, QAI Director of Marketing at 858.792.3531 or by email: ellen@qai-inc.com

Prior Notice on Importations

Proposed Legislation The FDA must receive prior notice of food—including dietary supplements and animal feed—imported or offered for import into the U.S. Shipments without adequate prior notice, or from unregistered facilities, will be refused admission and will be held at the entry port unless FDA directs removal to a secure location.

How It Could Affect Your Business Under the proposal, FDA must be notified, through an FDA internet-based system, by noon of the calendar day before the day the imported food will arrive at the U.S. border crossing or at the port of entry.

FDA's Reason for Proposal It will give FDA advance information of imported food shipments and allow FDA to target inspections more effectively. It will help ensure the safety of imported food products, before they enter domestic commerce, against terrorist acts and other public health threats.

Proposed Timeframe Begins December 12, 2003.

Registration

Proposed Legislation Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register with the FDA. The final rule will list types of facilities required to register and those exempt.

How It Could Affect Your Business The proposed regulation will require the owner, operator, or agent in charge of a domestic [or foreign facility](#) to submit a registration to FDA.

FDA's Reason for Proposal Their proposal is one of the keystones in implementing the Bioterrorism Act of 2002. This act provides FDA new authority in protecting the nation's food supply against terrorist acts and other threats.

Proposed timeframe By December 12, 2003.

Records Maintenance

Proposed Legislation Companies dealing with food must maintain records identifying the immediate source from which they received the food, as well as the immediate subsequent recipient.

How It Could Affect Your Business This requirement will apply to all foreign and domestic food sources and almost all recipients of food destined for consumption in the U.S. To minimize the economic burden on companies affected by the proposal, FDA's proposal allows companies to keep the required information in any form that they prefer and states that existing records can be used to satisfy the requirements if these records contain all the required information.

FDA's Reason for Proposal It will assist FDA in addressing credible threats of serious adverse health consequences, such as terrorism-related contamination, or death to humans or animals.

Proposed timeframe Six to 18 months from the date of publication of the final rule in the *Federal Register*, **depending on the size of business.**

**6 MONTHS - 500 OR MORE EMPLOYEES;
12 MONTHS - 11-499 EMPLOYEES;
18 MONTHS - 10 OR LESS EMPLOYEES.**

Detention

FDA will have authority to detain any food for which there is credible evidence that it poses a threat of serious adverse health consequences or death. This authority granted to FDA is self-executing and currently in effect, and provides an added measure to ensure the safety of the nation's food supply. The proposed rule includes procedures describing how FDA will detain an article of food and the process for appealing a detention order.