Bioterrorism Regulations:
Records Maintenance and Inspection of Records for Foods

The September 11, 2001 attacks and the subsequent anthrax incidents reinforced the need to enhance the security of the U.S. food supply. On June 12, 2002, Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002). The purpose of this law is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act of 2002 includes provisions calling for administrative detention of foods, registration of foreign and domestic food facilities, prior notice of food imports and the establishment and maintenance of records.

What Congress Mandated
Section 306 of Bioterrorism Act of 2002 authorizes the Secretary of Health and Human Services to have access to certain records kept by food processors when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food. Section 306 also requires the Secretary of Health and Human Services to promulgate proposed and final regulations within 18 months of enactment for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. This law limits the maintenance of records to two years.

Importance to Food Safety
The maintenance and inspection of records is intended to significantly improve the Food and Drug Administration’s (FDA) ability to contain threats from accidental or deliberate contamination of food. The recordkeeping provision creates a chain of custody that FDA can use to track foods implicated in emergencies.

FDA’s ACTIONS:
Notice of Proposed Rulemaking
On May 9, 2003, FDA issued a Notice of Proposed Rulemaking for records maintenance and inspection of records. Under the proposed rule, processors and importers of food would be required to keep records identifying the immediate source of food or ingredients and their subsequent distribution. The proposed rule provided numerous exemptions, for example, for farms and restaurants.

Final Regulation Repeatedly Delayed
Despite the fact that the Bioterrorism Act of 2002 set an 18-month deadline, FDA has repeatedly delayed the adoption of the interim final regulation. On December 3, 2003, FDA announced that the regulation would be finalized by the end of March 2004. In a May 27, 2004 press release, FDA announced that it plans to issue the interim final rule “shortly.” No regulation has been issued.
Bioterrorism Regulations: 
Prior Notice of Food Imports

The September 11, 2001 attacks and the subsequent anthrax incidents reinforced the need to enhance the security of the U.S. food supply. On June 12, 2002, Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002). The purpose of this law is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act of 2002 includes provisions calling for administrative detention of foods, registration of foreign and domestic food facilities, prior notice of food imports and the establishment and maintenance of records.

What Congress Mandated
Section 307 of the Bioterrorism Act of 2002 requires prior notice of imported food shipments. It requires the Secretary of Health and Human Services to issue regulations that specify the period of advance notice for food imports, but that notice should be “no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification.” Section 307 also requires the Secretary of Health and Human Services to promulgate proposed and final regulations within 18 months of enactment of the Bioterrorism Act of 2002, and if this deadline was not met, Congress stipulated that notice would be no less than 8 hours and no more than five days.

Importance to Food Safety
The prior notice of food imports provision gives FDA specific information in advance on food shipments arriving at U.S. ports of entry. This advance information will allow the FDA, working with U.S. Customs and Border Protection (CBP), to more effectively target inspections of imported foods. FDA inspectors currently visit only 90 of 360 ports of entry daily.

FDA’s ACTIONS:
Notice of Proposed Rulemaking
On February 3, 2003, FDA issued a Notice of Proposed Rulemaking. The proposed rule requires that prior notice of food imports be submitted to FDA no later than 12 noon of the calendar day before the day the article of food will arrive at a port of entry. The proposed rule exempts food carried by individuals for their own use or meat, poultry or egg products that are exclusively regulated by the U.S. Department of Agriculture at the time of importation. All other imported food, including beverages, would be subject to the prior notice requirements, whether or not the food is intended for consumption in the United States.

Interim Final Rule
On October 10, 2003, FDA issued the interim final regulation on prior notice of food imports. The interim final rule significantly reduces the time frame for advance notice listed in the proposed rule. The interim final rule requires prior notice of a food import of at least two hours before arrival by truck; four hours before arrival by air or by rail; or eight hours before arrival by ship.
Bioterrorism Regulations: Administrative Detention

The September 11, 2001 attacks and the subsequent anthrax incidents reinforced the need to enhance the security of the U.S. food supply. On June 12, 2002, Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002). The purpose of this law is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act of 2002 includes provisions calling for administrative detention of foods, registration of foreign and domestic food facilities, prior notice of food imports and the establishment and maintenance of records.

What Congress Mandated
Section 303 of the Bioterrorism Act of 2002 authorizes the Food and Drug Administration (FDA) to detain food for up to 30 days if FDA officials have credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals. The law also requires FDA to establish regulations setting forth expedited procedures for perishable foods, such as fresh produce, fresh fish and fresh seafood products.

Importance to Food Safety
The administrative detention provision allows FDA to identify and remove contaminated food from commerce. It is an essential tool that Congress provided FDA in order to respond to both bioterrorism and unintentional contamination of the U.S. food supply.

FDA’s ACTIONS:
Notice of Proposed Rulemaking
On May 9, 2003, FDA issued a Notice of Proposed Rulemaking authorizing an FDA officer or qualified employee to detain domestic or imported food for up to 30 days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. FDA also proposed labeling of the detained article of food with official tags or labels stating that the article of food must not be consumed, moved, altered, or tampered with. The proposed rule provided different timeframes depending upon whether the detained article of food is perishable or nonperishable, as required by Congress.

Interim Final Regulation
On June 4, 2004, FDA issued the interim final rule implementing section 303. The interim final rule provides procedures for the detention of an article of food for up to 30 days if FDA staff has credible evidence or information indicating that the article presents a threat of serious adverse health consequences or death to humans or animals. FDA made a few minor changes to the proposed rule, including requiring that an authorized FDA representative approve the detention order.
Bioterrorism Regulations:
Registration of Food Facilities

The September 11, 2001 attacks and the subsequent anthrax incidents reinforced the need to enhance the security of the U.S. food supply. On June 12, 2002, Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002). The purpose of this law is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act of 2002 includes provisions calling for administrative detention of foods, registration of foreign and domestic food facilities, prior notice of food imports and the establishment and maintenance of records.

What Congress Mandated
Section 305 of the Bioterrorism Act of 2002 requires the Secretary of Health and Human Services to develop a regulation to require domestic and foreign facilities that process, food for consumption in the United States to register with the Food and Drug Administration (FDA) by December 12, 2003. Each registration must contain information necessary to notify the Secretary of Health and Human Services of the name and address of each facility.

Importance to Food Safety
For the first time, FDA will have a complete roster of foreign and domestic food facilities. Section 305 will enable the FDA to quickly identify and locate food processors in the event of a deliberate or accidental contamination of food.

FDA’s ACTIONS:
Notice of Proposed Rulemaking
On February 3, 2003, FDA issued a Notice of Proposed Rulemaking for registration of food facilities. The proposed rule requires domestic and foreign food facilities that process food for human or animal consumption in the United States to register with the Agency. Except for specific exemptions, the proposed regulation applies to all facilities for all foods and animal feed products regulated by FDA, including dietary supplements, infant formula, beverages, and food additives. The proposed rule also would require facilities to update any changes to the information previously submitted within 30 days of the change.

Interim Final Regulation
On October 10, 2003, FDA issued an interim final regulation that makes several significant changes to the proposed rule. Under the final regulation, any domestic or foreign facility that processes food for human or animal consumption in the United States is required to register with the FDA by December 12, 2003, unless the facility is exempt. The interim final rule increases the timeframe in which registrants must update their information from 30 days to 60 days for required information. Also, a failure to register is a prohibited act under the interim final rule.