

Bioterrorism Bill Grants New FDA Authority to Ensure Safety of Food Supply

Bipartisan legislation, drafted largely in response to the terrorist attacks on September 11, passed the House and Senate with near unanimous votes. Included in the \$3 billion "Bioterrorism Preparedness Bill" is a section related to protecting the safety of our food supply against future bioterrorist attacks. These sections essentially amend the Federal Food, Drug and Cosmetic Act to authorize new authority for the Food and Drug Administration (FDA). While the bill was intended to help the government detect, prevent and treat terrorism-related health threats, new authorities granted to the government are not limited to serious health emergencies.

What follows is a detailed description of the provisions.

Detention of Products

Specifically, the Bioterrorism bill would allow FDA inspectors, during their routine inspections, to detain food products if the inspector feels that there is "credible evidence" that the food presents a serious threat. In the past, this detention authority was only granted to FDA by a court order. Under the new bill, there has to be concurrence by a high level FDA official—the Secretary or a district director—that the food in question poses a "serious threat" before it can be detained.

For example, if an FDA inspector suspects that a product has been tampered with, the FDA can hold that product for up to 20 days; if additional time is still needed, then no longer than 30 days. During this time, the product is marked as "detained" and cannot be processed. If a processor violates these detention requirements, then it is considered a "prohibited act". Penalties for violation could include monetary fines or even imprisonment. However, if the processor can verify that the detention is not warranted, then an appeal can be requested. This appeal to the FDA has to be acted upon within 5 days, either way, or the order is no longer valid.

Increased Scrutiny on Imported Foods

The bill authorizes \$100 million to take a closer look at what is coming in through U.S. ports of entry. This includes increasing the number of FDA inspectors, improvements in its computerized systems to track past food safety violations and funding to develop a faster way to determine if a food is adulterated. Specifically, if a food product is imported, the FDA can put a hold on that product at the port of entry for a reasonable period of time not to exceed 24 hours. This occurs when data points to credible information that a food product could be tainted and it allows FDA to inspect and examine the products. After 24 hours, the products are either deemed unsafe and detained or released.

New Registration Requirements for Food Processors

Upon completion of formal rulemaking, any domestic or foreign facility that manufactures, processes, packs or holds foods for consumption in the U.S. must be registered with FDA. Only foreign facilities from which food is imported that is not further processed or packaged are required to register. Farms, restaurants and other retail food establishments, and not-for-profits (e.g., soup kitchens) are exempt from this registration requirement. FDA wants this information to compile a complete and accurate database of food manufacturers for emergency notification purposes, if necessary. This could be critical in the event of a bioterrorist attack on our food supply and would facilitate easier communications between FDA and the food industry.

This new regulation will not take effect until it undergoes formal rulemaking to iron out all the details, which could take up to 18 months. Upon enactment, processors will have to notify FDA of their name, address and general food category (e.g., cheese, milk, frozen dairy desserts) along with contact information. Upon receipt of this information, the FDA will assign a specific registration number for each facility. This provision does not require an application, a review or licensing process.

If a food processor fails to register with FDA, it will be considered a "prohibited act", and subject to enforcement action by FDA. On imported foods, failure to register will require food to be held at ports of entry and not delivered to its destination.

FDA Records Inspection & Processors' Record Keeping

The bill expands the current FDA authority for inspecting records at food plants and upon completion of formal rulemaking, could require food processors to maintain additional records.

Under the new legislation, at the request of an FDA inspector or the Secretary of Health and Human Services, records can be inspected if there is a "reasonable belief" that food processed or held at the plant presents a serious health threat. FDA will now have access to and be able to photocopy ALL records related to manufacturing, processing, packaging, distribution, receipt, holding or importation. FDA is required to have effective procedures in place to prevent the unauthorized disclosure of trade secret or confidential information. Only recipes, formulas, financial data, pricing/sales, personnel records and research and development will be exempt from FDA access. Farms and restaurants will not be subject to these new record keeping requirements.

Even though the requirements for exactly which new records will be required by processors will not be finalized until formal rulemaking is complete, the number of records that need to be kept for tracing the source and distribution of food and packaging are to be kept at a minimum. The focus is going to be limited to one step backward or one step forward in the distribution chain.

Other Requirements for Imported Foods

In the legislation there are also new requirements for importers including: 1) prior notice to FDA on imported food shipments; 2) new FDA authority to "mark" foods that are refused and if the food is refused, all states are notified and the shipper cannot substitute another port; and 3) penalties for repeat or serious violations which could lead to disbarment. The prior notice provision will go into formal rulemaking which will clarify the amount of time importers have to notify FDA of incoming shipments.

June 2002