

Bioterrorism Act: Protecting the Food Supply

FDA Issues Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply

The U.S. Food and Drug Administration (FDA) on December 6, 2004, issued final regulations on the establishment and maintenance of records to protect the U.S. human food and animal feed supply in the event of credible threats of serious adverse health consequences or



Department of Homeland Security Under Secretary James Loy speaks at this year's annual Customs and Border Protection Trade Symposium. The CBP works closely with the FDA to ensure the safety of imported foods.

EU Striving for Safety 'from the Farm to the Fork'

Beyond trying to prevent, and being prepared in the event of bioterrorism, various laws and government agencies in the U.S. are in place to ensure the safety of the food supply in general. But who's looking out for consumers when they travel to a different country, such as one of the European Union countries? Consumer confidence in the safety of food products has sometimes been shaken in recent years by the cumulative impacts of food-related health crises. Responding to the challenge, the European Union has put in place a comprehensive strategy to restore people's belief in the safety of their food "from the farm to the fork."

There are three pillars to this strategy—new legislation on the safety of food and animal feed; sound scientific advice on which to base decisions; and enforcement and control.

Safety of Food and Animal Feed

The general principles of food safety are set out in a regulation adopted in 2002 and often known as the General Food Law. This constituted a thorough overhaul of EU food safety legislation, with a new emphasis on feed because feed contamination has been at the root of all major food scares of the last few years. A major change as a result is that food and feed businesses must ensure that from January 1, 2005, all foodstuffs, animal feed, and feed ingredients are traceable right through the food chain.

The General Food Law is supplemented by targeted legislation on a raft of food safety issues, such as use of pesticides, food supplements, colorings, antibiotics, and hormones in food production; and by stringent procedures on release, marketing, labeling, and traceability of crops and foodstuffs containing genetically modified organisms (GMOs). Updated rules on hygiene come into effect on January 1, 2006. The basic rules apply to all food and feed, and from farm to fork, but in addition there are specific precautions for a number of products ranging from meat to gelatin, and from dairy products to frogs' legs.

EU responsibility extends also to the welfare of animals and poultry, both on the farm and when they are being transported. The European Commission oversees measures to protect public health if there are outbreaks of animal or poultry diseases.

Rapid Alerts Nip Risks in Bud

In order to spot food and feed risks effectively, the EU operates a rapid alert system. All member states notify the Commission



death to humans or animals. FDA also issued draft guidance to FDA staff and industry, which details the internal procedures the agency will follow before requesting access to records.

“Publication of this recordkeeping rule represents a milestone in U.S. food safety and security,” said then Secretary of Health and Human Services (HHS), Tommy G. Thompson. “There is more work to do yet, but our nation is now more prepared than ever before to protect the public against threats to the food supply.”

This final regulation implements section 306 of the Bioterrorism Act, which directs the HHS secretary to issue regulations requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released.

“These records will be crucial for FDA to deal effectively with food-related emergencies, such as deliberate contamination of food by terrorists,” said Lester M. Crawford, Acting FDA Commissioner. “The ability to trace back will enable us to get to the source of contamination. The records also enable FDA to trace for-

ward to remove adulterated food that poses a significant health threat in the food supply.”

The final regulation is the fourth regulation designed to increase the safety and security of the U.S. human and animal food supply under the authority of the “Public Health Security and Bioterrorism Preparedness and Response Act of 2002” (the Bioterrorism Act).

For this fourth regulation concerning maintenance of records, the record retention period for human foods ranges from six months to two years depending on the shelf life of the food. Records for animal food, including pet food, must be retained for one year. The maximum record retention requirement for transporters of all types of food is one year.

Records must be retained at the establishment where the activities covered in the records occurred or at a reasonable accessible location. To minimize the burden on food companies affected by the final rule, companies may keep the required information in any format—paper or electronic. All businesses covered by this rule must comply within 12 months from the date the rule is published in the Federal Register, except small and very small businesses. Small businesses (11–499 full-time equivalent employees [FTEs]) must comply within 18 months

of any problems they uncover in imported or EU-produced food. By passing the information to all member states quickly, every government has an early warning system when feed or food could be unsafe because it has not been handled or processed properly, thus exposing consumers to the risks of food-borne illnesses such as salmonella.

Warning bells also sound when banned substances are identified or legal limits for high-risk substances have been exceeded. These substances may be veterinary medicine residues, food colorings known to be carcinogenic, or naturally occurring toxic moulds. The system deals with several hundred alerts on immediate risks each year.

What happens will depend on the type of risk. It may be enough to stop a single batch, or it may be necessary to stop all shipments of a particular product from the farm, factory, or port of entry. Products already in warehouses and shops may be recalled. Sometimes every shipment from one source is tested for some months, as has happened with imported shrimp. In emergencies, the European Commission can step in directly to protect public health rather than waiting to consult EU governments.

Sound Scientific Foundations

Science is the essential foundation on which the EU bases its decisions on any part of the food chain. The European Food Safety Authority plays a central role in this. EFSA has a wide brief. It can cover all stages of food production and supply, from primary production to the safety of animal feed, right through to the supply of food to consumers. It can also look into the properties of non-food and feed

GMOs and nutrition issues.

EFSA provides the European Commission with independent, scientific advice that is also made public to enable it to be fully open to scrutiny. EFSA provides input when legislation is being drafted and advice when policymakers are dealing with a food scare, like “mad cow disease,” dioxin in milk, or “bird flu” in poultry. In deciding what to do, the Commission applies the precautionary principle. In other words, it will act without waiting for scientific certainty if the scientists say there is at least a potential danger.

Enforcement and control

Legislation is pointless if it is not enforced. The Commission enforces EU feed and food law by checking that EU legislation has been properly incorporated into member state law, by double-checking compliance through reports from member states and other countries and through on-the-spot inspections in the EU and outside.

Inspections are the job of the Commission’s Food & Veterinary Office (FVO) based at Grange in Ireland. The FVO can check individual food production plants, but its main task is to check that EU governments and those of other countries have the necessary machinery for checking that their own food producers are sticking to the safety standards.

New rules that took effect on January 1, 2006, will streamline controls across the EU and put more emphasis on relating checks to likely risk. The European Commission will monitor whether EU governments are running their control systems effectively. Producers breaching the law will be dealt with more severely in many cases.

from this date, and very small businesses (10 or fewer FTEs) have to comply within 24 months from this date.

When FDA has 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, any records or other information to which FDA has access must be available for inspection and copying as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records access authority applies both to records required to be established and maintained by the final rule, or any other records a covered entity may keep to comply with federal, state, or local law or as a matter of business practice.

The Bioterrorism Act allows FDA to bring a civil action in federal court to enjoin the persons who fail to comply with this rule. FDA also can seek criminal actions in federal court to prosecute persons who fail to establish and maintain records, as required by the final rule.

FDA has already issued three other final regulations under the Bioterrorism Act, which are in effect. They cover:

- *Registration of foreign and domestic food facilities.* This regulation required foreign and domestic food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003. As a result of this, FDA for the first time has a

complete roster of foreign and domestic food facilities. This requirement enables the FDA to quickly identify and locate affected food processors and other establishments in the event of deliberate or accidental contamination of food.

- *Prior notice of food shipments imported or offered for import into the U.S.* This regulation required food importers to provide the FDA with advance notice of human and animal food shipments imported or offered for import on or after December 12, 2003. This advance information allows the FDA, working with U.S. Customs and Border Protection (CBP), to more effectively target inspections and ensure the safety of imported foods.
- *Administrative detention, so that food products that might pose a threat of serious adverse health consequences or death may be detained.* This third regulation, announced on May 27, 2004, established procedures for administrative detention of food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.
- Additional information about all four rules designed to protect the U.S. food supply is available at <http://www.fda.gov/oc/bioterrorism/bioact.html>. ■

FDA Proposes \$30.1 Million Budget Increase for Food Defense

The Food and Drug Administration (FDA) released highlights of its fiscal year (FY) 2006 budget request to the U.S. Congress totaling \$1.9 billion. This overall amount includes \$1.5 billion in budget authority and \$382 million in Congressionally authorized industry user fees. This request is 50% higher than the appropriations in FY 2001 and represents a 4.5% increase over the FY 2005 level.

More than ever, Americans expect FDA to protect them from risky products and potential terrorist threats, and the FY 2006 budget request should equip FDA to do that.

The agency's major request, an increase of \$30.1 million for food defense, is part of a collaborative effort by FDA, the U.S. Department of Agriculture's (USDA) Food Safety & Inspection Service (FSIS), the Department of Homeland Security (DHS) and the White House Homeland Security Council to defend the U.S. food supply from terrorist attacks. This brings the total budget authority for food defense related items to \$180 million from \$150 million, or an increase of 20 percent.

- The proposed increase for the food counter-terrorism program—a top Administration priority—includes

funds for the following long-range projects by FDA and FSIS: Expansion of the joint FDA-FSIS Food Emergency Response Network (FERN—\$20 million of the \$30 million requested) of laboratories capable of analyzing thousands of food samples for biological, chemical and radiological threat agents, which Congress funded in FY 2005. The FY 2006 request will add an estimated 19 FDA-funded state labs;

- Targeted research in those areas posing the greatest perceived threat to the food supply, based in part on the most recent intelligence. The increase in funding will support research related to prevention/mitigation technologies, tamper proof packaging, rapid test methods, and/or agent sensor technologies;
- Continued coordination and sharing of data with the Department of Homeland Security as part of the government-wide Bio-Surveillance Initiative; and,
- Sustained development of the agency's vital crisis- and incident-management infrastructure required to manage emergencies involving FDA-regulated products.