The Proposed Food Bioterrorism Bill

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In response to concerns about food and water safety, the House of Representatives passed a food bioterrorism bill in December, 2001. House Bill 3448 Public Health Security and Bioterrorism Response Act of 2001 was approved by the House on December 11, 2001, received by the Senate on December 18, 2001 and is currently in a conference committee with legislation likely this spring. The key provision of this bill is a coordinated national preparedness program for bioterrorism with an emphasis on public health and health services including pediatric care, controls on dangerous biological agents, and improved protection for the food and water supplies[1].

General Provisions

Through this bill, the federal government would commit major resources to state and local governments in the event of an emergency. There is a multi-billion commitment of funds to improve public health surveillance and training, laboratory readiness, and medical countermeasures (*e.g*. effective drugs, vaccines, biological products and medical devices) against biological agents. The Department of Health and Human Services through an Assistant Secretary for Emergency Preparedness will coordinate these efforts between DHHS, the Federal Emergency Management Agency, the Department of Defense and the Department of Veterans Affairs. In addition under proposed amendments to Section 319F of the Public Health Service Act (42 U.S.C. §§ 247d-6), a working group on Preparedness for Acts of Bioterrorism will coordinate the activities of: Defense, FEMA, the Attorney General, Veterans Affairs, Agriculture, Energy and EPA.

This working group would: prioritize research; facilitate the development, production and regulatory review of countermeasures for a bioterrorist attack on the civilian population; promote programs for pathogen detection; and prevention of infection of the civilian population, along with procedures to distribute and release strategic reserves of vaccines (including smallpox), drugs, and medical supplies rapidly. Special consideration is given in the Bill to needs of vulnerable populations such as children, the elderly and the disabled. A national stockpile of drugs, vaccine and medical supplies will be established for bioterrorist emergencies. Various communicable disease quarantine provisions are clarified in the Bill.

[1] Nuclear incidents are addressed through the general emergency preparedness measures and in addition the development of a national stockpile of potassium iodide in to counteract adverse health affects to the thyroid from release of radionuclides from a nuclear power plant.

A primary focus will of this legislation will be on improving the capabilities of the Centers for Disease Control and Prevention to defend against and combat public health threats through improved training, communications, and facilities, improved laboratory facilities related to bioterrorism and capability for public health surveillance and reporting. The program would give priority to funding programs that will support state and local efforts including funds for integrated regional public health laboratories and expanded diagnostic and biohazard capabilities into areas that currently lack these facilities. The proposed Bioterrorism Act also requires that secure networks be constructed for disseminating essential information on bioterrorist attacks or other public health emergencies. Current antimicrobial resistance programs will also be expanded.

The public health function of this bill extends to community service and mental health as well as the establishment of a National Advisory Committee of Children and Terrorism and an Emergency Public Information and Communications Advisory Committee.

Improving security for countermeasure development is a key aspect of this bill. These measures including fast tracking research on the epidemiology and pathogenesis of possible bioterrorist agents, development of new vaccines and therapeutic agents, diagnostic tests and emerging technologies designed to improve or enhance the ability of public health officials to detect, identify, diagnose or conduct public health surveillance activities.

Food Safety and Security Issues

Food safety and security of water supplies are also key provisions of this bill and the ones of most interest to us. Under the new bill, all food processors, packers, and distributors both foreign and domestic would be required to register with the FDA with a registration number to be assigned by the agency (proposed amendment to 21 U.S.C. §341 *et seq*.).

Food Imports

Principal among these new provisions are new requirements for food importers including new notification and record requirements. Along with foods are requirements for food and drug components[2]. Under the new law, a minimum 24-

[2] An importer of a food additive, color additive, or dietary supplement which will be used as a component in a processed food must provide a statement that:

1) the article is to be further processed by the initial owner or consignee,
2) identifies the manufacturer, and each processor, packer, distributor, carrier or other entity that had possession of the article in the chain of possession of the article from the manufacturer to the importer,
3) that the imported material will be used as per its original intent (*e.g.* as a food component). Certificates of analysis may be required,
4) the importer must maintain records of the use of the material or its destruction and be able to submit these records to the FDA upon request,

hour prior notice to the FDA will be required for shipments of imported foods. If notification is not given, the product will be held at the port of entry until proper notification is provided and the Agency has had the opportunity to examine the product (Section 306 of the Public Health Security and Bioterrorism Response Act of 2001; amending Section 801 of the Federal Food Drug and Cosmetic Act)[3]. The FDA will have the authority to determine whether there is any credible information or evidence indicating that an imported food poses adverse health consequences to humans or animals before the food would be released. USDA products are exempt under this bill[4].

Under this bill, the FDA can prohibit certain individuals from importing food (permissive disbarment) when: the person has been convicted of a felony for conduct relating to food imports; the person has repeatedly imported or offered for importation adulterated food, and the person knew, or should have known that the food was adulterated (proposed amendments to section 306(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §335a(b)).

The FDA would be given authority under the Bill to mark articles refused admission into the United States with all expenses born by the owner or consignees of the involved food[5] and drugs[6]. Any food marked "United States: Refused Entry" is considered under the FDCA to be misbranded[7].

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5) the importer must be able to account for any exports of the material. A bond must be posted which is sufficient to cover liquidated damages of the Department of Treasury in event of a default by the importer or consignee.

The FDA will have authority to demand any records associated with food imports and to review and copy these records (proposed amendments to 21 U.S.C. § 341 *et seq*). The Agency claims that food recipes, financial data, pricing data, personnel data, research data, or sales data (other than shipping data regarding sales) will be protected as sensitive information.

[3] PROHIBITED ACT - Section 301 of the Federal Food Drug and Cosmetic Act, as amended by section 305(b)(1) of this Act is amended by adding at the end the following: " (ee) The importing or offering for import into the United States of an article of food in violation of regulations under section 801(k)."

[4] This section may not be construed as authorizing the Secretary of Health and Human Services to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. §601 *et seq*.), the Poultry Products Inspection Act (21 U.S.C. §451 *et seq*.) or the Egg Products Inspection Act (21 U.S.C. §1031 *et seq*.).

[5] Section 801 of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 381(a) as amended by section 306(a) of this Act is amended…. :

"(l)(1) If a food has been refused admission under subsection (a) other than such a food that is required to be destroyed, and the Secretary determines that the food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary may require the owner of consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: "UNITED STATES: REFUSED ENTRY.'"

"(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee."

"(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with the Act."

There are also specific provisions against "port shopping"[8].

The proposed law would require the FDA to provide notices to the States where the food is held, or in which a manufacturer, packer or distributor is located when the agency has credible information or evidence that a food shipment or a portion of it may pose adverse health consequences to humans or animals. The FDA may make grants to States for conducting food inspections or investigations and may also assist States with the costs of taking appropriate action to protect the public health in response to the provisions of this new law, including planning and other types of preparedness.

The FDA will also increase inspection of imported foods for signs of intentional adulteration. And give high priority to making necessary improvements to information management systems within the Agency that contain information related to imported foods. Significant resources will be committed to rapid detection methods for adulterants and evaluation of new technologies that are more accurate, rapid or cost effective than current methods. Risk assessment of intentional adulteration of foods will also be an important focus of the proposed $100,000,000 effort by the agency over the next two years.

Detention of Adulterated Foods

Under this new law, the FDA would have expanded authority to detain foods (21 U.S.C. Sec. 334 as amended) for up to 30 days if the Agency has credible evidence that the food presents a threat of serious adverse health consequences or death to humans or animals[9]. The Agency can require that the food be removed to a secure facility.

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[6] Provisions for drugs include annual registration of foreign manufacturers, shipping, and drug and device listing.

[7] (b) MISBRANDED FOODS - Section 403 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §343) as amended by section 305 (b)(2) of this Act, is amended by adding at the end the following:
"(u) If it fails to bear a label required b the Secretary under section 801(l)(1) (relating to food refused admission into the United States)."

[8] Section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §342 is amended by adding at the end the following: "(h) If it is an article of food imported or offered for import into the United States and such article has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article is not adulterated, as determined by the Secretary." Temporary holds at a port of entry of 24 hours are permissible to allow for the Agency to inspect the food. The FDA has the authority to detain the food, have it held in a secure facility, and contact the state regarding the detention.

[9] PROHIBITED ACT - Section 301 of the Federal Food Drug and Cosmetic Act (21 U.S.C. §331) is amended by adding at the end the following: "(bb) The transfer of an article of food in violation of an order under section 304(h) or the removal or alteration of any mark or label required by the order to identify the article as detained."

Security of Drinking Water

New provisions for water safety are included under proposed amendments to the Safe Drinking Water Act (Title XIV of the Public Health Service Act). These amendments require that vulnerability assessments be completed for each community water system serving 3,300 persons or more. This vulnerability assessment would evaluate the risk of a water system to a bioterrorist attack or towards other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water or to present other significant health concerns. This assessment would include a review of pipes and constructed conveyances, physical barriers, water collection, pretreatment, treatment, storage and distribution facilities, electronic, computer and automated systems used by the public water system, the use, storage or handling of various chemical and the operation and maintenance these systems.

In addition, each community of must develop an emergency response plan that would include actions, procedures and equipment that could obviate or significantly lessen the impact of terrorist attacks or other intentional action on the public health and safety and supply of drinking water. The Environmental Protection Agency would provide guidance for smaller water systems.

Enhanced Funding of State and Local Government Programs

This bill if it becomes law would improve governmental response to a bioterrorist attack whether the vector is a biological weapon, or intentional contamination of food or water. The heightened inspection on imported food is warranted. However, foods for which the USDA has exclusive jurisdiction are not covered under this law. There are concerns regarding the increased burden for food security placed upon the food industry, particularly smaller companies, who may not have the resources to comply with new provisions. Although there are grants and other programs within the bill for providing funds for improving security, analytical capability, employee training, and enforcement and implementation *for state and local governmental agencies*, there are *no* similar provisions for the regulated businesses to cover the increased costs this would entail in the House Bill.

Disconcerting Legal Issues

The scope of key terms within the bill such as "credible … information" and "threat" of serious adverse health consequences" are not clearly defined. Under current recall regulations, a Class I recall involves " a *reasonable probability* that the use of or exposure to, a violative product will cause serious adverse health consequences or death " (21 CFR §. 7.3(m)(1)), but what will constitute a *threat*? How will the law differentiate between a *threat* and *hoax*, or will it matter? We understand what meets evidentiary standards under Federal and State Rules of Evidence, but what is *credible information* in the context of the Food, Drug and

Cosmetic Act? Will the first test case under this bill if it becomes law involve a terrorist contaminating the water and food in a small community reminiscent of the incidents in Antelope, Oregon in the 1980's? Will it be a political statement by an eco- or political terrorist, let's say contaminating fish with an exotic zoonotic agent? Or will it be some poor soul just scratching by unfortunate enough to carry a *Listeria sp*. contaminated ready-to-eat food? All three of these scenarios could fall within the scope of this law, is this really what we want?