In June 2002, the U.S. Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (commonly known as the Bioterrorism Act, hereinafter the Act). The law was in part a response to the events of Sept. 11, 2001, and subsequent concerns over the nation’s vulnerability to biological attack. The Act directed the Secretary of the Department of Health and Human Services (HHS) to take steps to protect the public from threatened or actual terrorist attacks on the U.S. food supply.

Both Customs and Border Protection (CBP), which had moved to the Department of Homeland Security (DHS) from the Treasury Department, and the inspectors from the Animal and Plant Health Inspection Services (APHIS), who moved to DHS from the U.S. Department of Agriculture (USDA), were tasked to enforce this law. Joining them was the Food and Drug Administration (FDA) which remained part of HHS. However, a Memorandum of Understanding (MOU) was signed between DHS and HHS on Dec. 3, 2003, to provide closer coordination between CBP and FDA agents, who often worked out of the same ports.

The Act has several major elements which at the time of passage caused considerable concern in the exporting and importing community with regard to the ability to comply within the deadlines established. The first requirement under section 305 of the Act was the registration of all foreign facilities that manufacture, process, pack or hold (i.e., store or warehouse) food for human or animal consumption. The second prong of the law was a requirement of “prior notice” of shipments of covered food products to allow FDA and CBP personnel sufficient time to assess the possible risks associated with a particular import. The final important change made by the Act was to require each foreign food exporter to have a “registered agent” in the United States who could be readily contacted by the FDA and CBP in case of an emergency. A recent test of this system by FDA found that approximately 90 percent of the domestic registered agents had valid phone and email addresses in its

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sample, but that only about 72 percent of the agents actually responded by email or talked to FDA.

FDA originally issued Interim Final Regulations published on Oct. 10, 2003, which were later replaced by a Final Rule issued on Sept. 28, 2005. The Final Rule did not make any changes to the regulatory requirements contained in the interim final rule. Recent data released by FDA shows that there are approximately 420,000 U.S. and foreign food facilities that are required to register, approximately half of which are in the United States. As of Sept. 14, 2006, a total of 298,236 registrations had been received, of which 171,837 were foreign and 126,399 domestic, indicating that there are still a large number of non-compliant facilities both in the United States and abroad. The most foreign registrations were from Japan, China, Mexico and Canada.

Is Problem Being Solved?

The Government Accountability Office (GAO) has regularly reported on the federal food safety oversight program as part of its overall review of “High Risk Programs.” The GAO study has found that each year about 76 million people contract food borne illness, about 325,000 require hospitalization and 5,000 die, according to the Centers for Disease Control and Prevention (CDC). In addition to deaths and illness, the economic impact is considerable. For example, industry representatives estimated that losses from the recent E. coli outbreak from spinach were in the range of $37 to $74 million. This is without any known links to terrorism. The GAO sees the challenge this way: “How several federal agencies can integrate the myriad food safety programs and strategically manage their portfolios to promote the safety and integrity of the nation’s food supply?” As noted in our earlier article in the June 2004 issue of this publication, efforts have been made since Sept. 11, 2001, to coordinate the work of CBP and FDA in this area.

The GAO study referred to the “fragmented federal food safety system” in which 15 agencies collectively administer at least 30 laws relating to food safety. The GAO conclusion was that the existing system has caused “inconsistent oversight, ineffective coordination and inefficient use of resources.” One alleged example of lack of coordination is that “USDA and FDA both inspect shipments of imported food at 18 U.S. ports of entry. However, these two agencies do not share inspection resources at these ports.” The GAO study found some imbalances in the amount of funds allotted to these efforts. For example, while FDA is responsible for about 80 percent of the food supply, it accounted for only 24 percent of the expenditures.

The public and the press have recently focused increased attention and concern over the safety of imported foods. A recent article in USA Today indicated that only “3 percent of imported fish, vegetables, fruit and other foods are inspected.” The article quoted Michael Doyle of the Georgia Center for Food Safety, who stated that “FDA does not have enough resources and control over the situation presently.” As the food supply becomes more globalized, and the volume of food imports increases (estimated at $70 billion in 2007—almost double the $36 billion in 1997), the percentage of food inspected has declined from 1.8 percent in 2003 to 1.3 percent in 2007. The recent scare over contaminated wheat gluten from China that contained melamine, apparently without the knowledge of the U.S. importers or FDA, has only increased the public’s attention and concern in this area.

What is of some concern is that the various food safety incidents that have occurred were caused by inadvertence or at worse negligence, not conscious acts of terrorism. The question that must be answered is: if the food safety system has failed in cases where no intentional terrorist driven efforts were involved, what would be the result if a direct assault was made on the U.S. food supply system by a foreign terrorist group?
foreign terrorist group? In fairness to FDA, the agency has been increasing its efforts to fulfill its responsibilities under the Bioterrorism Act, for example under section 302(d) that directs FDA to provide for research on tests and sampling methodologies designed to test food to detect adulteration, and which instructs FDA to give the highest priority to research related to detection of intentional adulteration. This “food defense” research program involves many offices in FDA as well as outside agencies such as the Department of Defense, the Environmental Protection Agency, USDA, DHS and the CDC. Yet the question of the preparedness for an intentional attack on the food system remains a valid one.

Possible Solutions

While much of the blame for these problems had been focused on FDA, there is a wider awareness that the food inspection functions of FDA are underfunded. Moreover, despite the MOU between HHS and the DHS, the CBP and FDA personnel are still reporting to and are funded by two different agencies. One solution would be to transfer the food inspection personnel from FDA (HHS) to the umbrella of DHS, much like what was done with the agricultural inspection personnel in USDA, who were transferred from USDA to DHS. While FDA might object that transferring some personnel devoted to inspections could leave the agency fractionized, the same issues existed and were apparently resolved with USDA, when the APHIS inspectors were transferred to DHS.

FDA inspections at the border would benefit from the increased interest and budget that is being directed to DHS activities by Congress due to concern about Homeland Security issues. FDA legacy inspectors transferred to DHS would still have to rely on help from FDA’s Center for Food Safety and Applied Nutrition (CFSAN) personnel, which would remain intact for numerous other domestic functions it performs. Also, the officials of DHS and legacy FDA inspection officials would need to continue to be in close communication and cooperation with other FDA offices, such as the Office of Regulatory Affairs, the Office of Criminal Investigations, the Assistant Commissioner for Counterterrorism and others. This could be done by modifying and expanding the existing MOU between DHS and HHS, but within the context of the FDA inspectors at the ports now being under the umbrella of DHS.

Integrating the food safety inspectors with the USDA, APHIS inspectors and CBP personnel under a single mission, command and uniform should help address some of the criticisms about lack of coordination and effectiveness of our food safety program and hopefully result in more resources for the under-funded FDA inspection program.

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2 Memorandum of Agreement between CBP and FDA, (Dec. 3, 2003) as authorized by FDCA, 21 U.S.C. §§ 372, 381(m), and 44 U.S.C. § 3510. For a discussion of this and an earlier look at these issues see Leslie Alan Glick, A Coordinated Response to Stop Bioterrorism at the Border, FDLI Update (May /June 2004), 18.
7 Id. at 26, 27.
8 See Glick, supra note 2.
9 High Risk Series: An Update, at 27.
10 Id.
11 Id. at 28.
12 Id. at 30.
14 Id.
15 Id.
16 FDA, Report to Congress, Second Annual Report, (Feb. 2005), at 2
17 Id. at 4.