Risk Assessment for Food Terrorism and Other Food Safety Concerns

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I. Introduction:

The events of September 11, 2001, and the subsequent anthrax incidents\(^1\) gave rise to concerns about unconventional terrorist attacks, including the threat of attacks on the U.S. food supply. Those events also heightened international awareness that nations could be targets for biological or chemical terrorism—a threat that had long concerned military and public health officials.

In the aftermath of those incidents, the Food and Drug Administration (FDA) took steps to improve its ability to prevent, prepare for, and respond to, incidents of food sabotage. Though motivated by the concerns about deliberate contamination, those activities built upon and expanded the agency's continuing efforts to protect consumers from foods that have been unintentionally contaminated (e.g., through processing failures or handling errors).

As part of those activities, FDA assessed the risk to, and vulnerability of, the U.S. food supply to an act of terrorism.\(^2\) However, most of those assessments contain classified information. To promote transparency, FDA prepared this publicly available assessment of the risks to public health of a terrorist attack on the food supply and of serious illness due to inadvertent food contamination.\(^3\)
The Risk Assessment follows the generally accepted framework for risk assessments endorsed by the Codex Alimentarius Commission, the U.S. National Academy of Sciences, and other authoritative bodies. The framework divides risk assessment into four components: (1) hazard identification, (2) hazard characterization (or dose-response assessment), (3) exposure assessment, and (4) risk characterization. Unlike traditional risk assessments, however, which focus on one hazard, this assessment addresses the broad range of hazards available to terrorists intending to sabotage food, as well as hazards that accidentally are introduced into food.

This Risk Assessment uses scientific evidence on food terrorism to the extent that it exists and is available, but balances this disclosure with the need to maintain the integrity of classified information. Thus, this assessment is based solely on unclassified information. In addition, the very nature of "bioterrorism" and the fact that it is a relatively new and evolving threat present challenges in quantitatively evaluating the associated risks. FDA has prepared a qualitative risk assessment that presents various risk scenarios, as well as discusses the quality of information available for, and the uncertainties associated with, the assessment. The agency has determined that this qualitative risk assessment, which discusses prior incidents of food contamination and available unclassified information on prior acts of food sabotage, is appropriate to the circumstances.

II. Risk Assessment

A. Hazard Identification

Even before the September 11th attacks, the U.S. Centers for Disease Control and Prevention (CDC) had developed a strategic plan on biological and chemical terrorism. The CDC plan identified and ranked several foodborne pathogens as critical agents for possible terrorist attacks. Among the high-priority biological agents ("Category A" agents) were *Bacillus anthracis* (anthrax) and *Clostridium botulinum* (botulism), both of which are deadly pathogens and may contaminate food. Most of the foodborne biological agents identified by CDC were classified as "Category B" agents because they are moderately easy to disseminate and cause moderate morbidity and low mortality. The Category B biological agents include *Salmonella* spp., *Shigella dysenteriae*, *E. coli* O157:H7, and ricin. Notably, several of the pathogens identified by CDC as critical biological agents also are known to pose a significant threat due to unintentional contamination of food.

In addition, the CDC identified certain chemicals as possible agents for a terrorist attack. Those included heavy metals, such as arsenic, lead, and mercury, and pesticides, dioxins, furans, and polychlorinated biphenyls (PCBs), all of which may be used to contaminate food. These toxins also have been introduced inadvertently into foods and linked to human health effects.

The CDC further warned:
... Public health agencies must prepare also for the special features a terrorist attack probably would have ... Terrorists might use combinations of these agents, attack in more than one location simultaneously, use new agents, or use organisms that are not on the critical list (e.g., common, drug-resistant, or genetically engineered pathogens). (9)

Acts of deliberate food contamination have already occurred in the U.S. In 1984, for example, the members of a religious cult contaminated salad bars with *Salmonella typhimurium* in order to disrupt a local election. This incident caused 751 cases of salmonellosis and resulted in the hospitalization of 45 of the victims. (10) In another incident, in 1996, a disgruntled laboratory worker deliberately infected food to be consumed by co-workers with *Shigella dysenteria* type 2, causing illness in 12 people. Four of the victims had to be hospitalized and five others were treated in hospital emergency rooms. (11) Furthermore, in May 2003, a supermarket employee pleaded guilty to intentionally poisoning 200 pounds of ground beef with an insecticide containing nicotine. Although the tainted meat was sold in only one store, 111 people, including approximately 40 children, were sickened. (12)

Examples of food sabotage can be drawn from other countries' experiences, as well. In September 2002, nearly 40 people died and more than 200 were hospitalized near Nanjing, China after the owner of a fast-food outlet poisoned a competitor's breakfast foods with rat poison. (13) One year earlier, 120 people in China were sickened when the owners of a noodle factory reportedly laced their food with rat poison. (14) A dozen children in Holland and West Germany were hospitalized in 1978 after citrus fruit from Israel was deliberately contaminated with mercury. (15) Finally, in Canada in 1970, a postgraduate student tainted his roommates' food with the parasite *Ascaris suum*. Four of the victims became seriously ill; two of these suffered acute respiratory failure. (16)

The incidents discussed above illustrate a few of the possible agents for food terrorism. The range of such agents is broad, and their characteristics varied; they may include:

- Biological and chemical agents;
- Naturally occurring, antibiotic-resistant, and genetically engineered substances;
- Deadly agents and those tending to cause gastrointestinal discomfort;
- Highly infectious agents and those that are not communicable;
- Substances readily available to any individual and those that are more difficult to acquire; and
- Agents that must be weaponized and those that are accessible in a useable form.

This assessment addresses the risk to public health not only of deliberate contamination of the food supply, but also of hazards that are inadvertently introduced into foods that FDA regulates.

**B. Hazard Characterization**
The hazard characterization analyzes the magnitude of the risk (i.e., the severity and duration of adverse effects), using reports of foodborne disease caused by unintentional contamination. Such reports are relevant to an analysis of both inadvertently and deliberately introduced hazards, because many of the pathogens that historically have been linked to unintentional food contamination, such as *E. coli* O157:H7 and *Salmonella* spp., were identified by the CDC as "critical" agents for food terrorism.\(^{17}\) Moreover, the risk to consumers and the public health response to these known pathogens would be comparable, regardless of whether the contamination was deliberate or accidental. Officials responding to a foodborne illness outbreak probably would not know whether the contamination was accidental or intentional until an investigation was performed to determine the source of the outbreak. Even then, officials might never be able to conclusively determine whether the food was deliberately sabotaged or inadvertently contaminated. For all of these reasons, the risk assessment uses incidents of unintentional food contamination as the basis for a characterization of hazards that could be either deliberately or unintentionally introduced into food.

### 1. Illnesses and deaths

The World Health Organization (WHO) estimates that microbiologically contaminated food and water cause approximately two million children worldwide to die from diarrhea each year. Even in industrialized countries, WHO estimates that one person in three suffers from a foodborne disease annually.\(^{18}\) Recognizing that foodborne illnesses "significantly affect people's health and well-being," the World Health Assembly in 2000 adopted a resolution stating that the assembly was "[d]eeply concerned that foodborne illness associated with microbial pathogens, biotoxins and chemical contaminants in food represent a serious threat to the health of millions of people in the world."\(^{19}\)

In the U.S., the CDC estimates that 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths occur annually due to food that has been inadvertently contaminated by pathogens.\(^{20}\) Based on current population data, this roughly translates to an estimate that, each year, one out of every four Americans will develop a foodborne illness.\(^{21}\)

Major outbreaks of foodborne illness occur all too frequently, sometimes affecting hundreds of thousands of people. Among the largest reported outbreaks caused by unintentional biological contamination was an outbreak of *Salmonella typhimurium* infection that sickened approximately 170,000 people in 1985 and was linked to post-pasteurization contamination of milk from a U.S. dairy plant.\(^{22}\) An outbreak of hepatitis A caused by tainted clams affected nearly 300,000 people in China in 1991 and may be the largest foodborne disease incident in history.\(^{23}\) In 1994, an outbreak of *Salmonella* Enteritidis infection linked to a contaminated ice cream pre-mix sickened an estimated 224,000 people in 41 states in the U.S.\(^{24}\) In 1996, about 8,000 children in Japan became ill, and some died, after eating *E. coli* 0157:H7-tainted radish sprouts served in school lunches.\(^{25}\)
Illnesses from pesticides, mycotoxins, heavy metals, cyanide, and other acutely toxic chemicals also have been reported. In one deadly incident, over 800 people died and about 20,000 were injured by a chemical agent present in cooking oil sold in Spain in 1981. In 1985, nearly 1,400 people in the U.S. reported becoming ill after eating watermelon grown in soil treated with the pesticide aldicarb. In Iraq in 1971-1972, more than 6,500 people were hospitalized with neurological symptoms and 459 died after eating bread made from mercury-contaminated wheat. Additionally, in the 1960's, more than 200 people in Japan suffered from mercury poisoning after eating highly contaminated fish caught in polluted waters.

In today's global marketplace, the contamination of food in one country can have a significant effect on public health in other parts of the world. In 1989, approximately 25,000 people in 30 states in the U.S. were sickened by *Salmonella* chester in cantaloupes imported from Mexico. In 1996 and 1997, 2,500 people in 21 states in the U.S. and two Canadian provinces developed *Cyclospora* infections after eating tainted Guatemalan raspberries.

If an unintentional contamination of one food, such as clams, can affect 300,000 individuals, a concerted, deliberate attack on food could be devastating, especially if a more dangerous chemical, biological, or radionuclear agent were used. It would be reasonable to assume that a terrorist using the food supply as a vehicle for attack would use an agent that would maximize the number of deaths associated with the contamination. Many of these agents are the same pathogens that have been linked to significant outbreaks of foodborne illness due to unintentional contamination.

### 2. Economic effects

Deliberate or accidental contamination of food also may have enormous economic implications in the U.S., where one out of every eight Americans is estimated to work in an occupation directly linked to food production. Indeed, food terrorists may have economic disruption as their primary motive. For example, the sabotage of Israeli citrus fruit exports, discussed above, was allegedly intended to damage Israel's economy.

At least three types of economic effects may be generated by an act of food terrorism: Direct economic losses attributable to the costs of responding to the act; indirect multiplier effects from compensation paid to affected producers and the losses suffered by affiliated industries, such as suppliers, transporters, distributors, and restaurant chains; and international costs in the form of trade embargoes imposed by trading partners.

Though the costs associated with the food sabotage discussed above are unavailable, reports from unintentional contamination incidents demonstrate the tremendous costs of responding to such events. In 1998, a company in the U.S. recalled nearly 16,000 metric tons of frankfurters and luncheon meats potentially contaminated with *Listeria monocytogenes*, at a total cost of $50 million to $70 million. The company reported spending more than $100 million in the following two years to improve food safety and convince consumers that its
products were safe.\textsuperscript{(35)} Indirect costs can be staggering as well. The U.S. Department of Agriculture estimates that foodborne illnesses linked to five pathogens costs the economy $6.9 billion annually.\textsuperscript{(36)} The outbreak from \textit{Salmonella}-contaminated ice cream, discussed above, was estimated to have cost the U.S. economy about $18.1 million in medical care and time lost from work.\textsuperscript{(37)} In addition, costs arise from the disruption of international trade, as was demonstrated when Belgium's dioxin incident caused the recall of food products distributed globally.\textsuperscript{(38)}

3. Social and political implications

The response to the 2001 anthrax incidents showed that limited dissemination of biological agents by simple means can cause considerable disruption and public anxiety, even if only a few cases of illness result.\textsuperscript{(39)} The potential magnitude of social impacts arising from a food terrorism incident may be best illustrated by examining the effects of the Bovine Spongiform Encephalopathy (BSE) (also known as "mad cow disease") crisis in Great Britain in the 1990's. When researchers first discovered BSE in British cattle in 1986, some speculated that BSE could be spread to humans.\textsuperscript{(40)} However, for the next decade British authorities consistently reassured citizens that BSE was only an animal disease.\textsuperscript{(41)} When, in 1996, authorities acknowledged that BSE could be linked to human disease and announced that ten people in the U.K. had been infected or died from a human form of mad cow disease, widespread panic erupted.\textsuperscript{(42)}

Even though the toll of human fatalities--137 deaths to date--was lower than the death toll from many other diseases, the effects of this public health crisis were widespread and long-lasting.\textsuperscript{(43)} Bans on imports of British beef lasted for several years.\textsuperscript{(44)} Furthermore, the public's shattered confidence in government forced the creation of a new food regulatory authority, the Foods Standards Agency.\textsuperscript{(45)} The slaughter of millions of cattle and other BSE control measures, together with depressed markets for British beef, crippled the country's cattle industry.\textsuperscript{(46)} Some key issues from the BSE crisis lingered until recently.

Fear and anxiety may contribute to reduced confidence in the political system and government, and may result in political destabilization, as was seen in Great Britain during the mad cow crisis.

C. Exposure Assessment

As discussed above, the CDC estimates that unsafe food causes 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the U.S.\textsuperscript{(47)} This roughly translates to an estimate that, each year, one in every four Americans will develop an illness due to the accidental food contamination.

Although the CDC has identified certain pathogens as critical agents for food terrorism, it is difficult for FDA to predict with any certainty the likelihood that an act of food terrorism
will occur. Indeed, Codex has recognized that uncertainty may be prevalent in the risk assessment process:

 Many sources of uncertainty exist in the process of risk assessment... of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis.\(^{(48)}\)

FDA further recognizes that the potential impact of a food terrorism event is influenced not only by the likelihood of occurrence, but also by the specific target and agent selected by a terrorist.

Despite these uncertainties, the WHO has warned that "the malicious contamination of food for terrorist purposes is a real and current threat.\(^{(49)}\) The CDC's infectious disease experts similarly have concluded that sabotage of food and water is the easiest means of biological or chemical attack largely because such attacks (albeit on a small scale) have been successful in the past.\(^{(50)}\) In addition, the CDC experts explain, the relative centralization of food production in the U.S. and the global distribution of food products give food a "unique susceptibility," and many points of vulnerability to sabotage intended to affect a large number of people exist in the food production and food distribution processes.\(^{(51)}\)

The threat to the U.S. food supply is more than theoretical. When U.S. troops entered the caves and safe houses of members of the al Qaeda terrorist network in Afghanistan in the months following the September 11th attacks, they found hundreds of pages of U.S. agricultural documents that had been translated into Arabic.\(^{(52)}\) A significant part of the group's training manual is reportedly devoted to agricultural terrorism--specifically, the destruction of crops, livestock, and food processing operations.\(^{(53)}\)

Moreover, recent threats of food sabotage from known terrorist groups have been reported. Specifically, the U.S. Central Intelligence Agency stated in January 2003 that it was investigating whether one of al Qaeda's leading experts on chemical and biological warfare was involved in a plot to poison food intended for British troops. The investigation stemmed from the discovery of ricin in a London apartment linked to suspected militants, one of whom worked for a catering company. The suspects were believed to have been in contact with people who worked on at least one British military base.\(^{(54)}\)

In early September 2003, the U.S. Federal Bureau of Investigation (FBI) issued a bulletin warning that terrorists might use two naturally occurring toxins, nicotine and solanine, to poison U.S. food or water supplies. The FBI noted that terrorist manuals and documents recovered in Afghanistan refer to the use of these substances as poisons. Citing the supermarket employee that deliberately contaminated ground beef with an insecticide containing nicotine, FBI officials advised: "Such lone offenders, whether al-Qaida [sic] sympathizers or domestic criminals, are a concern to FBI because they are so difficult to detect."\(^{(55)}\)
The U.S. is not alone in its concern about a food terrorist event. The WHO Secretariat noted last year that several countries have reported heightened states of alert for a biological or chemical attack on air, water, or food. (56) The events of September 11, 2001, and evidence from al Qaeda validate concerns about threat of terrorism against the United States. (57)

**D. Risk Characterization**

This Risk Assessment addresses a broad range of hazards that may be deliberately or accidentally introduced into the food supply that FDA regulates. Despite the difficulty of developing a quantitative risk assessment of cumulative risk in the present circumstance, FDA notes that the public health impact of unintentionally contaminated food has been documented by the CDC estimate that 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths from foodborne illness occur annually in the U.S. Other journal articles and risk assessments, referenced here, also provide data on risk of illness from the accidental introduction of pathogens into food. For example, the government's quantitative risk assessment for *Salmonella* Enteritidis (SE) in shell eggs and egg products estimated, based on modeling, that an average of 660,000 illnesses occur each year in the U.S. due to SE-contaminated eggs. The predicted average risk is 3.5 SE illnesses per one million egg servings per year. (58)

It is more difficult for FDA to characterize the risk of food terrorism, largely because of uncertainties associated with estimating the likelihood of occurrence—even though documented incidents of sabotage have occurred and recent reports have surfaced of al Qaeda plots to poison food supplies. Traditional risk assessments for acute hazards, particularly those using modeling, often generate estimates of risk on an annual basis, as was done in the SE risk assessment. (59) In the present circumstance, the agency has determined that the magnitude of the risk of food terrorism, and the uncertainty associated with that risk characterization, depend on the temporal basis of the risk estimate. Specifically, if a small increment of time, such as one day, is used to estimate the risk of an act of deliberate contamination, then the likelihood of occurrence would be low. If, however, a larger increment of time, such as the period of one month, is used, then the risk would be greater, and if the agency considers the likelihood of occurrence over the period of one year, then the risk of an act of food terrorism is significantly higher. To ensure that this assessment is useful for planning purposes, FDA has determined that it is appropriate to characterize the risk of occurrence of an act of food sabotage or a significant incident of unintentional food contamination on an annual basis.

The agency has considered, for the purposes of risk characterization, the known exposure to food that has been inadvertently contaminated and the past incidents of deliberate contamination, as well as the evidence that terrorists have targeted our food supply. In light of this information and the uncertainties attendant to characterizing the risk of an act of food terrorism, FDA has concluded that there is a high likelihood, over the course of a year, that a significant number of people will be affected by an act of food terrorism or by an incident of unintentional food contamination that results in serious foodborne illness.
III. Conclusion

The CDC’s strategic planning workgroup on biological and chemical terrorism warned, more than a year before the September 11th attacks and the anthrax incidents:

An act of biological or chemical terrorism might range from dissemination of aerosolized anthrax spores to food product contamination, and predicting when and how such an attack might occur is not possible. However, the possibility of biological or chemical terrorism should not be ignored. Preparing the nation to address this threat is a formidable challenge, but the consequences of being unprepared could be devastating.60

Though the likelihood of a biological or chemical attack on the U.S. food supply is uncertain, significant scientific evidence documents the risk to public health of food that has been inadvertently contaminated. Notwithstanding the uncertainties described in this risk assessment, and given the broad range of agents that may contaminate the food supply that FDA regulates, the agency concludes that there is a high likelihood, over the course of a year, that a significant number of people will be affected by an act of food terrorism or by an incident of unintentional food contamination that results in serious foodborne illness.

FDA has determined that this qualitative risk assessment, which discusses prior incidents of food contamination and available unclassified information on prior acts of food sabotage, is appropriate to the circumstances.

Notes


(2) In addition, the agency prepared a report to Congress on food-related terrorism issues.

(3) This Risk Assessment specifically analyzes the risk of contamination of the broad range of foods that FDA regulates. All foods, except meat, poultry, and processed egg products, fall under the agency's jurisdiction. Thus, FDA regulates approximately 80% of the U.S. food supply. The remainder is regulated by the U.S. Department of Agriculture.


(5) U.S. Centers for Disease Control and Prevention, Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response, Recommendations of the CDC Strategic Planning Workgroup, 49 Morbidity and Mortality Weekly Report, Recommendations and Reports (RR-4) 5-8 (2000).

(6) For example, Salmonella bacteria introduced inadvertently into food are estimated to cause 1.3 million illnesses, 15,600 hospitalizations, and 550 deaths each year in the U.S. Paul S. Mead et al., Food-Related Illness and Death in the United States, 5 Emerging Infectious Diseases 607-25 (1999).

(7) U.S. Centers for Disease Control and Prevention, supra note 5, at 5-8.


(9) U.S. Centers for Disease Control and Prevention, supra note 5, at 4.


(14) Id.


(33) Chalk, supra note 31, at 3, 5-6.


(38) Pate & Cameron, supra note 32, at 16.


(41) Id.

(42) Id.

Swedish National Defence College, supra note 40, at 2.


Approximately 4.5 million head of cattle were destroyed in the U.K., at a cost of $ 4 billion. U.S. Department of State, Mad Cow Disease: Agriculture Issues (Mar. 12, 2001). Attaché reports from London in 1996 indicated that nearly 10,000 people in the transport and meat processing industries were laid off as a result of the mad cow crisis. U.S. Department of Agriculture, Foreign Agriculture Service, BSE Update 04/02/96. See also id. at 5-6.

Mead, supra note 6. This estimate accounts for underreporting of foodborne illness, as well as the proportion of foodborne illness that is caused by pathogens or agents that have not yet been identified and thus cannot be diagnosed. Id. at 607.

Codex (ALINORM 03/41), supra note 4.

World Health Organization, supra note 11, at 1.

Khan, supra note 15, at 3-4 (comparing aerosolized attacks to food and water sabotage).

Id. at 4-5.

Katherine Peters, Officials fear terrorist attack on U.S. food supply, Government Executive (June 10, 2003).

Id.


World Health Organization, supra note 11, at 2.

remain a nation at risk to terrorist attacks and will remain at risk for the foreseeable future.”


(59) Id. See also, U.S. Food Safety and Inspection Service, Draft Risk Assessment of E. coli O157:H7 in Ground Beef, supra note 17.

(60) U.S. Centers for Disease Control and Prevention, supra note 5, at 1