

GAO

Report to the Chairman, Permanent
Subcommittee on Investigations,
Committee on Governmental Affairs,
U.S. Senate

October 1999

FOOD SAFETY

Agencies Should Further Test Plans for Responding to Deliberate Contamination



**Resources, Community, and
Economic Development Division**

B-283528

October 27, 1999

The Honorable Susan M. Collins
Chairman, Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

Dear Madam Chairman:

Concerned about the vulnerability of the nation's food supply to acts of deliberate contamination with a biological agent, you asked that we review the preparedness of the federal food safety regulatory agencies to respond to acts or threats of deliberate food contamination, including those by terrorists. The federal food safety agencies primarily concerned with such contamination are the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), which regulates the safety of meat, poultry, and some egg products, and the Department of Health and Human Services' Food and Drug Administration (FDA), which regulates the safety of all other food products.¹ In some cases, such as eggs, the responsibilities of these two agencies overlap. Other federal, state, and local agencies also share responsibility for the safety of the nation's food supply.

Specifically, you asked us to (1) determine the extent to which food has been deliberately contaminated with a biological agent (bacteria, virus, or toxin) or threatened to be contaminated with such an agent and (2) describe the plans and procedures that federal food safety regulatory agencies have for responding to threats and acts of deliberate food contamination with a biological agent.

Results in Brief

To date, deliberate contamination of food with a biological agent has rarely occurred in the United States, according to federal agencies. We identified two such acts since 1984, both of which produced short-term illnesses among a combined total of about 765 people, but no deaths. Similarly, threats of contamination with a biological agent occur infrequently: From October 1995 through March 1999, federal agencies reported receiving three such threats—two of these were hoaxes, and the other is still an open investigation.

¹Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System (GAO/T-RCED-99-256, Aug. 4, 1999).

FDA has written procedures for contacting key FDA and other federal officials and experts to quickly develop an approach to respond to threats or acts of contamination. The approach may involve assessing the credibility of a threat or requesting a recall of the contaminated food. FSIS also has written procedures for responding to acts of contamination, which include conducting a preliminary investigation to assess the health hazards and, if necessary, requesting a recall. For threats of contamination, FSIS is developing a plan that will include coordination steps with other affected federal agencies.

We are recommending that the effectiveness of federal food safety procedures be tested using a variety of scenarios involving food deliberately contaminated with biological agents and including various players, such as state and local agencies.

Background

A number of federal, state, and local agencies have responsibilities for responding to incidents of food contamination. FSIS and FDA lead the federal food safety efforts and play a key role in removing contaminated food from the marketplace. In addition, these two agencies and the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) may work with state and local health departments to investigate foodborne illnesses.² Finally, the Department of Justice's Federal Bureau of Investigation (FBI) may lead criminal investigations associated with incidents of deliberate food contamination.

Biological agents can be introduced into food either inadvertently—through poor food-handling or food-processing techniques—or deliberately. Deliberate food contamination with a biological agent can be identified (1) during an investigation of an outbreak of a foodborne illness or (2) by a warning or threat of contamination. Many investigations of foodborne outbreaks are conducted each year, but distinguishing between deliberate and inadvertent contamination of a foodborne outbreak can be difficult. Moreover, it is often difficult to associate an outbreak of foodborne illness with a specific incident of contamination. Food contamination can result in illnesses that range from temporary maladies, which may not require medical treatment; to acute and chronic illnesses, such as kidney failure in infants; to death.

²According to CDC, it also has the overall responsibility to lead an effort to upgrade the national public health capability to counter bioterrorism and, in fulfilling this responsibility, is preparing a strategic plan for bioterrorism preparedness and response.

Under federal law, acts or threats of deliberate food contamination using a biological agent can be investigated and prosecuted as acts of tampering or terrorism.³ The Federal Anti-Tampering Act of 1983 was enacted after an unknown individual(s) contaminated Tylenol packages with cyanide, killing seven people in the Midwest. This law makes it a federal crime to tamper with certain consumer products, including food, that travel in interstate commerce. USDA's Office of Inspector General, FDA's Office of Criminal Investigations, and the FBI have concurrent jurisdiction to investigate tampering of food products. With few exceptions, the agency responsible for regulating the affected product—FDA or USDA—is the lead agency for the criminal investigation. If the food contamination appears to be caused by a terrorist, then the FBI is the lead criminal investigative agency. Terrorism is a deliberate act or threat committed by an individual or group for political or social objectives, according to the FBI.⁴ Individuals can also be prosecuted for deliberate actions that result in the adulteration of meat, poultry products, and other food under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetics Act, respectively.

Deliberate Food Contamination Using a Biological Agent Is Infrequent

Acts or threats of deliberate food contamination using a biological agent have been rare in the United States, according to federal agencies. We identified two such acts in the last 15 years. The bacterial pathogens used in these incidents—Salmonella and Shigella—cause severe diarrhea and death in certain vulnerable groups. The Salmonella case is considered the only act of terrorism using a biological agent in the United States, according to the FBI. Similarly, threats of such contamination have been rare—three were reported by federal officials from October 1995 through March 1999.

The first act of deliberate contamination occurred in September 1984, when 751 persons became ill with gastroenteritis, an inflammation of the stomach and intestines. The local health department, with assistance from CDC, found through its investigation that food at salad bars was contaminated with Salmonella Typhimurium.⁵ More than a year later, the

³18 U.S.C. section 1365; 18 U.S.C. section 175-178 and 2331-2339; and 50 U.S.C. chapter 40.

⁴There is no uniform definition of terrorism among federal government agencies.

⁵The Salmonella germ is a group of bacteria that can cause diarrheal illness in humans. In the United States, the most common types are Salmonella Typhimurium and Salmonella Enteritidis. Many raw foods of animal origin (eggs, poultry, and meat) have naturally occurring pathogens, such as Salmonella, but thorough cooking kills them. Ready-to-eat foods that are contaminated with Salmonella and are eaten without cooking may cause illness.

FBI learned through a former member of a religious cult that the cult had used the Salmonella to contaminate the food. The cult's intent was to incapacitate people so they would be unable to vote in a local election. Because of the political intent, the FBI subsequently considered the incident as an act of terrorism. Two former members pled guilty to tampering with consumer products under the Federal Anti-Tampering Act of 1983. They were each sentenced to 4-1/2 years in prison.

The second act, in October 1996, affected 13 persons who developed severe diarrhea. Twelve of these individuals worked in a laboratory at a large medical facility, and the other had eaten food brought home from work. No deaths resulted, but five individuals were treated and released from emergency centers, and four were hospitalized with acute diarrhea. Within 4 days, state and local public health officials determined that the affected individuals had been infected with the same strain of Shigella dysenteriae, which was also found in leftover food at the laboratory. Because this strain of bacteria is generally found only in the developing world, public health officials suspected that the food was deliberately contaminated. The local government successfully prosecuted the responsible individual, who was sentenced to 20 years in prison.

Three threats of deliberate food contamination with a biological agent—two cases were determined to be hoaxes and the other is still an open investigation—occurred from October 1995 through March 1999, according to the federal officials we contacted. Two involved FDA-regulated food, while the other was an FSIS-regulated product. Specifically:

- In the first threat, in March 1997, a disgruntled employee made financial demands on a bottling plant company, stating that a carbonated beverage had been contaminated with a biological agent. FDA's Office of Criminal Investigations and the FBI jointly investigated the case and within 1 week determined that the claim was a hoax. The defendant was sentenced in September 1997 to 1 year in prison and 1 year on probation.
- In the second case, in December 1998, a police department received a call directing them to locate a note. The note indicated that a person associated with a terrorist group threatened to contaminate meat with a biological agent at an FSIS-regulated slaughter and processing facility. A large response effort was undertaken. The FBI and USDA's Office of Inspector General conducted a detailed search of the plant and its warehouses to determine whether products had been tampered with. FSIS, with advice from CDC and the Occupational Safety and Health

Administration, evaluated the health risk. The FBI and USDA's Office of Inspector General interviewed over 800 individuals to identify and eliminate suspects. Within 3 days, the company was allowed to distribute its products. The case is still open. The responsible individual has not been identified.

- In the third case, in March 1999, a state agriculture department was notified that a note had been found alleging that milk had been contaminated with a biological agent. Within hours, state and local public health and law enforcement agencies, as well as the state agriculture department, quarantined the suspected milk, and the FBI launched a criminal investigation. In the same period, the plant, at the request of FDA and the state agriculture department, halted production. The case was confirmed as a hoax within 12 hours; no criminal charges were brought.

FDA and FSIS Have or Are Developing Procedures to Respond to Deliberate Food Contamination

Both FDA and FSIS have written policies and procedures for responding to acts of deliberate food contamination with a biological agent. FDA has written procedures for responding to threats of contamination as well. FSIS is developing procedures for responding to such threats.

FDA Has Procedures to Respond to Threats or Acts of Deliberate Contamination

FDA has procedures to respond 24 hours a day to threats or acts of deliberate contamination with a biological agent. These procedures guide the investigation of a possible food contamination incident and, if necessary, the removal of contaminated food from the marketplace. More specifically, FDA headquarters is primarily responsible for coordinating the initial response to an incident. Typically, this effort involves first notifying CDC, FBI, USDA, FDA's Office of Criminal Investigations, industry representatives, and/or other countries to alert them to the possibility of contaminated food. Next, the procedures call for FDA headquarters to contact key officials and field staff to share information and determine FDA's best course of action to protect public health. At the same time, FDA initiates an investigation—generally led by its field staff—to determine, among other things, the source and extent of contamination. This investigation can include (1) interviewing affected persons, medical personnel, local and state health officials, and law enforcement officials; (2) sampling any suspected product; and (3) determining the specific pathogen and food involved. Finally, on the basis of the investigation results, FDA can request the manufacturer or distributor to recall the product. If the manufacturer or distributor does not voluntarily comply

with FDA's recall request, the agency can request (1) states to immediately embargo the product, (2) the Department of Justice to file a complaint to prevent the company from further distributing the product, and/or (3) the Department of Justice to seek a court order to allow FDA to seize the contaminated food. In addition to the investigation that may result in the possible recall of deliberately contaminated food, the FBI and/or FDA's Office of Criminal Investigations may conduct a criminal investigation of the incident. This investigation begins as soon as it is suspected that the contamination was caused deliberately.

FDA officials believed their procedures worked well in the case of the March 1999 milk contamination threat. However, on the basis of this incident, they slightly modified their procedures. The key modification instructed field staff to let the FBI—rather than FDA—collect food samples in situations where it is suspected that a terrorist contaminated the food with a biological agent. Another modification directed field staff to take a new step—alerting the local FDA Office of Criminal Investigations and the local FBI office to possible criminal activity. While FDA headquarters would also notify the FBI, this additional step is designed to ensure redundancy in order to provide a fail-safe notification system.

FSIS Has Procedures for Responding to Acts of Deliberate Food Contamination and Is Developing Procedures for Threats

Like FDA, FSIS has written procedures to evaluate the public health risk posed by contaminated food and to determine whether a recall needs to be requested. However, the agency does not have procedures for responding to threats of food contaminated with a biological agent.

In August 1999, FSIS developed a manual that consolidates its procedures for responding to reports of deliberately and inadvertently contaminated meat and poultry. Under these procedures, the agency conducts a preliminary investigation to help determine whether a recall of the product is warranted. Like FDA's investigation procedures, FSIS' procedures may have staff interview affected persons, contact state and local health departments, and collect samples. If this investigation indicates a recall is necessary, FSIS convenes a recall committee, which makes a final decision. In unusual cases, FSIS may call upon a team of its scientists to assess public health hazards, such as those posed by pathogens that FSIS does not normally investigate. If FSIS requests a recall, it asks the manufacturer or distributor to develop an action plan and then monitors the company's effort. If the company refuses to recall the contaminated product, the agency may detain the product for 20 days while seeking a court order to seize it. Although FSIS does not have the authority to enforce a recall, the

agency has not used its detention authorities because no company has refused a recall request.

The December 1998 threat of meat contamination prompted FSIS to begin developing a plan to respond to threats of contamination. The plan will cover tampering and terrorism, and will include, among other things, coordination activities for emergency response planning. FSIS expects to complete the plan by December 1999.

For the December 1998 threat, USDA used its congressionally mandated Food Emergency Rapid Response and Evaluation Team for the first time. The team is designed to quickly bring together all the different USDA agencies that may need to respond to a food emergency. FSIS is the lead agency for the team, which consists of high-ranking departmental officials and is chaired by the Under Secretary for Food Safety, who also oversees FSIS. During the December 1998 threat, the team was used to inform top departmental officials about the nature and status of the Department's response. Since its creation in April 1998, the team has met quarterly to, among other things, develop its charter and a departmentwide plan for food emergencies.

In addition to establishing the emergency response team, the Department recently took another action to improve its ability to deal with incidents of deliberate food contamination. In August 1999, USDA and the Department of Defense jointly planned and conducted a multiagency exercise in which a terrorist, without warning, deliberately contaminated FSIS-regulated food with a biological agent.⁶ Participants included numerous USDA agencies, FDA, CDC, the FBI, a state agriculture department, state and local health departments, local physicians, and industry. The exercise gave the agencies a chance to familiarize themselves with each other's roles and responsibilities in responding to such a terrorist incident. USDA is awaiting the evaluation of the exercise, which is being done by a Department of Defense contractor.

Conclusions

Although few actual incidents or threats of deliberate food contamination with a biological agent have occurred to date, there is little assurance that this track record will continue. Consequently, it is important that federal food safety regulatory agencies be prepared to respond quickly to protect

⁶During this exercise, the participants progressed through a scenario and reacted as if the situation were real. *Combating Terrorism: Analysis of Federal Counterterrorist Exercises* (GAO/NSIAD-99-157BR, June 25, 1999) discusses the 201 counterterrorism exercises conducted by the federal government in recent years.

the public health. FDA and FSIS have or are in the process of developing response plans or procedures for contamination incidents. However, the effectiveness of these procedures is largely untested. The recent USDA exercise to test federal, state, and industry responsiveness to a hypothetical contamination incident was certainly a reasonable start in assessing the effectiveness of current plans and procedures. However, this exercise was limited to examining how effectively the food safety system responded to one of many possible sets of circumstances in which food could be deliberately contaminated with a biological agent. For example, the exercise did not examine how the system would respond to deliberate contamination involving food regulated by FDA or food jointly regulated by FSIS and FDA. More extensive testing of federal, state, local, and industry responses to a variety of different types of contamination incidents would help ensure that appropriate plans and procedures are in place to deal with actual cases of deliberate food contamination.

Recommendation

To better ensure the effectiveness of the federal food safety regulatory agencies' response to deliberate food contamination using a biological agent, we recommend that the Secretaries of Agriculture and Health and Human Services direct the Under Secretary for Food Safety and the Commissioner, Food and Drug Administration, respectively, to test the effectiveness of their response plans and procedures, using simulated exercises and, where appropriate, to modify their plans and procedures on the basis of these tests. The exercises should be designed to evaluate the effectiveness of responses by federal, state, and local agencies, as well as industry, to a variety of incidents of deliberate food contamination with a biological agent.

Agency Comments

We provided a draft of this report to FDA, USDA, CDC, and the FBI for review and comment. We met with FDA officials, including the Senior Advisor for Regulatory Policy, who agreed with our recommendation and said FDA would implement it as resources become available. We also met with USDA officials, including the Deputy Assistant to the Assistant Deputy Administrator for District Enforcement Operations, who also agreed with our recommendation. These officials suggested that the Congress ensure adequate funding for food safety regulatory agencies to test the effectiveness of their plans. In response to the recommendation in our draft report, USDA stated that, to the extent possible, it will develop and execute realistic exercises using available intelligence information concerning methods of introduction, specific biological or chemical agents

used, and other pertinent information. USDA also said it will use lessons learned from both the exercises and the intelligence community to help design additional scenarios. Although CDC did not comment specifically on our recommendation, the agency agreed that it is important that federal food safety regulatory agencies be prepared to respond quickly to protect the public health against acts of deliberate food contamination with a biological agent. Furthermore, while CDC recognized that FDA and FSIS are the primary food safety regulatory agencies, it pointed out that it has the overall responsibility to lead an effort to upgrade the national public health capability to counter bioterrorism. To fulfill that responsibility, CDC is preparing a strategic plan for bioterrorism preparedness and response. We have incorporated this information into our report. In addition, CDC, FDA, and USDA made technical clarifications, which were incorporated as appropriate. The FBI had no comments on the draft report.

Scope and Methodology

To determine the extent to which food in the United States has been threatened or deliberately contaminated with a biological agent, we interviewed and obtained information from FDA, USDA, and the FBI on threats and acts of deliberate food contamination and terrorism. The information does not include possible cases that may have occurred and been investigated by state and local agencies but not reported to the three federal agencies. We also conducted a literature search and interviewed officials from CDC and selected state health agencies to ensure the completeness of our information.

To determine what plans and procedures federal food safety regulatory agencies have to respond to deliberate food contamination using a biological agent, we reviewed the following agency documents: emergency plans, procedures, guidelines, manuals, memoranda of understanding, presidential decision directives on terrorism, the Terrorism Incident Annex to the Federal Response Plan, the FBI's draft Concept of Operations Plan, the FBI's Weapons of Mass Destruction Incident Contingency Plan, Health and Human Services' (HHS) Health and Medical Services Support Plan for the Federal Response to Acts of Chemical/Biological Terrorism, and budget documents. In addition, we interviewed agency officials from USDA, including FSIS, the Office of Inspector General, and the Agricultural Research Service; HHS, including the Office of Emergency Preparedness, CDC, and FDA and its Office of Criminal Investigations; and the FBI.

We conducted our review from February 1999 through September 1999 in accordance with generally accepted government auditing standards.

As arranged with your office, unless you announce its contents earlier, we plan no further distribution of this report until 30 days after the date of this report. At that time, copies of this report will be sent to the Honorable Carl Levin, Ranking Minority Member, Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs; the Honorable Dan Glickman, Secretary of Agriculture; the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Catherine E. Woteki, Ph.D., Under Secretary for Food Safety, USDA; the Honorable Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA; the Honorable Roger C. Viadero, Inspector General, USDA; the Honorable Jane Henney, M.D., Commissioner, Food and Drug Administration, HHS; the Honorable Jeffrey P. Koplan, M.D., Director, Centers for Disease Control and Prevention, HHS; and the Honorable William Freeh, Director, Federal Bureau of Investigation, Department of Justice. We will also make copies available on request.

If you or your staff have any questions about this report, please contact me or Cathy Helm, Assistant Director, at (202) 512-5138. Key contributors to this report were Erin Barlow, Rebecca Johnson, and Rosellen McCarthy.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Robertson". The signature is written in a cursive, flowing style.

Robert E. Robertson
Associate Director, Food
and Agriculture Issues

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