United States General Accounting Office

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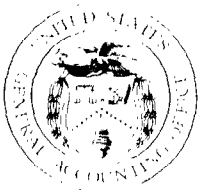
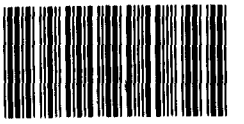
Report to the Honorable Leon E. Panetta, House of Representatives

October 1990

FOOD TAMPERING

Legal Authority Adequate to Deal With Threats





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GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-239068

October 31, 1990

The Honorable Leon E. Panetta
House of Representatives

Dear Mr. Panetta:

In the wake of the March 1989 discovery of cyanide in grapes from Chile and the subsequent 5-day suspension of all Chilean fruit imports, you expressed concern that such food tampering incidents could seriously disrupt the American food supply. You asked us to assess whether there is sufficient legal authority and other mechanisms in place to minimize the effects of future incidents. As agreed with your office, we reviewed whether the Food and Drug Administration (FDA)

- has sufficient regulatory authority to deal with food tampering threats;
- complied with pertinent laws and regulations in its action against Chilean fruit, and whether its actions were consistent with actions taken on other food tampering incidents; and
- consults with other federal agencies and affected parties on food tampering threats.

We also agreed to summarize studies on the potential impact of food tampering threats involving product recalls in the U.S. food supply.

Background

The Federal Food, Drug, and Cosmetic Act provides the basic statutory authority governing the treatment of domestic and imported food products. The act requires that foods that are imported or distributed and sold in the United States be pure and wholesome, safe to eat, and produced under sanitary conditions. It prohibits the importation or sale in the United States of any food that contains an added poisonous or other harmful substance that may pose a health risk.

Under the act and applicable regulations, FDA has been delegated responsibility from the Secretary of Health and Human Services (HHS) for ensuring that domestic and imported products it regulates meet the requirements of the act.[1] The U.S. Customs Service shares responsibility with FDA for regulating imported food products in that it controls the entry of all imported products into the United States. Imported foods that fail to meet the requirements of the law are to be detained at the

[1]Meat, poultry, and eggs are regulated by the U.S. Department of Agriculture. The Department of Commerce and FDA share responsibility for seafood inspections.

entry location and must be brought into compliance, destroyed, or removed from the United States.

The Chilean fruit episode demonstrates FDA's use of its authority.[2] In March 1989, the U.S. Embassy in Chile received warnings that Chilean fruit destined for the United States had been poisoned with cyanide. As a result, FDA increased its inspection of Chilean fruit and, on March 12, 1989, found grapes that contained cyanide, which were from a vessel carrying Chilean fruit that had arrived in Philadelphia. Based on this finding, fruit imports from Chile were suspended for 5 days, beginning March 13, while FDA developed a more comprehensive inspection program for Chilean fruit. On March 17, the suspension was lifted and all Chilean fruit that passed FDA's inspection was allowed to enter U.S. markets. That same day, FDA was notified of a third telephone threat in Chile. However, no additional contaminated fruit was found and import inspections returned to normal by mid-April 1989.

Results in Brief

It appears that FDA has sufficient statutory authority and procedures in place to deal with food tampering threats. FDA has a variety of options it can use to deal with unsafe food, ranging from encouragement of voluntary actions on the part of product owners, manufacturers, or importers to correct a problem to court-ordered seizure of food products. For example, in light of threats and a finding of contamination involving Chilean fruit, FDA had sufficient authority to (1) suspend Chilean fruit imports, (2) warn consumers not to eat Chilean fruit, (3) recommend that retailers remove Chilean fruit from the market, (4) deny entry to an entire shipment of Chilean fruit, and (5) conduct increased inspections of arriving Chilean fruit. If these actions had not been sufficient to keep the contaminated fruit out of commerce, FDA could have seized the product.

FDA's actions taken during the Chilean fruit incident were consistent with the actions it took on prior tampering threats involving imported food. FDA officials believe that FDA has sufficient regulatory authority to deal with food tampering threats.

FDA is not required by law to consult with other federal agencies before taking action against an adulterated food product. Nevertheless, FDA has sought advice from others when confronted with a food tampering

[2]For a related GAO report on FDA's actions on Chilean fruit imports see Food Tampering: FDA's Actions on Chilean Fruit Based on Sound Evidence (GAO/HRD-90-164, Sept. 6, 1990).

threat. During the Chilean fruit incident, FDA consulted with several federal agencies and affected parties, including the Departments of State and Agriculture and representatives of the Chilean government and food industry, regarding proposals to confront the danger.

We did not identify any studies that assessed the impact of food tampering incidents or food recalls on the U.S. food supply. In this regard, FDA is not required by law to consider the economic or supply consequences of its actions on the American or international food markets before acting. Nevertheless, in exercising its authority, FDA has been sensitive to the impact of its actions. In the Chilean fruit incident, FDA took into account the possible effects of its actions on the U.S. food supply in deciding how to respond to the tampering threat. Because the United States is the single largest market for Chilean fruit exports, FDA also recognized that any actions taken against Chilean fruit imports could have serious consequences for U.S. importers as well as the Chilean economy. Thus, FDA discussed with Chilean representatives an inspection plan that was intended to protect public health and return Chilean fruit to the market.

Scope and Methodology

In performing our work, we focused primarily on the requirements of the Federal Food, Drug, and Cosmetic Act because this is FDA's primary authority for regulating food, and on FDA's response to threats made against Chilean fruit, because this was the most recent imported food tampering incident to affect the United States. We also interviewed and obtained information from FDA officials, including the former FDA Commissioner who was responsible for the actions taken against the Chilean fruit, the Customs Service, the Department of Agriculture, the Department of State, the Federal Bureau of Investigation (FBI), and the Chilean Exporters Association.

To determine whether FDA's actions on Chilean fruit imports were consistent with applicable laws and regulations, we reviewed court decisions interpreting the applicable statutes. We also reviewed the manner in which FDA responded to prior threats against imported food to compare whether its actions were consistent with those it took in the Chilean fruit incident.

To determine whether FDA consults with other federal agencies and affected parties when confronted with a food tampering threat, we reviewed FDA records of meetings and discussions with others during the course of the Chilean fruit tampering threat and interviewed various

federal and private officials. We also attempted to identify any studies conducted on the potential effect of food tampering incidents on the U.S. food supply.

We performed our work between October 1989 and June 1990 in accordance with generally accepted government auditing standards.

FDA Has Adequate Authority to Deal With Food Tampering Threats

FDA's authority appears adequate to deal with food tampering threats and its actions in the Chilean fruit incident were within its authority. Current law and FDA regulations governing adulterated food products provide FDA with several regulatory options to assure the safety of domestic and imported food products.

For domestic food products, FDA has authority to conduct periodic inspections of food facilities and to analyze product samples. When violations are discovered, FDA may request firms or owners to voluntarily correct problems or to destroy or recall a product. When FDA believes a domestic food product is adulterated and no corrective action is taken voluntarily, it must pursue legal action through the Department of Justice, which must convince a court that the questioned goods are in fact adulterated. Only after this has occurred can the goods be kept off the market. Persons or firms responsible for violations may be prosecuted in federal court, and, if found guilty, be fined, or imprisoned, or both.

In contrast, FDA may refuse entry if an imported food appears to be adulterated. There is no requirement that the imported food actually be adulterated or that FDA make such a determination. If FDA determines that an imported product appears to be adulterated, the owner, shipper, or importer has three options: (1) destroy the product; (2) remove it from the United States; or (3) with FDA's permission, bring the product into compliance with the law, if possible. In a case involving cyanide poisoning, the product cannot be brought into compliance; thus, it must be destroyed or shipped out of the United States.

In the case of the Chilean fruit, once FDA determined that some fruit unloaded from a ship in Philadelphia contained cyanide, FDA

- refused to admit any of the ship's fruit,
- notified state health departments and other countries that also imported Chilean fruit of the cyanide finding,

- recommended that U.S. retail outlets remove Chilean fruit from distribution and that consumers refrain from eating Chilean fruit they had purchased, and
- increased inspections of incoming Chilean fruit and fruit in cold storage warehouses.

These actions were consistent with FDA's statutory authority and regulations for dealing with imported foods that appear to be adulterated. In the opinion of FDA, the Federal Food, Drug, and Cosmetic Act and FDA regulations provide FDA with sufficient authority to take action when confronted with an adulterated food product resulting from a tampering threat.

FDA Has Taken Similar Action on Other Imported Food Tampering Incidents

Between 1984 and 1989, FDA investigated about 3,800 tampering threats and incidents involving a wide variety of food, drugs, and other products that FDA regulates. Our review of two prior threats involving imported food showed that FDA has been consistent in its actions. FDA officials said that the Chilean fruit incident was the largest tampering incident FDA has investigated because the threat did not specify the type(s) of fruit poisoned or the vessel(s) on which the fruit was being shipped, as had been done in some other tampering incidents. It was also the first occasion that FDA found an imported food product that had been tampered with actually arriving in the United States. Thus, FDA had no exact precedent to guide its investigation of this incident. However, FDA's actions on the Chilean fruit were consistent with its actions on two previous tampering threats involving imported food.

One 1985 incident involved tea. An unknown person sent a letter to the U.S. Embassy in Sri Lanka claiming that tea bound for the United States had been poisoned with cyanide. Similar to its actions on Chilean fruit, FDA (1) refused entry of Sri Lankan tea into the United States and (2) increased its examinations of Sri Lankan tea for cyanide. After receiving no additional threats nor finding cyanide in tea that was sampled, FDA lifted its ban on Sri Lankan tea imports 4 months after denying them entry.

The second incident occurred in 1978 when terrorists contaminated with metallic mercury a shipment of Israeli oranges bound for Germany and the United States. Oranges unloaded in Germany were found to contain mercury. When the remainder of the shipment arrived in the United States, FDA performed visual examinations and conducted other tests on 77,000 oranges. FDA did not find mercury in any of the inspected

oranges. After detaining the shipment for 4 days while tests were being conducted, FDA released it for distribution to markets.

FDA Has Consulted With Other Agencies on Food Tampering Incidents

The Federal Food, Drug, and Cosmetic Act does not require FDA to consult with other federal agencies in determining that a food product is adulterated and, thus, poses an imminent danger to health. Nor does the act require FDA to consult with other agencies on how to remedy the problem or on the potential impact of its actions.

However, in practice, FDA has consulted with federal and private agencies before deciding on a course of action involving food tampering incidents. In the incident involving Sri Lankan tea, FDA consulted with the Department of State, the Sri Lankan Ambassador, the Office of the Secretary of HHS, and the tea trade association regarding actions necessary to deal with the threat. FDA also notified Canada and other countries of the threat.[3]

In the Chilean fruit incident, after determining that fruit aboard the vessel that arrived in Philadelphia was adulterated, FDA consulted with several federal agencies regarding proposals to confront the danger. Before taking action against Chilean fruit imports on March 13, 1989, the FDA Commissioner contacted the Secretary of HHS and the Office of the President on the proposed actions. Both the Secretary of HHS and the Office of the President supported the Commissioner's proposals. Additionally, FDA consulted with the Departments of State and Agriculture and the Customs Service. Because FDA is the primary public health agency for dealing with these situations, these agencies deferred any decisions regarding the fruit to FDA and made no recommendations to FDA for dealing with the tampering incident.

Although the various federal agencies made no recommendations to FDA, they did provide FDA with technical and other assistance. U.S. Department of Agriculture personnel, who grade incoming fruit for quality, provided FDA inspectors with guidance on normal and abnormal defects they might encounter, such as nail or staple holes and blemishes. When the Customs Service became aware of the initial threat against Chilean fruit, it placed a temporary hold on arriving shipments while it consulted with FDA on an appropriate course of action. When FDA subsequently discovered contaminated fruit, Customs suspended Chilean fruit

[3]FDA records on the extent of consultations held on the incident involving Israeli oranges were not available.

imports at FDA's request while FDA developed a more comprehensive inspection plan for arriving Chilean fruit.

FDA Consulted With the State Department and Chilean Organizations

The State Department also played a key role during the course of the Chilean fruit tampering incident and was in close communication with FDA. The Department notified FDA of the initial and subsequent tampering threats and supported FDA's efforts to convince representatives of the Chilean government and fruit industry of the need for increased inspections of incoming Chilean fruit shipments.

Additionally, FDA consulted with the Chilean Foreign and Agricultural Ministers, the Chilean Ambassador to the United States, and representatives of the Chilean Exporters Association and the American Produce Association. The main focus of these consultations was to devise an inspection plan for Chilean fruit and release any fruit that passed inspection. The Chilean representatives made recommendations to FDA concerning the proposed plan. They recommended that FDA examine 1 to 2 percent of the shipments because of the time and expense of performing more extensive examinations. However, FDA believed this inspection level was too low. FDA's statistical calculations showed that a 10-percent inspection level was necessary to provide a sufficient level of confidence that any additional tainted fruit would be found.

The State Department helped to convince the Chilean representatives of the need to inspect more fruit than what Chile proposed. Ultimately, FDA and the Chilean government agreed on an inspection level for incoming Chilean fruit.

In sum, although FDA is not required by law to consult with others in determining that a food product might be adulterated or on how to remedy the problem, it has consulted with and sought advice on how to deal with a food tampering threat.

FDA Has Considered the Economic and Supply Impact of Its Actions

FDA's primary mission is to protect the public from unsafe food products. The Federal Food, Drug, and Cosmetic Act does not require FDA to minimize disruption to the American food supply in considering action when it discovers an adulterated food product. Neither does the law require FDA to consider the economic impact of its actions. However, FDA has considered these matters in its decisions involving food tampering incidents.

Although we did not identify any studies on the impact on the American food supply from the tampering incident, it would appear there were no significant disruptions. Fruit was available in the United States from other sources and the suspension of Chilean fruit imports lasted for only 5 days.

Because the United States is the largest single market for Chilean fruit exports, FDA was aware of the serious financial consequences on U.S. importers and the Chilean economy that would likely result from a suspension of Chilean fruit imports. Therefore, a major focus of FDA's discussions with Chilean government and food industry representatives was to develop an inspection plan that would protect public health and return Chilean fruit to the marketplace. FDA appears to have achieved its objectives. No additional contaminated Chilean fruit was found and while there was an impact on the Chilean economy it appears to have been shortlived. One year after the poisoning incident Chilean fruit exports to the United States reached an all time high, indicating that exports to the United States and other countries have not been seriously affected by the incident.

We did not obtain written comments on the report, but discussed it with FDA officials. Where appropriate, we incorporated their comments into the report.

We are sending copies of this report to other interested committees; the Secretary of Health and Human Services; the Director, Office of Management and Budget; and other interested parties. We will also make copies available to others on request.

Should you have any questions concerning this report, please call me at (202) 275-6195. Other major contributors are listed in the appendix.

Sincerely yours,

Mark V. Nadel

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Associate Director for National and
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