United States Senate

COMMITTEE ON FOREIGN RELATIONS
WASHINGTON, DC 20510-6225

May 17, 1989

The Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
441 G Street N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

On Sunday, March 12, the Food and Drug Administration allegedly discovered two grapes contaminated with traces of cyanide which were found among fruit unloaded from the ship ALMERIA STAR at the Port of Philadelphia. This ship had docked on Friday, March 10 and had begun unloading on Saturday, March 11. On Monday, March 13, the Commissioner of the Food and Drug Administration, after consulting with the Secretary of the Department of Health and Human Services and other unknown government officials, ordered a ban on the further importation of Chilean fruit of all kinds and the destruction of Chilean fruit at U.S. wholesale and retail outlets.

The result of this hasty action was severe economic repercussions to at least 68 U.S. direct importers of Chilean fruit, and to thousands of U.S. retailers who had Chilean fruit in stock and on display. It has been estimated that the impact on U.S. businesses amounted to at least $100 million.

However, the impact in Chile was even greater. As a result of this one isolated U.S. government action, 20-25% of the grape crop was destroyed in Chile, either on the vine or in warehouses through overlong storage. Some 20,000 to 100,000 Chilean workers were out of work as a result of this action, with an economic impact of at least $300 million. Since Chile has led the continent in job creation and is the only economy in Latin America that can be considered as truly developing, the economic set-back created by the hasty action of a handful of U.S. government officials will have a great impact upon whether Latin America views the United States as a stable importer.

The development of world markets depends not just upon price, but upon perceptions that the United States will be a long-range stable customer. Thus the sudden embargo on Chilean fruit may well have a long-range impact upon the efforts of the United States to create two-way trade patterns so that we may increase sales of our goods abroad.

Less than a month later, the FDA lifted the ban, and Chilean fruit returned to U.S. stores. The FDA admitted that it had no evidence, other

than the two specimen grapes reported on March 12, to support the contention that Chilean fruit was being poisoned as a threat to U.S. consumers. Yet, the economic damage to the growers, the importers, and the retailers had been done, not to speak of damage to our international trade policy and foreign policy.

In the light of the extensive damage to both countries on the basis of insupportable evidence, a number of fundamental questions have arisen in studies we are doing in the Committee on Foreign Relations. Therefore, I am asking the General Accounting Office to investigate the following fundamental issues:

1. Does the FDA have established procedures to investigate the possibility of contaminated food imported into the United States?

2. Were those procedures followed?

3. Does the FDA have established criteria to govern emergency decisions to embargo food imports?

4. Were those criteria thoroughly considered in the decision to ban Chilean fruit?

5. Did those criteria meet the test of reasonableness?

6. Did those criteria sufficiently balance the possible threat to consumers against the weight of the evidence?

7. Is there any historical precedent for an emergency import embargo so sweeping in its economic impact?

8. Which government officials were involved or consulted in the emergency decision to ban Chilean fruit?

9. Was the evidence of contamination taken in accord with established evidential principles for authentic chain of custody, protection of the integrity of the specimens, and safeguards against mislabeling, substitution, or counterfeiting of specimens?

10. Was the laboratory testing of the specimens in accord with recognized scientific principles of chemical analysis, recording, and replicability of the experiment?

11. Was the sample sufficiently large to reach the scientific and practical conclusions which would require emergency action?

12. Was it technically possible for grapes punctured by a needle, as alleged, to survive 12 to 14 day shipment without dissicating and shriveling?

13. Is the evidence convincing that the two specimens purportedly analyzed were poisoned in the country of shipment rather than after the shipment arrived?

14. What are the cumulative costs to the U.S. economy of the emergency boycott and destruction of stocks on hand?

15. Were any actions taken in this episode which appear to have violated any U.S. statutes or executive regulations?

In order to assist you to answer these questions, I am attaching a series of chronological questions and points of information which are necessary to establish the factual base.

It is important to realize that U.S. importers and wholesalers need to have at least six month's planning time to arrange financing and shipment of next season's imports. Shipping normally begins on December 1. Therefore I ask that you supply an interim report by June 15, and a final report by July 15, so that suitable and timely actions may be considered in the Committee on Foreign Relations.

Sincerely,

Jesse Helms

JESSE HELMS:jl

Attachment: Chronological Questions

QUESTIONS REGARDING THE MARCH 1989 BAN ON CHILEAN FRUIT

The recent government ban over fruit imported from Chile raises fundamental questions for the nation and for the food industry at home and abroad:

1. Did the FDA find any grapes that could be harmful to anybody? Specifically, were the two grapes they identified harmful in any way?
2. Since the FDA itself said that finding the two grapes was akin to finding "a needle in a haystack," how did it discover them amid more than an estimated 1,600,000,000 grapes being unloaded at U.S. ports at the time?
3. Do we have scientific evidence to suggest that grapes can be injected with cyanide or any other liquid?
4. How can the FDA prevent overreaction to hoaxes while also ensuring the safety of our food supply?
5. How much of a loss did the food industry suffer as a result of the FDA action?

Following are more detailed questions:

March 2-5, 1989: According to the United States Embassy in Chile (See Cultural and Press Service, Embassy of the United States of America, Santiago, Chile, "A Chronological Summary of the Threat to Chilean Export Fruit," March 20, 1989) (hereinafter, "U.S. Chronology"), the Embassy received the first anonymous phone call stating that there was poisoned fruit on March 2, 1989. The Embassy considered the call a hoax and did not recommend any preventive measures. On March 4, 1989, however, the FDA suspended importation of Chilean fruit and increased inspection to 10 percent.

Questions:

1. Why did the U.S. Food and Drug Administration (hereinafter, "FDA") take these measures to suspend and increase inspection if the call was deemed a hoax?
2. Why was there no publicity during the period of suspension and increased inspection if there was a real threat?
3. Did the FDA produce any written records or communications in response to the call?
4. Did the FDA receive a transcript or report of the telephone call to the U.S. Embassy in Chile from the Department of State with any sort of advisory?

March 5-6, 1989: On March 5, 1989, the FDA received a report indicating that it was all but impossible to inject

sodium cyanide or other liquids successfully into a ripened grape. On March 6, 1989, the FDA lifted the ban on importation of grapes.

Questions:

1. Did the FDA end the suspension on importation of grapes, in part or in whole, as a result of the March 5, 1989, report?

2. What was the FDA's response to any laboratory reports submitted to it by others?

3. Did the FDA ignore or reject the findings of any report from any source?

March 8, 1989: According to the United States Embassy in Chile (See U.S. Chronology), the Embassy received a second anonymous phone call, and the caller said there was poisoned fruit "which still has not left Chile." The U.S. Embassy in Chile viewed this second call as a probable hoax (See U.S. Chronology). In fact, the Embassy has said that it did not recommend any steps be taken. Furthermore, the U.S. Embassy in Chile denied that the first or second caller specified where the suspect fruit could be found.

Questions:

1. Did the FDA react differently than after the first call? If so, why?

2. More specifically, why did the FDA deem the first

phone call a hoax and not the second?

3. Did the FDA officials produce any written records or communications in response to the call?

4. Did the FDA receive a transcript or report of the second call to the Embassy in Chile from the Department of State with any sort of advisory?

March 11-12, 1989: FDA inspectors began inspecting fruit on March 11, 1989, in Philadelphia.

Questions:

1. If the caller did not suggest the ship, why did the FDA select the Almeria Star for inspection and not the other ships unloading Chilean fruit at East Coast ports after the reported second call?

2. Please describe all information used by the FDA in deciding to inspect the Almeria Star which had left Chile before the first reported call.

3. What procedures were used to inspect the fruit? Specifically:

a. How many pallets of grapes and other fruits were inspected?

b. Were instructions given to take fruit from inside of the pallets?

c. How many pieces of fruit were photographed?

d. How many were sent to labs?

e. How many were tested?

f. What criterion was used to determine if fruit should be tested?

g. How were the records kept?

h. How many inspectors examined fruit?

i. How many hours did the inspectors work?

j. Were the inspectors FDA officials?

k. What training did the inspectors have to inspect fruit?

l. What instructions were the inspectors given by the FDA, i.e., did the FDA tell the inspectors how to examine the fruit or what a contaminated piece of fruit looks like?

m. Was the inspection done on a random sample basis?

n. Were the inspectors told to examine a specific brand of grapes or fruit from a specific grower? If yes, please describe in detail how the FDA determined which specific brands of grapes to inspect.

o. Did the FDA, prior to the inspection of the grapes in Philadelphia, determine what contaminated grapes would look like? If so, who made this determination and by exactly what laboratory tests?

p. When did the FDA officials ascertain what contaminated grapes would look like?

q. was this part of the information shared with the

FDA officials inspecting the fruit?

r. Who discovered the allegedly poisoned grapes?

March 12, 1989: According to the U.S. Embassy in Chile and an FDA press release, FDA inspectors in Philadelphia found traces of cyanide in two grapes.

Questions:

1. Exactly what testing procedures were employed by the FDA to detect the presence of cyanide in the grapes? Specifically:

a. Who conducted the tests?

b. What were the qualifications of the testers?

c. Did the FDA send one grape to Cincinnati for testing and two grapes to Philadelphia? If so, why?

d. Were different tests employed at the two different locations?

e. Were the tests conducted according to established FDA procedures. If yes, what were the procedures and are they published in any document?

f. Were the results recorded in any report or memorandum?

g. Who received the results of the tests?

h. When were the results reported and what was done

with the results?

i. Is it correct that the grape sent to Cincinnati tested negative and the two tested in Philadelphia came out positive?

j. Was there a meeting in Maryland about this time of FDA officials. If so, who attended and what was discussed? Was this when the decision was made to detain all Chilean fruit?

2. Considering the March 5, 1989 report, did the FDA attempt to inject a grape with cyanide to determine if this procedure was even a possibility? If so:

a. Who conducted this test?

b. Were the results recorded in any report or memorandum?

c. Who received the results of this test?

d. Were any outside experts consulted?

3. What assurances were made that the lab tests detecting the cyanide were accurate? Specifically:

a. Were the same tests used in Philadelphia and Cincinnati?

b. What was measure of probable error?

c. Was the degree of probable error considered in the decision made by the FDA to detain all Chilean fruit?

4. FDA representatives said that when one grape with

cyanide was punctured in the laboratory, so much cyanide gas was emitted from it that the lab had to be evacuated.

a. Does the FDA support or deny this statement?

b. How can this statement be true when "the amount of cyanide remaining in the grapes was far below the amount that would sicken even a child?"

c. Please provide the names of those in the laboratory and who was there at the moment of evacuation.

d. For exactly how long did they evacuate the lab?

5. The FDA produced a picture of the suspect grapes with white crystaline rings around puncture holes in apparently healthy grapes with intact skins.

a. Please explain how this was done when laboratory tests show cyanide-injected grapes produce dark circles with lost skin and a shriveled appearance.

b. If one of the three grapes tested negative, why do all three appear alike in the picture?

6. What did the tests ultimately conclude?

March 13, 1989: The FDA issued a press release stating that it had "found and confirmed traces of cyanide in a small sample of seedless red grapes from Chile and, as a result, is detaining all grapes and other fruit from that country and is urging that they be withdrawn from the U.S. market." The press release also stated that the "amount of cyanide

remaining in the grapes was far below the amount that would sicken a child."

Questions:

1. Only two grapes were reported to be contaminated with minute amounts of cyanide by officials who inspected thousands of crates of grapes, nectarines and other Chilean fruit in Philadelphia, as well as thousands of crates in other ports. (See Philadelphia Inquirer, , Thursday, March 16, 1989.) Does the FDA deny this fact?

2. Experts have stated that the grapes were as harmless as water, almonds, beans or bacon which naturally contain similar levels of cyanide. Does the FDA deny this fact?

3. Based on these facts, why did the FDA detain all Chilean fruits entering this country, urging that fruits be removed from stores and homes and causing similar actions to be taken by other nations?

4. Did the FDA consider the following question: If a terrorist seriously intended to poison fruit, why would he try to inject a grape when much larger fruits could be made more deadly?

5. Did the FDA consult the State Department or the National Security Council or any other Federal agency prior to issuing the March 13, 1989 announcement?

a. Did any agency dissent from the FDA's decision

to detain Chilean fruit?

b. If yes, what was the argument?

6. Are there any written records detailing or explaining the FDA's decision to go public with the traces of cyanide and to detain all grapes, including any memorandums, notes or reports?

7. Why did the FDA or State Department send alerts to other countries announcing a threat of contamination?

8. The Food, Drug and Cosmetic Act provides for the FDA to go to court to obtain an injunction against the sale of contaminated food products.

a. Did the FDA do that here? If not, why not?

b. When, why and how does the FDA decide to proceed by press release rather than the statutory procedure?

March 14, 1989: The Bureau of Alcohol, Tobacco and Firearms of the U.S. Department of Treasury (hereinafter "ATF") issued a memorandum to "Chief, Field Operations" stating it was necessary for ATF to sample Chilean wines in response to the FDA action on Chilean grapes.

Questions:

1. Which agency determined that the threat of contamination extended to wine?

2. Why did the Government determine that the threat of contamination extended to bottled wine when the grapes

for wine obviously were picked long before the March 2, 1989, phone call?

3. Was the order to examine wine revoked?

4. If there was an order to revoke, what agency gave the order?

5. What involvement, if any, did the FDA have?

Aftermath of March 13, 1989: According to the Wall Street Journal, (April 14, 1989), under the FDA's oversight an importer-paid force of 450 inspectors in Philadelphia inspected millions of cases of grapes and other fruits.

Questions:

1. After the two (or three) contaminated grapes were discovered, how many inspectors examined fruit and in what locations?

2. How many pallets of grapes and other fruits were inspected?

3. Was this done randomly?

4. What training did the inspectors have?

5. What instructions were given by the FDA?

6. Were the FDA inspectors employees of the FDA or new hires?

7. If newly hired, what hiring criteria was used by the FDA?

8. Why did the FDA assign so many inspectors in

Philadelphia?

9. Why not other locations?

10. How much did this cost?