

ANALYSIS OF FDA ACTION ON CHILEAN GRAPES IN MARCH

11TH, 1989

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FOOD REGULATION IN THE UNITED STATES

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INTRODUCTION

Since the colonial era, the United States has been concerned about quality and safety of imported food. Federal activity regulated imported foods, even before that the first federal food law for domestic product was enacted by Congress. There are several examples of laws enacted by congress to prevent importation of adulterated food in XIX century. When Congress enacted the Federal Food Drug and Cosmetic Act (FDCA), it established that imported products must meet the same standards as the food that is produced domestically. Some incidents with intentional contamination of food and specially imported food were the precedent for The Bioterrorism Act.

This paper will analyze the tampering episode of Chilean grapes that occurred in March 1989, which took place after an anonymous caller to the United State (U.S.) the embassy in Chile announced that fruit headed to the U.S. had been injected with cyanide.¹ The objective is to determine if the actions taken by federal agency Food Drug Administration (FDA) were discriminatory against Chilean product according to the law, in this particular case, by reviewing roll of agencies involved, FDA's procedures, comparing FDA's decisions taken during the crisis with similar incidents, results of Chilean fruit industry legal and diplomatic actions and at the end a final analysis about

¹ Knight Ridder financial news, January 4th 1996, available at <http://volokh.com/sasha/grapes.html> (Last visit November 23, 2008).

Chilean and FDA's position in this conflict.

I. ROLL OF AGENCIES INVOLVED

Different agencies enforce legal regulations for imported food. FDA regulates the importation of most foods and is primary responsible on making sure the imported products are safe before enters in the country. This section identifies the agencies that took part on the Chilean grapes operative, roll they played and finally analyses legal fundamentals of FDA's actions during the ban over Chilean grapes.

A. Agencies Involved

There were three agencies involved in handling this case. All of them have interacted in a coordinate manner to enforce regulations in this tampering episode. How did they coordinate? And in what way were they involved during this event? The objective is to describe their interaction and responsibility during this case.

In March 8th, a second anonymous threat claiming that, Chilean fruit shipped to United States had been poisoned put in alert the Department of State. They notified the Bureau of Customs and Border Protection (CBP or "Customs"), which in turn notified FDA. ²

The Department of State is the Cabinet-level foreign affairs agency of the United States governments. The Department of State was involved through the embassy in Chile that was the one who received the call threat. The Bureau of Customs and Border Protection (CBP or "Customs") and the

² U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 2-3 (September 6, 1990).

FDA agree in a Memorandum of understanding to help enforce Section 801 of the Food, Drug and Cosmetic Act. Customs holds imported food from commerce until release by FDA.³ Once the Chilean fruit was refused in admission Customs supervised the destruction of the product.⁴ FDA was the agency that enforces food safety regulations for import foods.

B. Legal fundamentals for FDA actions

This section will analyze FDA's legal function and respond in this case to determine if action was according legal frame.

FDA has been delegated responsibility from Secretary of Health and Human Services for examination of foods, drugs, cosmetics, and medical devices offered for entry into the United States.⁵ Federal Drug and Cosmetic Act (FD&C) established imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions. Moreover, if import product appears from the examination to be adulterated then such article shall be refused admission.⁶ In addition, the courts give FDA broad discretion in measurement of defects in imported foods.⁷ In this case upon finding Chilean two grapes with small amount of cyanide, FDA denied entry to the ship's fruit. Also, FDA is authorized under §705 (b) to disseminate information regarding food,

³ FDA, Memorandum of Understanding with Customs Service, MOU 225-79-40 03, available at <http://www.fda.gov/oc/mous/domestic/225-79-4003.html> (Last visit November 29, 2008).

⁴ FD&C Act section 801

⁵ *Id.*

⁶ *Id.*

⁷ *Caribbean Produce Exchange, Inc. v. Secretary of Health and Human Services*, 893 F.2d 3 (1st Cir. 1989).

drugs, devices, or cosmetics in situations involving, in the opinion of the FDA, imminent danger to health or gross deception of the consumer.⁸ Therefore, FDA's actions were consistent with its legal authority.

II. FDA'S PROCEDURES DURING THE CHILEAN GRAPES CASE

The Chilean grapes tampering incident was surrounded by controversy. Chilean fruit industry had questioned FDA's procedures during the tampering episode. To better understand how FDA handled this situation the next analysis will describe the general procedure for inspection on imports, the measures taken by FDA in this case and the arguments arose by Chilean fruit representatives to object these measures.

A. FDA procedures for import products

As a regular procedure for import products FDA has to rely on inspections at the U.S ports of entry. FDA decision on whether to collect a sample based on the nature of the product, FDA priorities and history of the commodity. Generally samples are less than one percent, but it has been cases where FDA has increases the amount of sample if product is suspected to be adulterated or misbranded. If the product is consider to be adulterated or misbranded FDA may refuse entry of the product after paperwork inspection and physical examination. The FDA district office will then issue a "Notice of FDA Action", which identifies the nature of the violation. Products non-conforming with FDA requirements have to be re-exported or destroyed.

B. Procedures and measures taken with Chilean fruit

FDA put in place an operative that led to increase inspections on Chilean fruit in all port across United State. A number of samples that contain suspicious-looking

⁸ FDAC section 705; 21 U.S.C. Section 375.

fruit from a ship docked in Philadelphia were tested in two different laboratories. Out of all samples two grapes tested positive for cyanide.⁹ FDA used cyanosmo test and chloramines-T test.¹⁰ The last method was modified based on FDA's experience with cyanide that had been placed in other food products.¹¹ After FDA found contaminated grapes the ban was imposed even though government officials agreed the amount of cyanide found in the two grapes was virtually harmless.¹² The General Accounting Office (GAO) report determined FDA consulted with officials from several federal agencies, the Chilean government, and the Chilean fruit industry about the tampering incident and actions needed to protect public health.¹³ On March 14th, 1989, The New York Times and nation wide press published breaking news about FDA urging consumers not to eat fruit from Chile after traces of cyanide were found in two grapes at the Port of Philadelphia.¹⁴ The agency's action removed a large portion of the fruit from supermarket shelves throughout the country.¹⁵ On March 16, FDA said in a prepared statement "Fruit is being held and refrigerated at the dock until the findings and the entire situation can be

⁹ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 12 (September 6, 1990).

¹⁰ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 7 (September 6, 1990).

¹¹ *Id.*

¹² FindArticles.com, Sen. Helms calls Chilean grape scare "fishy". October 19, 2008, available at http://findarticles.com/p/articles/mi_m3289/is_n1_v159/ai_8856725/pg_1?tag=artBody;col1 (Last visit November 23, 2008).

¹³ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 6 (September 6, 1990).

¹⁴ The New York Times. "US Urge consumers not to eat fruit from Chile", March 14, 1989, available at <http://query.nytimes.com/gst/fullpage.html?sec=health&res=950DEFDD143EF937A25750C0A96F948260> (Last visit November 23, 2008).

¹⁵ *Id.*

evaluated”.¹⁶ The end of the ban happened on March 18, 1989, a new press release announcing that FDA would allow most Chilean fruit to return to American grocery shelves over the next five to nine days.¹⁷

C. Controversy for FDA measures

Although it was short, the ban’s impact on the Chilean economy was widespread and the Chilean Congress confirmed exporters’ estimates that private-sector losses reached some US\$330 million.¹⁸

After the suspension of Chilean fruit imports, controversy arose over FDA’s handling of the situation.¹⁹ Chilean authorities disagreed with the FDA’s measures they considered disproportionate.²⁰

John Ziolkowski, a trade specialist for Republican members of the Senate Agricultural committee said “Clearly a lot of mistakes were made,” and then he adds “How were these grapes selected among the millions coming from Chile”.²¹ Senator

¹⁶ The New York Times. “CHILE ENVOY IN U.S. ON TAINTED FRUIT”, March 16, 1989, available at

<http://query.nytimes.com/gst/fullpage.html?res=950DE1DC1F3BF935A25750C0A96F948260&sec=&spon=&pagewanted=1> (Last visit November 23, 2008).

¹⁷ The New York Times. “US will permit fruit from Chile to enter the market”, March 18, 1989 <http://query.nytimes.com/gst/fullpage.html?res=950DEFDF1630F93BA25750C0A96F948260&sec=health&spon=&pagewanted=1>

¹⁸ Eduardo Engel M.R.A Engel, *Poisoned Grapes, Mad Cows and Protectionism*, w6959 National Bureau of Economics Research (NBER), Rev.5, (1999).

¹⁹ U.S. General Accounting Office (GAO), *FDA’s Actions on Chilean Fruit Based on Sound Evidence*, 6 (September 6, 1990).

²⁰ Eduardo Engel M.R.A Engel, *Poisoned Grapes, Mad Cows and Protectionism*, w6959 National Bureau of Economics Research (NBER), Rev.5, (1999).

²¹ FindArticles.com, Sen. Helms calls Chilean grape scare “fishy”. October 19, 2008, available at http://findarticles.com/p/articles/mi_m3289/is_n1_v159/ai_8856725/pg_1?tag=artBody;coll (Last visit November 23, 2008).

Helms and Rep. Leon Panetta asked the GAO to investigate.²² Initially Chileans agreed on an examination plan operated under FDA supervision to examine five percent of all Chilean fruit.²³ However, Chilean authorities alleged FDA rushed to declare the ban based in inaccurate and contradictory technical evidence.²⁴ Also, some representatives of Chilean fruit industry suggested this was a plot to place financial pressure on the Pinochet regime¹⁹. They pointed FDA's procedure reveal over sampling grower "Julia Saavedra", where the two contaminated grapes came from, who had just 26 pallets out of 4045 pallets in the ship.²⁵ This fact it would suggest in their opinion FDA had prior information about where to look for the poisoned grapes.²⁶ Other allegations were improperly conducting its laboratory test and mishandling fruit samples.²⁷ Chilean fruit industry sponsored experiments to replicate the tampering event conducted by the UC Davis. The results showed probability of the product to be contaminated in Chile was almost inexistent because the cyanide high volatility. One of the researchers at UC Davis have said that the result obtained by FDA lab was most likely by contamination in the lab with reactive used to calibrate the test. In August, 1990 Chilean Senator Romero also exposed the theory that two grapes were contaminated at the FDA laboratory either by

²² *Id.*

²³ *Id.*

²⁴ Sergio Romero, Senator, Chilean Senate, Senatorial ordinary sessions "Grapes supposedly poisoned. Discriminatory measures against Chilean fruit agree by USA senate" (August 8, 1990) (Transcript available at http://www.senado.cl/prontus_senado/site/extra/sesiones/pags/pags/diar/21071106190926.html)

²⁵ FindArticles.com, Sen. Helms calls Chilean grape scare "fishy". October 19, 2008, available at http://findarticles.com/p/articles/mi_m3289/is_n1_v159/ai_8856725/pg_1?tag=artBody;col1 (Last visit November 23, 2008).

²⁶ *Id.*

²⁷ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound

accident or intentionally.²⁸ Nevertheless, the GAO report did not mention anything about the fact that the sample was completely destroyed during the FDA's lab testing process so there was no sample left to allow a third part re-testing. In addition, even the FDA's officials recognized to be lack of experience in this kind of issues in fruit. When the two berries of grapes were found the FDA's officials described this fruit as a suspicious because it was turgid and it had a white ring around it, but it is a fact cyanide injection would produce dehydration and a black ring instead. Fred L. Fricke, which was part of the FDA Forensic Chemistry Center in Cincinnati had said about this episode "we had very little knowledge about what effect the cyanide would have on fruit".²⁹

III. COMPARING FDA'S MEASURES IN SIMILAR INCIDENTS

One last allegation done by the Chilean senate was that FDA's actions were not consistent with actions taken in similar incidents such as Tylenol (1982), Lip-Ton Cup-a-Soup (1986) and Yogurt Breyer (1989).³⁰ However, the Tylenol tampering mentioned derived in Congress passed the Federal Anti Tampering Act of 1983.³¹ The Act gave FDA

Evidence, 6 (September 6, 1990).

²⁸ Sergio Romero, Senator, Chilean Senate, Senatorial ordinary sessions "Grapes supposedly poisoned. Discriminatory measures against Chilean fruit agree by USA senate" (August 8, 1990)(Transcript available at http://www.senado.cl/prontus_senado/site/extra/sesiones/pags/pags/diar/21071106190926.html)

²⁹ U.S Food and Drug Administration, FDA's Forensic Center, Speedy, Sophisticated Sleuthing, July –August, 1995, available at http://www.fda.gov/Fdac/695_toc.html (Last visited November 23, 2008).

³⁰ Sergio Romero, Senator, Chilean Senate, Senatorial ordinary sessions "Grapes supposedly poisoned. Discriminatory measures against Chilean fruit agree by USA senate" (August 8, 1990)(Transcript available at http://www.senado.cl/prontus_senado/site/extra/sesiones/pags/pags/diar/21071106190926.html)

³¹ The Federal Anti Tampering Act of 1983, Pub. L. No. 98-127, 97 Stat. 831 (1983) (codified at 18 U.S.C. § 1365 (2003)).

more power to act over tampering incidents.³² In the other two cases, there were some differences that would explain the reaction of FDA. First, no telephone threats were received in those tampering incidents and it was only after the victims felt sick or died that tampering was discovered. The other difference was that the products were manufactured in United States. Both companies affected by tampering voluntarily removed their products during the FDA investigations. On the other hand FDA investigated about 3800 tampering threats, between 1984 and 1989.³³ FDA's actions were consistent with at least two similar cases, one involved tea on 1985 and the second incident in 1978 when by terrorist actions a shipment of Israeli oranges was found to contain mercury.³⁴ Also, FD&C Act standard for domestic goods establish that domestic goods can not be condemned unless they actually are shown to be adulterated or misbranded while for imports denial product just need to appear to be adulterated or misbranded.³⁵ 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.³⁶ Finally, Bush administration had been largely criticized because lack of reaction in the Pam Am attack. Dr. Young acknowledged that a recent terrorist event where a bomb blew up a Pam Am flight in December 1988, after a phone threat had influenced his decision.³⁷

³² *Id.*

³³ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 9 (September 6, 1990).

³⁴ *Id.*

³⁵ FDCA section 801; 21 U.S.C section 381

³⁶ U.S. General Accounting Office (GAO), FDA's Actions on Chilean Fruit Based on Sound Evidence, 19-20 (September 6, 1990).

³⁷ Eduardo Engel M.R.A Engel, Poisoned Grapes, Mad Cows and Protectionism, w6959 National

IV. CHILEAN LEGAL AND DIPLOMATIC ACTIONS AGAINST FDA'S MEASURES

Since the beginning of the ban Chilean government and Chilean fruit industry tried to obtain a reversal of the measures. Chilean government sent an official delegation to set up negotiations at the highest level in the US, looking for a diplomatic solution.³⁸ In addition, in 1991 President Aylwin's government together with exporters launched separate administrative and legal actions against FDA.³⁹ However, after unfavorable results by the legal way they insisted in a diplomatic solution. The Chilean arguments to support legal actions and the FDA defense, as well as Chilean diplomatic actions are going to be described here.

A. Chilean legal actions

Based on this evidence, Chilean fruit industry decided on February 28th 1991, to take legal actions against FDA for material damages resulting from US' measures.⁴⁰ The basic law that allowed them to sue the government is called the Federal Tort Claims Act (FTCA).⁴¹ Under FTCA before taking an agency to court, the claimer must exhaust all possible administrative remedies. In this case this case means to file a claim with the FDA. The Chileans had to file 2400 individual claims, but FDA denied all 2400.⁴² At this

Bureau of Economics Research (NBER), Rev.6, (1999).

³⁸ Eduardo Engel M.R.A Engel, Poisoned Grapes, Mad Cows and Protectionism, w6959 National Bureau of Economics Research (NBER), Rev.4(1999).

³⁹ Eduardo Engel M.R.A Engel, Poisoned Grapes, Mad Cows and Protectionism, w6959 National Bureau of Economics Research (NBER), Rev.8 (1999).

⁴⁰ Eduardo Engel M.R.A Engel, Poisoned Grapes, Mad Cows and Protectionism, w6959 National Bureau of Economics Research (NBER), Rev.7 (1999).

⁴¹ Knight Ridder financial news, January 4th 1996, available at <http://volokh.com/sasha/grapes.html> (Last visit November 23, 2008).

⁴² *Id.*

point Chileans were able to file a suit in Federal court.⁴³ The FDA's defense was that the case should not go to court because of "discretionary function exemption" (DFE).⁴⁴ DFE retains sovereign immunity for the United States when a federal employee acts "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty."⁴⁵ The Chileans appealed it all the way to the Supreme Court and after six years of litigation the court finally declined to hear the appeal of the 2400 Chilean fruit growers.⁴⁶

B. Chilean diplomatic actions

Also, in a parallel effort Chilean president invited its counter part to use the 1914 Bryan-Suarez Mujica Treaty, to resolve their differences.⁴⁷ US Government rejected Chilean request, suggesting the creation of a bi-national working group.⁴⁸ The Chilean Government accepted this proposal, with negotiations culminating, in February 1994, in the proposal of several tariff compensations to favor Chilean exports.⁴⁹

FINAL ANALYSIS

Although, the regulatory system has worked in this case to enforce the law and to protect consumers there are still arguments that can be discussed in favor and against of the FDA's actions. The following analysis it will be focus in two main points: the facts that supported Chilean claim against FDA's procedure and the second point is the legal

⁴³ *Id*

⁴⁴ *Id*.

⁴⁵ 28 U.S.C § 2672

⁴⁶ Knight Ridder financial news, January 4th 1996, available at <http://volokh.com/sasha/grapes.html> (Last visit November 23, 2008).

⁴⁷ Eduardo Engel M.R.A Engel, Poisoned Grapes, Mad Cows and Protectionism, w6959 National Bureau of Economics Research (NBER), Rev.7 (1999).

⁴⁸ *Id*.

support to the FDA's measures.

Representatives of Chilean fruit industry have considered the fact that FDA avoided legal battle as indirect recognition of irregularities and negligence committed. Despite the GAO report which had validated FDA's procedure there were still many unsolved questions. Chilean claim was based in several facts such as is statistically unlikely to find two grapes contaminated out of millions of boxes. Also the box that contained the contaminated grapes did not have any other contaminated berry inside. In addition, if in fact the fruit was contaminated in Chile how cyanide, which is a highly volatile substance under these conditions, could remain in such a high concentration after two weeks traveling from Chile? A lot of research has been done after this incident about cyanide contamination in fruit and even though when there is some chance for fruit of retaining some of the poison under very special temperature conditions, package, etc it looks almost impossible. Therefore, the thesis of an accidental contamination inside of the laboratory would be the most probable way to explain the levels of poison founded for FDA's lab. However, unfortunately the experience shows that law and agency's procedures are been perfected after incidents like this or like the Tylenol tampering had happened.

FDA has in this case the law on its side. It is the author's point of view that in this case Chilean fruit industry or any other exporter country in a similar situation has very little chance to success in the legal arena. By FDA invoking DFE allowed it to reject legal proceedings. However, even if this case goes to trial judges defer to it most of the time. Also, as it has been exposed during this paper, FDA still would be backed up by the law

⁴⁹ *Id.*

because it has a wide set of legal tools to enforce regulation for import products if the imported product is suspected to be adulterated. Therefore, under this legal frame it should be most likely for the FDA to choose the cost associated with a ban rather than the cost of getting a possible adulterated imported product in the market.

CONCLUSION

Based on its finding, FDA acted within its legal authority to suspend imports of Chilean fruit. However, considering the law does not established maximum levels parameters to deem a product as adulterated product and FDA has broad discretion to interpret the law this actions could be successfully used as a “protectionism measures”. Therefore, mechanism and agency’s procedures to avoid unnecessary economic impact in international trade should be considered in cases like bioterrorism threats.