AD-A167 412 IMPORTED WINES: IDENTIFYING AND REMOVING WINES CONTAMINATED WITH DIETHYLENE GLYCOL(U) GENERAL ACCOUNTING OFFICE WASHINGTON DC RESOURCES COMMUNITY A..
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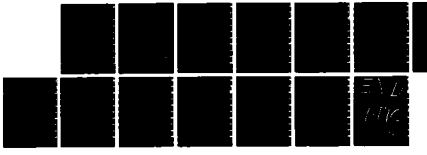

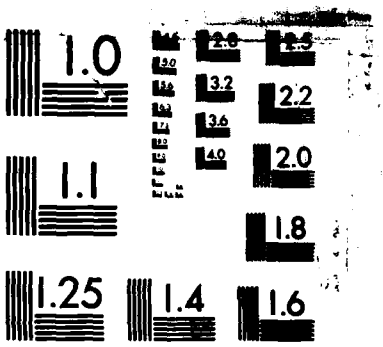

MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS 1963-A

United States General Accounting Office

GAO

Report to the Honorable Frank Horton
House of Representatives

March 1986

IMPORTED WINES

Identifying and Removing Wines Contaminated With Diethylene Glycol

GAO/RCED-86-112

GAO

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

Resources, Community, and
Economic Development Division
B-222128

March 4, 1986

The Honorable Frank Horton
House of Representatives

Dear Mr. Horton:

Pertains to a General Accounting Office (GAO) review of

This report is in response to your October 30, 1985, request that we review federal agency actions in dealing with the contamination of imported wines with the industrial chemical diethylene glycol (DEG), particularly Austrian wines where the contamination was the more significant. As agreed with your office, this report provides a description of problems with wines contaminated with DEG; a discussion of the jurisdictional responsibilities of the Department of Treasury's Bureau of Alcohol, Tobacco, and Firearms (BATF) and the Department of Health and Human Services' Food and Drug Administration (FDA); and a discussion of BATF actions in directing the testing and removal of contaminated wines from the market.

To address these areas we obtained information from FDA and BATF as well as the U.S. Customs Service. We interviewed various officials at these three agencies located in headquarters, laboratories, and regional offices. In addition, we reviewed available pertinent documents to obtain factual evidence of actions taken. (A more detailed discussion of our objective, scope, and methodology is provided in appendix I.)

After learning of the possible contamination of Austrian, West German, and Italian wines with DEG—used as a sweetening agent—BATF began testing selected wines for DEG's presence. As of December 3, 1985, BATF testing found 81 different brands of contaminated wines and directed the importer of record to halt all sales of these wines. In an effort to augment its own testing, BATF also directed importers and wholesalers to test all Austrian wines under their control and halt all sales of such wines until testing showed them to be free of DEG. BATF did not require this testing from importers and wholesalers of West German and Italian wines because of the effort that would be required to test the large volume of wines imported from these countries and indications that DEG levels were significantly lower than that found in Austrian wines.

BATF's efforts to verify importers' actions in testing and removing contaminated wines from the market were limited. Also, BATF did not pursue efforts to identify either all the Austrian wines being marketed

in the United States or those importers and wholesalers involved in marketing those wines. As a result, the extent to which all wines were tested and all contaminated wines were removed from the market cannot be determined.

BATF did not determine the amount of DEG that would pose a significant health risk nor was such a determination made by FDA. Lacking such a determination as well as the assurance that all contaminated wines were removed from the market, the adequacy of BATF's actions in protecting the public from unreasonable health risks is uncertain.

Background

Wines containing DEG came to the attention of U.S. authorities through an article in The Washington Post on July 12, 1985, describing West Germany's detection of contaminated Austrian wines. Within a week the Canadian Food and Drug Administration notified BATF that it had tested and found some contaminated Austrian wines. The Austrian government was initially unable to determine if contaminated wines had been exported to the United States. On July 18, 1985, BATF initiated a testing program to try to identify which contaminated wines had entered the U.S. market. Subsequently, BATF received information from the governments of West Germany, the United Kingdom, and Canada that DEG was found in some West German and Italian wines. As a result BATF began testing these wines for DEG.

U.S. authorities were concerned about the contamination of these wines because of the toxicity of DEG and the large volumes of imported wines shipped to the United States each year. BATF statistics show the following 1984 annual U.S. import volumes for still (nonsparkling) wines: Austria, 174,000 gallons; West Germany, 16 million gallons; Italy, 63 million gallons. These statistics show that of the top 25 countries, Italy is ranked first, West Germany third, and Austria 16th on the basis of volume.

The Contamination of Imported Wines With DEG

DEG has reportedly been used by Austrian winemakers as a sweetening agent since as early as 1979. Austrian wines are graded by sweetness and are generally more expensive than most wines. The most intensely sweet wines are made from grapes that are left on the vine long after the regular harvest. These grapes must be picked individually and fermented with great care. The resulting wine is less common and more expensive than similar wines from the same vineyard. Some Austrian producers allegedly added DEG to their wines to rid themselves of the

risk and expense associated with producing very sweet wines. How DEG got into Italian and German wines is uncertain.

Discovery and Action by the Austrian Government

The contamination of Austrian wines with DEG had come to the attention of Austrian authorities by April 1985. Austrian tax auditors suspected DEG use from information provided on producers' expense receipts. The Austrian Ministry of Agriculture was subsequently notified, and the testing of the wines by the Austrian government was initiated on a limited basis. Because Austria sent about 65 percent of its total wine exports in 1984 to West Germany, the Austrian authorities notified the West German government about this situation on April 24, 1985.

The Austrian government has since taken actions to increase the safety of its wines. According to the Austrian Embassy, about 50 members of companies that produce, bottle, and export these contaminated wines as well as some wine growers, consultants, and wholesalers were jailed. The trials of these defendants began in October 1985. By November the Austrian *Parliament* passed a new wine law specifying new production, export, and labeling requirements. This new wine law specifies that all exported Austrian wine must receive a certificate indicating that it was tested for DEG.

What Is DEG?

DEG, discovered in 1859, has been commercially available for industrial applications since 1928. DEG is a colorless, nonvolatile liquid having a sweet taste. It is used as a plasticizer, lubricating agent, and solvent for resins, gums, dyes, and oils. DEG is effective for softening and controlling the moisture content of tobacco, cork, glue, paper, and sponges. It is also used as a conditioning agent and lubricant for cotton and wool fibers. In addition, DEG is a component and solvent in antifreeze and some automotive brake fluids.

Toxicity and Health Risk Associated With DEG Consumption

DEG is a highly toxic substance. In 1937 a pharmaceutical preparation containing 72 percent DEG caused more than 100 deaths across the United States. After 2 to 5 days of consuming this "elixir," patients complained of nausea with vomiting, intense gastrointestinal cramping and diarrhea, and back pain. These symptoms were followed by progressive liver and kidney damage, and death. The major cause of death was kidney failure. However, no sickness or death worldwide has yet been reported from drinking wines contaminated with DEG.

On the basis of the 1937 episode, researchers have concluded that the toxic effects of DEG in humans varies with the age, weight, and especially the health of an individual. According to a 1979 FDA toxicology abstract, large doses of DEG can be fatal to humans. The study also indicates that repeated doses of DEG over time can have a cumulative effect, and may produce kidney and liver damage.

Various toxicology evaluations have addressed the DEG doses that may be fatal to humans and the range of DEG doses that may have cumulative effects. These evaluations indicate that consuming DEG could pose harmful effects to humans either as a single dose or by repeated doses over a period of time.

A 1965 study[1] published in the Archives of Environmental Health stated that on the basis of the elixir episode a fatal dose of DEG is about 1 milliliter per kilogram of body weight. That is, the fatal dose for a person weighing 60 kilograms (about 132 lbs.) is approximately 60 milliliters (about 57 grams or about 2.0 ounces). (Note: a gram is about 0.035 ounces and a kilogram is about 2.2 pounds.) However, a July 1985 internal evaluation of DEG prepared by FDA's Division of Toxicology states that based on the elixir episode some fatalities occurred with the consumption of as little as 25 milliliters (about 24 grams, or a little less than 1 ounce). Press articles have reported that the Austrian Ministry of Health has stated that the consumption of 14 grams could be lethal to someone in poor health.

FDA also considered the cumulative effect of DEG and extrapolated its toxicity to a 60 kilogram (about 132 pound) person. The July 1985 study determined that crystals and stones may begin to form in the kidneys from 6 to 12 grams (about 0.2 to 0.4 ounces) of DEG per day. According to the author of this evaluation, a person in poor health could develop these symptons after several days of ingesting DEG at these doses.

Regulatory Jurisdiction of Federal Agencies

FDA and BATF both have authority to regulate against the presence of DEG in imported wines. FDA may prohibit the marketing of contaminated wine under authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). BATF may regulate against the marketing of the mislabeled imported wines under authority of the Federal Alcohol Administration

[1]"Urinary Bladder Response to Diethylene Glycol," Archives of Environmental Health, vol. II, October 1965.

Act (FAA Act). BATF also has authority to regulate imported wines under certain sections of the Internal Revenue Code of 1954.

The FFDCA, enacted in 1938, is primarily concerned with the protection of consumers from unsafe food and other products. The act prohibits adulterated or misbranded food or drink products, including alcoholic beverages, and their components from being imported or introduced into interstate commerce. Adulterated foods are defined as foods that contain a harmful or poisonous substance that can make it injurious to health; misbranded foods are defined as foods that are labeled in a false or misleading fashion. FDA is authorized to seize food products, detain imported food products and secure injunctions against the importation of contaminated shipments to protect the consumer from harmful food products. Criminal penalties may be invoked against firms or individuals for violating the FFDCA's provisions.

The FAA Act, enacted in 1935, is primarily concerned with protecting the consumer from improperly labeled alcoholic beverages. In this case, while the FAA Act is not aimed at controlling health risks, BATF has used its labeling authority to prohibit the marketing of alcoholic beverages that are mislabeled by virtue of being contaminated and therefore pose a health risk. The act gives the Secretary of the Treasury, as delegated to the Director of the BATF, the authority to (1) specify what ingredients are allowed in alcoholic beverages, including wines (for imported wines this would occur as part of the label approval process) and (2) regulate their labeling and advertising. This authority is directed at providing the consumer with adequate information concerning the identity and quality of alcoholic products.

Under the act, importers and wholesalers of alcoholic beverages in interstate or foreign commerce must (1) obtain a basic operating permit, (2) obtain a certificate of label approval from BATF, and (3) bottle, package, and label such alcoholic beverages in conformity with BATF regulations. BATF has promulgated regulations covering various aspects of labeling wines including such factors as packaging, bottling, and classifying the wine. The FAA Act authorizes BATF to require such reports as are necessary to carry out its powers and duties under the act. Also, under its regulations, BATF may request that it be provided with a full and accurate statement of the contents of wine containers to assure that the wine is properly labeled.

BATF takes the position that it has the authority to seize and cause the forfeiture of mislabeled imported wines under a provision of the

Internal Revenue Code of 1954 that makes it unlawful to possess or use any property in violation of the internal revenue laws or regulations under such laws. BATF's regulations pertaining to the importation of alcoholic beverages require imported wines to be packaged, marked, branded, and labeled in conformity with the FAA Act. These regulations were promulgated under a general rulemaking provision of the Internal Revenue Code. Accordingly, BATF maintains that imported wines that are labeled in violation of the FAA Act are also in violation of the internal revenue laws or regulations and subject to seizure and forfeiture.

Both FDA and BATF have regulatory authority over the presence of DEG in wines. FDA's authority arises from the FFDCA's prohibition of the entry of food or beverages contaminated with harmful substances into the U.S. market. DEG, a toxic substance, would be such a contaminant. The BATF's authority in this instance arises from its authority over mislabeled imported alcoholic beverages. Wines containing DEG that have not been classified and labeled "imitation" have been mislabeled in violation of BATF regulations.[2]

Extent to Which BATF and FDA Test Wines for Contaminants

Neither BATF nor FDA routinely test wine for the presence of contaminants. BATF normally samples alcoholic beverages to determine ingredient levels and to verify the accuracy of the labeling. These tests cannot determine the presence of contaminants, such as DEG, since its detection requires a specific test that BATF normally does not use. Although FDA tests samples of domestic and imported food products for pesticide residues, FDA does not usually test imported alcoholic beverages for contaminants, such as DEG. Since the discovery of DEG in Austrian wines, BATF started testing for the presence of DEG as part of its regular sampling program.

According to BATF officials, since 1982 they have been testing 500 samples of alcoholic beverages each year (100 samples from each of 5 metropolitan areas). In each metropolitan area, 20 samples are selected from 5 retail outlets. Most of the samples tested in each area are wines. All samples are tested to verify their alcohol content and total volume level. Additional tests are conducted on samples depending on the type of alcoholic product. For example, additional tests on wines may include

[2]While both the FFDCA and FAA Act contain labeling provisions, BATF and FDA follow a federal court ruling that BATF has exclusive jurisdiction, rather than concurrent jurisdiction with the FDA, to regulate the labeling of alcoholic beverages. Although alcoholic beverages are not subject to the labeling provisions of the FFDCA, they are subject to FDA regulation under the adulteration provisions. (Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976).)

verifying potassium, carbon dioxide, sulfur dioxide, and sodium levels. These tests determine the fermentation level and spoilage but do not detect the presence of contaminants. DEG testing was added to the program in July 1985.

FDA has instituted programs to monitor domestic and imported food products for pesticide residues. According to FDA headquarter's documents, FDA collects and analyzes about 5,000 imported commodity samples yearly to identify pesticide residues on the commodity as it enters U.S. commerce. Although FDA does not normally test imported wines for the presence of contaminants, FDA inspectors at its regional offices may at their own discretion test food and drink samples to address a particular concern. For example, in 1985 some domestic wines were tested by its regional laboratories for the presence of sulfite used as preservatives. According to FDA laboratory directors, no imported wines have been tested for contaminants during the past several years.

BATF Actions to Identify DEG Contaminated Wines

On July 18, 1985, BATF initiated a DEG testing effort because it decided that it could conduct the testing more quickly than FDA. Since BATF issues the permits to importers that are required for importing alcoholic beverages into the United States, its files have the names and addresses of wine importers and the wines they are authorized to import into the United States. According to BATF, DEG is not a BATF approved ingredient, and wines containing DEG are in violation of the labeling provisions of the FAA Act. (See pp. 4 to 6.) BATF informed FDA officials that it had developed a testing strategy for detecting Austrian wines contaminated with DEG. According to FDA officials, FDA concurred with BATF's decision and deferred to BATF on the testing of wines for DEG.

Identifying Contaminated Austrian Wines

There are about 1,800 different Austrian wines approved by BATF for importation into the United States, and BATF officials estimate that about one-half of these (about 900) are still actively being imported. BATF adopted a dual approach for addressing the problem of contaminated Austrian wines in the U.S. market. One approach was used for those wines entering the U.S. market after July 18, 1985, and another for those imported into the United States before July 18, 1985.

The first approach dealt with Austrian wines arriving after BATF initiated its DEG testing effort on July 18, 1985. BATF asked the U.S. Customs Service to hold all shipments of Austrian wine entering after July 18, 1985, until testing conducted at BATF laboratories could determine if the

samples were free of DEG. U.S. Customs and BATF inspectors located throughout the nation's ports of entry drew samples from each detained shipment, and submitted them to BATF laboratories for testing. BATF directed U.S. Customs to refuse entry to wines that were found to contain DEG. BATF officials told us new shipments of Austrian wine were still being detained and tested for DEG as of February 21, 1986.

BATF's other approach for addressing the possible entry of contaminated wines in the United States market dealt with wines imported into the United States before July 18, 1985. BATF requested that wholesalers and importers of Austrian wine have private laboratories test samples of all Austrian wine that they imported prior to July 18, 1985, and that were still under their control, to determine if they are free of DEG.

Importer and Wholesaler Testing of Austrian Wines

BATF officials told us that importers and wholesalers were notified of the need to test their Austrian wines for DEG. The notification was by telephone, by memorandum, or in some cases, both. BATF provided its five regional offices (located in Chicago, New York City, Atlanta, Dallas, and San Francisco) with a sample memorandum for contacting wholesalers and importers about the potential contamination of Austrian wines. This memorandum indicated that importers and wholesalers engaging in any transactions with contaminated Austrian wines, after notification of the problem and without having them tested, would be deemed to be in willful violation with the conditions (which include compliance with the FAA Act's labeling provisions) of the basic permit required for importing alcoholic beverages into the United States. As a result, their FAA permit might be suspended or revoked. BATF directed the importers and wholesalers to submit all results of DEG testing conducted by private laboratories to BATF headquarters. In addition, they were directed to notify BATF headquarters immediately if an Austrian wine sample was found to be contaminated with DEG and to forward these samples for BATF retesting and confirmation.

To ensure that all importers and wholesalers of Austrian wines were notified, BATF chose to notify all importers and wholesalers granted BATF operating permits for importing and wholesaling imported alcoholic beverages. BATF officials said they made an initial attempt to identify all importers and wholesalers that handle Austrian wines and which wines they handled but did not pursue these efforts because BATF decided that

it would involve extensive time and effort. Therefore, BATF has not identified those importers and wholesalers that could possibly have Austrian wines in their inventories and would be subject to the testing requirement.

BATF estimated that there may be more than 500 different importers that have been granted certificates of approval for Austrian wines. In addition, BATF officials indicated that an unknown number of wholesalers (believed to be many more than the number of importers) handle Austrian wines. BATF officials informed us that they had received results on private laboratory testing from 26 different importers or wholesalers covering 330 wine samples (not necessarily 330 different wines because the same wine may be sampled by different importers, wholesalers, and BATF).

By requiring importers and wholesalers to have samples of all Austrian wines under their control tested for DEG by private laboratories and by conducting its own tests of all Austrian wines entering the United States after July 18, 1985, BATF made an effort to have all Austrian wines tested for DEG that are currently being marketed in the United States. The extent to which BATF was successful in getting all Austrian wines tested for DEG is unknown because BATF did not identify which importers and wholesalers sold and distributed Austrian wines, nor did it identify which Austrian wines were currently being marketed in the United States. As a result, BATF lacked the information necessary to (1) effectively monitor and review the actions of the importers and wholesalers in complying with the testing requirement and (2) determine the extent to which Austrian wines currently marketed in the United States were in fact tested.

BATF Testing of Austrian Wines

In addition to testing by importers and wholesalers, BATF tested samples of Austrian wines in its own laboratories. The samples tested by BATF included wines detained by Customs, samples of wine collected from retail outlets by BATF personnel, and samples of wines sent to BATF by wine dealers and consumers. The wines selected for testing by BATF personnel included suspected brands and others judgmentally selected by BATF personnel. Suspected brands included brand names similar to those previously found to be contaminated as well as other brands imported from these producers.

BATF uses two types of tests to detect the presence of DEG in the wine samples: gas chromatography and mass spectrometry. Gas chromatography is used as a screening test for determining if a substance may contain DEG. Samples found to contain possible traces of DEG by this test are retested by a mass spectrometer. This test provides confirmation of DEG's presence by comparing suspected traces of DEG with a pure form of DEG. According to BATF laboratory staff, while gas chromatography serves as a rapid screening tool, mass spectrometry is more reliable for identifying and measuring the amounts of DEG.

BATF's testing was done at its laboratories located in San Francisco, California, and Rockville, Maryland. Because the San Francisco laboratory does not have a mass spectrometer, its testing was limited to the gas chromatograph test and served as an initial screen to identify wines suspected of containing DEG. These suspected wines were then retested by the Rockville laboratory using the mass spectrometer to confirm the presence of DEG and measure its concentration.

BATF tested 364 samples of Austrian wine. However, the number of Austrian wines represented by these samples could be considerably less because duplicate samples of some wines were tested by BATF. BATF found that 86 of the Austrian wine samples contained DEG and that these 86 samples represented 54 different wines indicating a duplication rate of about 37 percent (32 out of 86).

Identifying Contaminated German and Italian Wines

After BATF initiated the testing of Austrian wines, it learned that some West German and Italian wines might also contain DEG. This resulted from information received from the governments of West Germany, the United Kingdom, and Canada. This information led BATF to begin testing some West German and Italian wines for DEG in August 1985.

BATF's approach for the German and Italian wines was different from its approach for identifying contaminated Austrian wines. Unlike the Austrian wines, the German and Italian wines were not stopped at ports of entry by the U.S. Customs Service nor tested for DEG by BATF prior to Customs' release. In addition, BATF did not request importers and wholesalers of German and Italian wines to have private laboratories test their wines.

According to BATF officials, the testing of West German and Italian wines was limited because of the effort that would be required to test the large

volumes of these wines (1984 import volumes: Austrian, 174,000 gallons; West German, 16 million gallons; and Italian, 63 million gallons). Another factor influencing this decision was the information from the British, Canadian, and German governments indicating that the DEG levels found in these wines were significantly lower than that found in Austrian wines.

Testing of West German and Italian wines was limited to the testing of selected brands by BATF. These brands included some suspected brands and others judgmentally selected by BATF personnel. The suspected Italian brands included those identified by the British and Canadian governments. Suspected German brands included those wines from the same producers or regions of Germany where the German government found DEG. Because of the manner in which samples were selected, the testing results cannot be projected to all imported German and Italian wines.

Results of BATF Testing for DEG in Wines

BATF laboratory documents indicate that 1,167 foreign wine samples were tested for DEG through December 3, 1985. The samples tested are comprised of 364 Austrian; 438 German; 298 Italian; and 67 other countries including Hungary, France, Yugoslavia, Rumania, Spain, Australia, Greece, and Switzerland. In addition, BATF tested 224 samples of domestic wines. The number of specific brands tested is unknown due to duplicate samples taken from different sources. For example, a total of 127 contaminated samples involved only 81 different brands identified as contaminated with DEG by BATF; a duplication rate of 36 percent.

DEG was found only in Austrian, West German, and Italian wines. The 81 different imported wines contaminated with DEG consisted of 54 Austrian, 20 Italian, and 7 German.

Varying amounts of DEG have been found in wine imports by the BATF testing program. The DEG found in the Austrian wines ranged from 0.1 to 19.66 grams per liter, and about two-thirds had DEG levels over 1 gram per liter. (Note: a gram is about 0.035 ounces.) Three of the 54 contaminated Austrian wines contained between 10 and 20 grams per liter.

The contaminated West German and Italian wine samples had much lower DEG levels. The seven contaminated German wines contain DEG levels ranging from 0.005 to 0.1 grams per liter. The 20 contaminated

Italian wines contain DEG levels ranging from 0.009 to 0.06 grams per liter.

Table 1 presents summary information on the 81 contaminated wines and the amount of the DEG found, with references to associated toxicity.

Table 1:DEG Levels in Contaminated Wines

	Number of contaminated wines		
DEG ranges	**Austrian**	**German**	**Italian**
Less than 1 gram per liter	17	7	20
1 gram to 6 grams	30	0	0
6 grams to 12 grams[a]	3	0	0
Over 12 grams per liter[b]	2	0	0
DEG levels not specified[c]	2	0	0
Total	**54**	**7**	**20**

[a]A July 1985 FDA Division of Toxicology DEG evaluation determined that crystals and stones may begin to form in the kidneys through the repeated ingestion of 6 to 12 grams per day.

[b]A July 1985 FDA Division of Toxicology DEG evaluation based on the elixir episode states that some fatalities were observed with DEG levels as low as about 24 grams. In addition, press articles have reported that the Austrian Ministry of Health has stated that the consumption of 14 grams could be lethal to someone in poor health.

[c]DEG levels for 2 of the 54 Austrian wines were not identified in the records provided to us.

Between December 4, 1985, and January 31, 1986, BATF tested an additional 286 wine samples for DEG and found 4 additional contaminated Italian wines with DEG amounts ranging from 0.003 to 0.029 grams per liter.

BATF Actions to Get Contaminated Wines Removed From the Market

BATF relied on the importers and wholesalers to remove contaminated wines from the market. They did not routinely observe or review importers and wholesalers' action in doing so. Consequently, BATF does not know the extent to which wines contaminated with DEG were removed from the market.

BATF is authorized to halt sales of any wines containing DEG and, according to the Deputy Director of BATF, it is their policy to halt all sales of wines that its testing has found to contain DEG regardless of the amount of DEG found. BATF officials told us that when BATF's laboratory determined that a wine contained DEG, the importer of record was contacted by telephone, told of the contamination and directed to halt all sales of the contaminated wine by the importer, its wholesalers and retailers.

BATF did not generally observe the actions of the importer or subsequently review importers' actions to verify that the contaminated wine had been removed from the market. And BATF did not require the importer to report to BATF on its actions to remove the contaminated wines. For the most part, BATF officials told us that their follow-up is limited to having its inspectors spot-check the wines on the retailers' shelves to see if any of the contaminated wines are still being sold. There are approximately 350 BATF inspectors and more than 300,000 retail outlets nationwide, according to BATF officials.

In addition to notifying the importer of record, BATF also issued 14 press releases between July 18, 1985, and January 8, 1986, to inform the public of the wines found to contain DEG. In addition, BATF established a DEG task force in August 1985 to deal with the numerous information requests that BATF was receiving from concerned consumers, press, importers, wholesalers, and retailers.

Conclusions

BATF did little to verify that importers tested wines and removed contaminated wines from the market as BATF required. Instead, BATF relied on the voluntary cooperation of importers and wholesalers to comply with these BATF requirements. Because of this limited verification and the fact that BATF did not pursue efforts to identify which Austrian wines were being marketed in the United States and which importers and wholesalers were involved in marketing the wines, the extent to which all Austrian wines were tested and all contaminated wines were removed from the market cannot be determined. We believe that the way BATF dealt with DEG in wines does not provide a high degree of confidence that all DEG contaminated wines were identified and removed from the market.

In its decisions on the extent of effort required to identify and assure removal from the marketplace of DEG contaminated wines, BATF did not consider the important distinction between removing wines that are simply mislabeled and removing wines that are not only mislabeled but also pose a significant risk to health. If DEG contamination was strictly a question of an unapproved substance being present that did not involve any health risks, the consequences of not finding and removing the wines are not as critical as they would be if the unapproved substance also represented a potential health risk. Since DEG is toxic its presence in wines could represent a health risk in addition to causing the wine to be

legally mislabeled and nonmarketable. Therefore, we believe that government efforts to find and remove DEG contaminated wines need to provide an appropriate degree of assurance that wines with DEG in amounts representing a significant risk to health are identified and removed from the market. BATF did not conduct a risk assessment or seek an assessment from FDA to determine what amount of DEG in wine would represent a significant risk to health. In the absence of such a health assessment, BATF actions do not provide a high degree of assurance that wines contaminated with DEG in amounts posing a significant risk to health were identified and removed from the market.

Recommendations

We recommend to the Secretary of Treasury that the Director of the Bureau of Alcohol, Tobacco, and Firearms be directed to consult with the Commissioner of the Food and Drug Administration to determine whether the actions taken by BATF in sampling, testing, and having wines contaminated with the industrial chemical diethylene glycol removed from the marketplace were adequate to protect the public health and safety and to take whatever action is warranted as a result of these consultations. We further recommend that the results of such consultation be used to develop appropriate policies and procedures for working with FDA regarding any future contamination of alcoholic beverages.

In addition, we recommend that the Director of the Bureau of Alcohol, Tobacco, and Firearms report to the appropriate oversight committees as well as to the House Government Operations Committee on the results of these consultations and any actions taken.

The views of responsible agency officials were sought during our work and are incorporated as appropriate. As agreed with your office, we did not ask BATF or FDA to review and comment officially on a draft of this report. As discussed with your office, unless you publicly announce its

contents earlier, we plan no further distribution of this report until 30 days after issuance. At that time we will send copies to the Director of BATF and the Commissioner of FDA and other interested parties and will make copies available to others upon request.

Sincerely yours,

J. Dexter Peach
Director

Appendix I

Objectives, Scope, and Methodology

Our objective is to provide Representative Frank Horton with a report on the contamination of imported wines by the chemical DEG, which includes a description of the problem with DEG contaminated wines, a discussion of the jurisdictional responsibilities of BATF and FDA, and a discussion of BATF actions in directing the testing and removal of contaminated wines from the market. We agreed that we would concentrate our work on Austrian wines since they contain the highest level of DEG. After several briefings with Mr. Horton's office, we agreed to provide a report based on the work we had done through January 31, 1986, in these five areas.

To answer these questions, we obtained pertinent documents from BATF and FDA. We obtained all available documents from BATF in order to analyze its testing program. Numerous gaps and inconsistencies in BATF's recordkeeping prevented us from fully verifying many BATF actions. We also obtained specific information from FDA on the toxicity of DEG. Finally, we considered other applicable documentation as well as the appropriate laws and regulations.

To obtain the views of BATF, we interviewed 14 officials representing 7 offices: the Office of the Director, Office of the Director for Compliance Operations, Office of the Chief Counsel, Industry Compliance Division, BATF National Laboratory, and two regional offices. We interviewed five FDA officials representing five offices: the Division of Regulatory Guidance, Division of Chemical Technology, Division of Toxicology, and two regional laboratories. We also talked with officials at the U.S. Customs Service and the Department of Agriculture in order to obtain additional information. We interviewed three officials in the Technical Services Division at the U.S. Customs Service. At the Department of Agriculture, we interviewed four officials: two officials in each of its Foreign Agricultural Service and Agricultural Research Service. In addition to these 26 key officials, we also contacted the Embassies of Austria and Italy to obtain their views on their governments' actions. We did not review the annual sampling program of alcoholic beverages by BATF or FDA. Therefore, we are not in a position to comment on the scope or methodology of either of these efforts nor of the statistical projectability of any findings resulting from these efforts.

We discussed the matters contained in the report with responsible BATF and FDA officials and their comments are incorporated as appropriate. However, we did not obtain the views of these officials on our conclusions and recommendations, nor did we request official BATF or FDA comments on a draft of this report. With this exception, our review was

performed in accordance with generally accepted government audit standards. Our work was conducted from November 1985 through January 1986.

END

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