PROTECTING THE PUBLIC: Increased Benefits Possible From ATF's Alcohol And Tobacco Laboratories

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Office of Inspector General

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Contents

Audit Report 2

Results in Brief 2

Background 3

Findings and Recommendations 6

Beverage Alcohol Test Results Not Always Used 6
Recommendation 16

Formula Approval Process For Non-Beverage Alcohol And Specially Denatured Alcohol Results In Few Rejections 17
Recommendation 23

Appendices

Appendix 1: Objectives, Scope, and Methodology 25
Appendix 2: Management Comments 27
Appendix 3: Major Contributors To This Report 31
Appendix 4: Report Distribution 32

Abbreviations

ATF	Bureau of Alcohol, Tobacco and Firearms
CFR	Code of Federal Regulations
COLA	Certificate of Label Approval
FDA	Food and Drug Administration
FEMA	Flavor and Extract Manufacturers Association
FY	Fiscal Year
NBA	Non-Beverage Alcohol
NLC	National Laboratory Center
NRC	National Revenue Center
OIG	Office of Inspector General
SDA	Specially Denatured Alcohol

September 14, 2001

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The Bureau of Alcohol, Tobacco and Firearms' (ATF) Alcohol and Tobacco Laboratory tests thousands of products annually for compliance with labeling requirements, tax classification, and unauthorized substances or contaminants. In addition, the laboratory reviews and approves formulas for non-beverage products.

This audit evolved from an audit in our *Office of Audit Annual Plan for Fiscal Year 2000* on ATF laboratories[1]. Our objective in this audit was to determine how effectively the laboratory has been contributing to ATF's alcohol programs. To conduct our review, we visited the laboratory, sampled test results for several programs, reviewed files, and interviewed responsible officials. Our review covered activity during the period Fiscal Years (FY) 1998 through 1999.

Results in Brief

ATF's Alcohol and Tobacco Laboratory generally provided timely and responsive service for the period of activity we reviewed. Nonetheless, the laboratory appeared to provide a significant number of test results to ATF program managers that were often not used. For example, we found that no follow-up occurred for 278 violations identified by the laboratory in testing of 1,097 samples selected in FYs 1998-1999 under the Beverage Sampling Program. We found similar lack of follow-up for violations identified from product samples through

[1] Our ATF laboratories audit was divided into two, one on ATF's Forensic Science Laboratory (the subject of a separate, earlier report titled *CRIMINAL ENFORCEMENT: ATF Forensic Science Laboratories Need To Improve Workload Management*, OIG-01-068, 4/30/01) and the second on the Alcohol and Tobacco Laboratory.

compliance inspections and the Certificate of Label Approval (COLA) program's pre-import sampling.

We also found that the laboratory's review of all non-beverage alcohol (NBA) and specially denatured alcohol (SDA) formulas did not appear necessary to achieve the same benefits. While ATF is currently required by its own regulations to review formulas, we found that the laboratory reviewed 7,377 formulas during FY 1999, yet rejected only 211. Further, a significant portion of these formulas result in the production of small quantities of alcohol products with relatively small excise tax impact. For example, 473 companies submitted 2,594 returns to ATF for excise tax refund in FY 1999 totaling $292 million, an average of about $113,000 per claim. However, we reviewed a summary listing of these tax returns for FY 1999 and found that 63 entities, or 13 percent, involved annual returns of less than $5,000.

We recommended that ATF conduct a cost-benefit assessment of its laboratory testing of beverage alcohol products, particularly when the test results are often not used by program officials. We also recommended that ATF continue to examine the formula approval process to determine whether the process can be less burdensome on both the manufacturer and ATF, while not reducing the risk of using non-beverage alcohol for beverage purposes.

ATF management concurred with our findings and recommendations except for our recommendation for an overall assessment of laboratory testing. Instead, ATF proposed alternative actions designed to make more effective use of the laboratory tests. Such actions include finalizing guidelines for beverage sampling, monitoring test results on compliance inspections, and modifying procedures on pre-import sampling. These actions when fully implemented should generally satisfy our recommendations. ATF's response to our draft report is provided as Appendix 2.

Background

The Alcohol and Tobacco Laboratory conducts testing of alcohol and tobacco products. In FY 1998, the laboratory analyzed 7,432 alcohol and tobacco samples. Beverage and non-beverage alcohol products were analyzed to ensure that marketed products were in compliance

with Federal regulations. Beverage alcohol products included distilled spirits, wine and malt beverages. NBA products include food, flavorings, medicinals, toiletries, industrial solvents and fuels.

Beverage Alcohol Testing

ATF inspectors collect samples of beverage alcohol products at both the producer and retail levels. Samples are obtained from domestic manufacturers during compliance inspections and obtained at the retail level through the Beverage Sampling Program. ATF inspectors forward the samples to the ATF Alcohol and Tobacco Laboratory for testing. The laboratory has two branches, one located in Rockville, MD, and the other in Walnut Creek, CA. The results of beverage sample tests are sent to the Market Compliance Branch, which initiates follow-up actions when violations are found. The results of a compliance inspection test are returned to the field inspector who sent the samples to the laboratory.

When violations are found, follow-up actions can range from a letter to the importer or manufacturer explaining the results of the tests and need for corrective action, to having ATF field personnel obtain additional samples to determine how prevalent the problem may be in the product tested. If similar violations are found from testing of follow-up samples, ATF may conduct an investigation to determine the cause of the problem resulting in the product's non-compliance or contamination.

ATF conducts routine tests on all samples and, in addition, performs certain product-specific tests. All submitted samples are examined for fill and proof; undergo a routine battery of tests for contaminants ------ ---------- ---------- ---------- ----- --------; and are evaluated by visual examination for suspended particulate matter and/or any other contaminant. In addition, specific types of products are examined for other contaminants, ---------- ------- ---------- --------- ---------- ---------

Non-Beverage Alcohol Testing

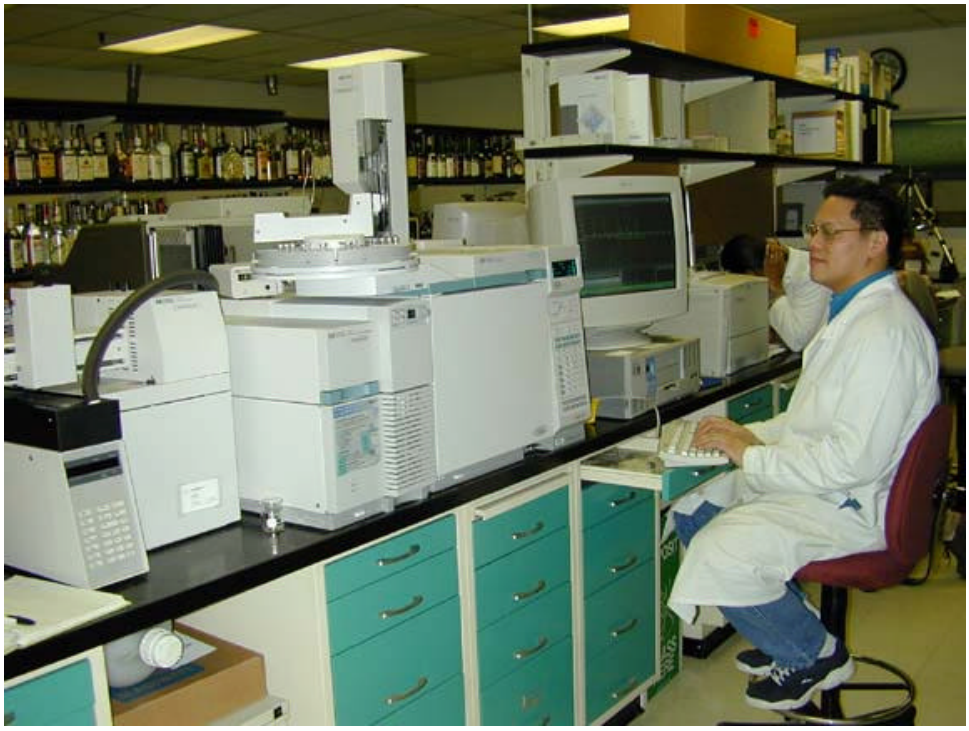
The Alcohol and Tobacco Laboratory has a non-beverage section which is responsible for approving formulas for non-beverage and specially denatured products. Federal regulations (27 CFR, Parts 17

and 20) require manufacturers to file formulas with the ATF's laboratory. Every year, the laboratory receives thousands of formulas for review. In FY 1999, the laboratory received 7,377 formulas. Laboratory personnel review the formulas to ensure the products could not be consumed as beverages, and meet both Federal and non-Federal standards for product safety and effectiveness.

When manufacturers purchase the alcohol for their non-beverage products, they pay excise tax to the alcohol producer. Companies who used taxpaid alcohol to make medicines, foods and flavorings are eligible for a refund. In FY 1999, ATF authorized the refund of $290 million in Federal excise taxes to manufacturers. To qualify for a refund (also known as drawback of the tax), these products must be unfit for beverage use. The laboratory personnel examine formulas and analyze product samples to ensure the product contains the stated amount of alcohol and can not be used as a beverage. Unfit for beverage use is determined by a laboratory panel which conducts organoleptic (taste) tests.

No excise tax is assessed on an SDA formula when it is used in processes or articles from which potable alcohol cannot be recovered. Companies must obtain approval for their particular use of SDA prior to manufacturing.

Figure 1. ATF Technician Conducting Laboratory Tests



Source: ATF National Laboratory

Findings and Recommendations

Finding 1 Beverage Alcohol Test Results Not Always Used

We reviewed laboratory test results for beverage alcohol samples selected for testing under several ATF programs during FYs 1998-1999. These samples were tested for alcohol proof level, product fill level, prohibited ingredients, contaminants, and the like. This testing often resulted in the laboratory identifying product violations. Despite these results, which were often provided timely, program managers appeared to make very limited use of the results.

Specifically, we found that:

- No follow-up was conducted on 278 violations found through laboratory testing of 1,097 products for the Beverage Sampling Program.

- Violations from samples submitted by inspectors following compliance, product integrity, and drawback inspections were not always communicated to the companies by the inspectors. In addition, corrective actions were not always recommended and follow-up not performed.

- Violations found by the laboratory in samples taken from pre-import sampling under the COLA program generally resulted in ATF only issuing warning letters to the manufacturers and producers. After issuing these letters, ATF did not take any follow-up action to ensure the violations were corrected.

We attribute the conditions above to two factors. First, ATF lacks clear guidelines about how the results should be used. ATF program managers appear to have a large amount of discretion regarding the use of these test results. Second, the program managers may not have considered the violations significant enough to warrant follow-up. If that was the case, it may indicate that certain laboratory tests have provided limited benefit to the alcohol programs. Accordingly, we believe ATF should assess the costs and benefits of performing these tests, and consider being more selective in requesting laboratory services under these programs.

Laboratory Test Results Are Often Provided Timely

We assessed the timeliness of the laboratory in providing tests results to four of ATF's alcohol integrity programs or activities. These programs or activities included the Beverage Sampling Program, compliance inspections, pre-import sampling under COLA, and consumer complaints. Our assessment focused only on timeliness in providing test results to the program staff, as we were not able to evaluate the quality of laboratory services.

The laboratory's goal is to provide test results within 30 days to requesting officials for the Beverage Sampling Program. We believe the 30 days represents a reasonable time period for providing test results. We found that 53 of 85 samples reviewed by the laboratory, or 62 percent, were analyzed and results returned within 20 days. The remaining test results were provided between 21 and 40 days following the request for services. The table below shows the results of our analysis.

Table 1. Number Of Days For Laboratory To Provide Results Of Beverage Alcohol Testing

PROGRAM	No. of Samples Reviewed	Results in 20 Days or less	Results in 21 to 40 Days	Results in 41 to 60 Days
Beverage Sampling	20	0	20	0
Compliance Inspections	16	16	0	0
Pre-Import	39	29	10	0
Consumer Complaints	10	8	2	0
TOTAL	85	53	32	0

No Follow-Up Testing Done For The Beverage Sampling Program

Under the Beverage Sampling Program, ATF inspectors collect samples of alcoholic beverage products from retailers in various cities and forward the samples to the ATF laboratory in both Rockville, MD, and Walnut Creek, CA, for testing. The products are tested for alcoholic content, fill, and the presence of possible contaminants and/or prohibited ingredients.

We reviewed laboratory data developed from the testing of these products and found that, during 1998 and 1999, ATF laboratories tested 428 and 669 products, respectively, or 1,097 total products. The laboratories reported 278 violations from this testing. However, no follow-up actions were taken based on these findings. According to program officials at the time of our review, they were in the process of issuing requests to the field inspectors to follow-up on the violations. But the letters had not yet been issued at that time, some 10 months after the FY 1998 violations were reported to ATF's Product Compliance Branch[2], which oversees the program.

In 1999[3], 88 percent of the violations identified were for incorrect proof or product fill discrepancies. As we had reported in a separate audit

[2] The Product Compliance Branch no longer exists. The responsibilities have been taken over by the Market Compliance Branch.
[3] This data was for calendar year 1999.

report in FY 2000,[4] follow-up procedures were not clear and, in terms of follow-up sampling, needed to be more legally sound to impose sanctions.

Follow-up actions could range from a letter to the importer or manufacturer explaining the results of the tests and need for corrective action, to having ATF field personnel obtain additional samples to determine how prevalent the problem may be in the product tested. If similar violations were found from testing of the follow-up samples, ATF could conduct an investigation to determine the cause of the problem resulting in the product's non-compliance or contamination.

We selected 12 samples from FY 1998 to assess the follow-up actions performed. The 12 samples contained 8 proof violations, 1 fill violation and 3 labeling violations. According to the Chief, Market Compliance Branch, who is responsible for the program, no follow-up letters were issued requesting field inspectors to obtain additional samples. She indicated that the letters were written but had not been mailed.

An ATF Specialist indicated that the program was not properly administered during the last 2 years. The Chief, Market Compliance Branch stated that new procedures had been developed for the program and ATF intended to improve the program's follow-up process.

ATF Did Not Always Ensure Violations Found In Inspection Samples Were Corrected

When violations were found from samples obtained during inspections, ATF did not always ensure that companies were notified or that effective corrective action was conducted or even proposed.

We obtained laboratory test result data for the months of May 1998 and March 1999 from the Walnut Creek Laboratory. We selected for review a group of samples submitted from 10 inspections. The laboratory had identified violations from these tested samples. The 10 violations included 8 for proof, 1 for fill, and 1 for mislabeling due to excessive sugar. The inspections were conducted for compliance,

[4] *Increased Benefits Possible From The Bureau Of Alcohol, Tobacco And Firearms Beverage Sampling Program*, OIG-00-110, 7/17/00.

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product integrity, and drawback. We contacted the ATF inspectors who submitted the samples and inquired whether the inspectors had: (1) contacted the companies about the violations; (2) proposed corrective actions; and/or (3) performed any follow-up to see if the corrective actions were completed.

Companies Not Always Notified

We found no evidence that ATF notified the companies for 4 of the 10 cases. For these four cases, we found the following:

- In two cases, ATF personnel did not notify the company because they did not know the test results were in the file until they received a call from the auditors. One ATF inspector stated that he was not aware the test results were issued to him. He said that he must have been on another assignment when the results were returned. The results were issued approximately 12 months earlier. The other inspector was in a new job and could not remember. She suggested that we contact her old office. We contacted the Acting Supervisor who stated that the results must have "…fallen through the cracks."
- In another two cases, the ATF inspectors were uncertain whether the company was ever notified of the violations; however, there was nothing in the files to indicate notification had occurred.

Corrective Actions Often Not Proposed Or Taken

For the 10 violations, we found that ATF had proposed corrective actions for only 5. ATF did not propose corrective actions for 5 violations, including one that ATF considered a state issue.

No follow-up occurred for any of the 10 cases we reviewed. As explanation for why corrective action or follow-up did not always occur, we obtained the following information regarding several of the above violations:

- One ATF supervisor, at the time of our audit, indicated that often the inspection reports were completed before the samples were returned from the laboratory. She was not aware that the report had to be held up until the results were issued. For example, in one instance the report was reviewed and signed off on

May 19, 1998, and the laboratory results were issued on May 27, 1998. When we called in February 2000 to further inquire about laboratory results and follow-up, the inspector said he could find nothing in the file about the laboratory tests.

- Another inspector said that the violation was not a California violation and could not be enforced through Federal regulations. The product was an over-filled malt beverage. According to Federal regulations, 27 Code of Federal Regulations (CFR), Part 7, Subpart C, section 7.20 (a), labeling requirements for malt beverages contained in this subpart only apply to the extent that state law imposes similar requirements with respect to the labeling of malt beverages. Since California does not have a law similar to the Federal law regarding mislabeling due to improper fill levels, she stated that ATF could not enforce the provision that applies to misstatements.

- In another instance, the ATF inspector obtained a sample during a drawback inspection, and the test result indicated the sample was under-proof. When a drawback is processed for a product that is under-proof, the claimant receives more of a refund than deserved. The ATF inspector informed the claimant by telephone that the claimant needed to adjust the next refund claim. However, no follow-up was conducted to ensure the adjustment was made.

- A sample obtained from a product integrity inspection conducted at a winery indicated that the product had a problem with alcohol content. The additional alcohol placed the product in a higher tax classification. The inspector recommended the company adjust its next tax return. However, we reviewed the next tax return submitted to the National Revenue Center and found that the company continued to use the lower tax rate.

The following table summarizes the actions and follow-up for the 10 samples.

Table 2. Proposed Corrective Action And Follow-Up For Sampled Violations

Inspection Type	Violation Type	Company Informed of Violation	Proposed Corrective Action	Follow-up Performed
Uncertain	Over proof[5]	Uncertain	No record in file	None
Compliance	Over fill	Yes-closing conference	None Needed-no state law	None Needed
Product Integrity	Over proof	Yes-phone	Adjust next claim	None
Drawback	Over proof	Yes-however, sample inadequate-no more product left	Take sample at next inspection	None
Uncertain	Over proof	Uncertain	None	None
Drawback	Under proof	Yes-phone	Adjust next claim	None
Product Integrity	Total acid and residual sugar	Yes-Closing Conference	Winery perform additional testing	None
Mini-Product integrity	Under proof	Yes-phone	Vineyard decided to destroy product	None
Mini-product integrity	Under proof	No	None	None
Product Integrity	Over proof	No	None	None

Pre-Import Violations Often Resulted In Little Action

ATF often tests imported alcoholic products before they are allowed entry into the U.S. marketplace. Testing of products submitted for pre-import analysis is usually conducted under the COLA program.

During FYs 1997 and 1998, this pre-import testing resulted in identification of 649 violations. The violations largely involved proof and fill levels. Of the violations identified during that 2-year period, 242 violations (37.3 percent) were for over-proof and 241 violations (37.1 percent) were for under-proof. About 15 percent of the violations involved fill level. The remainder generally involved prohibited ingredients, limited ingredients, or label errors.

[5] When alcohol content violations were found, we used terms such as “over proof” and “under proof” to further clarify the type of alcohol violation.

Following the testing of these products, ATF issued warning letters to importers, directing the importers to provide these cautions to the manufacturers. Little additional follow-up occurred.

Pre-Imports Tested Under Label Program

ATF requires certain imported alcoholic beverages—rum, vodka, gin, brandy, non-grape wine, and specialty products—to undergo a laboratory analysis by ATF's National Laboratory Center (NLC) in Rockville, MD, prior to the submission of an application for a COLA. All labels on alcoholic beverages need ATF approval. Samples must be accompanied by a method of manufacture and a list of every ingredient used in the manufacture of the alcoholic beverage. The products are tested for proof, fill, labeling, limited and prohibited ingredients, contaminants, and other requirements. The purpose of the tests is to ensure the products are properly classified for tax purposes and safe for human consumption. Upon completion of the analysis, a pre-import letter, which provides the proper class and type designation for the product is issued to the importer or to the importer's designated representative. A copy of the pre-import letter is also submitted to ATF with the COLA application.[6]

The section chief for the Beverage Section in the Rockville laboratory estimated that about half of the laboratory staff's time was devoted to pre-import approval. In 1999[7], the Rockville laboratory tested 911 samples of alcoholic products, of which 533, or 59 percent, were for pre-import approval. The laboratory conducted a battery of tests on each of the imports. The tests varied depending on whether the product was wine, distilled spirits, or a malt beverage. Although the tests were different, we noted the laboratory performed from 15 to 18 tests on each product. The section chief was unable to provide data on the cost of the various tests; however, he estimated that the labor involved in analyzing each sample was at least 3 hours.

We reviewed violations found during testing of imports prior to ATF's label approval, and noted that most of the violations were for proof or fill, and generally only resulted in letters to the importers suggesting that they warn the producers of the violations.

[6] See OIG report *Improvements Needed In the Bureau Of Alcohol, Tobacco And Firearms' Administration Of The Certificate Of Label Approval Program*, OIG-01-066, 4/25/01.
[7] This data was for calendar year 1999.

Types of Pre-Import Violations

The table below summarizes the violations from pre-import testing identified during the period FYs 1997-1998.

Table 3. Pre-Import Sample Violations (FYs 1997-1998)

	PRE-IMPORT VIOLATIONS			
Reason For Rejection	**FY 1997**	**FY 1998**	**Totals**	**Percentage**
Overproof	138	104	242	37
Underproof	122	119	241	37
Overfill	5	1	6	1
Underfill	19	18	37	6
Labeling	9	7	16	2
Limited Ingredients	8	5	13	2
Prohibited Ingredients	24	7	31	5
Contaminants	1	0	1	0
Non-standard Fill	30	27	57	9
Headspace	4	1	5	1
Totals	360	289	649	100

Source: Chief, Alcohol and Tobacco Laboratory

Warning Letter Often Resulted From Pre-Import Testing

To determine what ATF program personnel were doing with the violation data, we selected 40 pre-import approval samples for which the laboratory had found a violation. Of the 40 violations, we noted that 28 were for proof; 6 were for improper classification[8], and, 2 were for health issues. We found that, following the testing, ATF issued letters to the importers with a warning. The warning told the importers to caution the producers that the alcoholic/net content of the product must be exactly as stated on the label. ATF officials stated that, had the violations involved health issues, program personnel would not have approved the products for importation.

[8] For example, if the vodka was diluted, then the label must state the classification as diluted vodka.

Prior to FY 1998, ATF also included follow-up of these products in the following year's testing. In FY 1997, ATF directed field inspectors to include products found to have violations during pre-import testing in their FY 1998's sample selection for the Beverage Sampling Program. However, ATF did not continue this practice in FYs 1998 or 1999.

We believe that without information to indicate problems may exist, it may not be necessary for ATF to randomly conduct a wide range of tests to determine a product's correct classification and safety for human consumption. In fact, health issues, such as prohibited or limited ingredients, were generally not found in testing we reviewed but from reviewing the method of manufacturing.

For example, one violation we observed involved the use of prohibited ingredients in a product. The product included two dyes, E122 (carmoisine, red) and E151 (brown), that are not permitted in the U.S. However, these dyes were not identified through laboratory testing; in fact, no laboratory analyses were even performed. The correspondence suggested that the product contained these dyes. On a second health issue violation, the product contained an ingredient not suitable for use in alcohol beverages; but again, no laboratory testing was needed to determine that this was a health issue.

Lack Of Clear Guidance

ATF programs lack clear guidelines about how laboratory test results should be used. Generally, the programs require samples to be submitted to the laboratory for proof, fill, contaminant, and other testing, but do not offer guidance on what to do with the results. For example, we could not find procedures for what type of actions should be initiated when over-proof violations occur. When follow-up samples are requested, it is not clear how many samples should be obtained from a particular product batch.

However, ATF program managers also have discretion about the action they take following the laboratory violation reports. Should they determine that the results are not significant enough for follow-up action, they are at liberty of limiting the follow-up. For example, because 88 percent of the violations in 1999 found in testing products under the Beverage Sampling Program were for *only* proof or fill discrepancies, rather than product contamination, managers may have considered follow-up unnecessary. If that is the reason why action is

not taken for a large proportion of program test results, ATF may need to assess whether all of these laboratory tests make sense considering the lack of more serious violations in recent years.

Recommendation

1. The Director of ATF should conduct an overall assessment of its laboratory testing of alcoholic beverages. The assessment should include a determination of the costs and benefits of the various tests. Based on this assessment, the Director should determine whether to continue or modify the nature and level of testing.

   Management Comment. ATF does not believe an overall assessment of its laboratory testing is necessary. Instead, ATF has developed actions for the three areas discussed in our report. For the Beverage Sampling program, ATF has set a target of January 1, 2001, for consolidating and finalizing all guidelines. Additionally, the Market Compliance Branch will have all sample results in process acted on by October 1, 2001. All future laboratory results will be acted on within 15 calendar days.

   Concerning samples submitted during inspections, ATF is developing a process for independent monitoring of test results by the Market Compliance Branch. The process identifies *timely* as notification to Field Operations by the Market Compliance Branch within 15 days of receiving a laboratory report. Field Operations will have 60 days to secure additional samples and 90 days to initiate an investigation as requested by Market Compliance Branch.

   For pre-import testing, ATF will modify its procedures as follows: (1) products found out of tolerance on fill or alcohol will be identified in notices sent to the field division where the importer is located, with a request for an inspection/sampling to be conducted 3 to 6 months after COLA approval; and (2) products that were resubmitted after being found to contain prohibited ingredients will be referred for inspection/sampling that will be conducted 3 to 6 months after COLA approval.

   OIG Comment. Although ATF did not agree to conduct an overall assessment of its laboratory testing of alcoholic beverages, the actions initiated and proposed should ensure better use of the

laboratory results. This action meets the intent of our recommendation. We consider this recommendation to have a managerial decision with a projected final action of January 1, 2002.

Finding 2 Formula Approval Process For Non-Beverage Alcohol And Specially Denatured Alcohol Results In Few Rejections

To protect excise tax revenue and consumers, ATF's Alcohol and Tobacco Laboratory reviews formulas used by manufacturers for non-beverage products[9]. The laboratory's review and testing is intended to ensure that the products are indeed unfit for beverage use. Although filing of formulas is not required by statute, it is required under Federal regulations (27 CFR, Part 17 and 20) that ATF issued. For many of these formulas, ATF also receives and tests samples.

Companies submitted more than 7,300 formulas to ATF in each of FYs 1998 and 1999. We found, however, that during this period:

- the laboratory's review of NBA and SDA formulas resulted in a very small number of rejected formulas; and

- formulas were reviewed, tested, and approved regardless of the amount produced or excise tax impact, which was often very small.

Considering the small number of rejected formulas, and the often small quantity and taxes associated with a significant percentage of these products, we believe ATF has an opportunity to explore methods to reduce the number of formulas submitted for approval.

ATF Reviews Formulas And Samples To Protect Tax Revenue And Consumers

The non-beverage section of the Alcohol and Tobacco Laboratory is responsible for the approval of NBA and SDA formulas[10]. ATF

[9] The non-beverage products refers to non-beverage alcohol (NBA) products and products made with specially denatured alcohol (SDA) called "articles."

[10] The section is comprised of ----- employees, including -------- who are responsible for reviewing non-beverage formulas, ---- -- ------ responsible for reviewing specially denatured alcohol formulas, and ---- ------ is assigned to tobacco issues.

conducts its formula review of NBA and SDA products to protect tax revenue and consumers. Tax revenue is protected by ensuring that excise tax drawback is not authorized for products that could be used as beverages. Consumers are protected by ensuring that banned ingredients are not included in the production process.

Tax Revenue Protection

ATF authorizes a drawback of Federal excise tax to manufacturers who used tax-paid alcohol to make medicines, foods and flavorings. To qualify for a drawback (which is similar to a refund), these products must be unfit for beverage use. ATF laboratory personnel examine formulas and analyze product samples to ensure the product contains the stated amount of alcohol and could not be used as a beverage. Products are determined unfit for beverage use by a panel of laboratory personnel who conduct organoleptic (taste) tests.

Additionally, ATF protects excise tax revenue by regulating the use of SDA in chemical processes and articles. No excise tax is assessed on SDA when it is used by companies in processes or articles from which potable alcohol cannot be recovered. These companies must obtain approval for their particular use of SDA prior to manufacturing. Examples of SDA products include cosmetics, industrial chemicals and fuels such as "gasahol."

Consumer Protection

A formula may be disapproved for drawback either because it does not prescribe appropriate ingredients in sufficient quantities to make the product unfit for beverage use, or because the product is neither a medicine, a medicinal preparation, a food product, flavor or a flavoring extract. Also, according to 27 CFR, Part 17.136, a product will not meet the above criteria, if the formula would violate a ban or restriction of the U.S. Food and Drug Administration (FDA) pertaining to such products.

Accordingly, the *ATF Form 5154.1* used by manufacturers for submitting formulas contains questions that address consumer protection. For example, the form requires the manufacturer to indicate if all the ingredients are approved by FDA for use without limitation or restriction. If the manufacturer indicated that the product

had restricted ingredients, laboratory personnel would reject the formula.

Minimal Numbers Of Formulas Have Been Rejected

The laboratory received 7,309 non-beverage formulas in FY 1998 and 7,377 in FY 1999, respectively. ATF received and tested samples for many of these products. ATF rejected 313 formulas in FY 1998 (4.3 percent of the formulas received) and 211 formulas in FY 1999 (2.9 percent of the formulas received).

The following table illustrates the number of formulas received, formulas with samples, samples tested and formulas rejected during FYs 1998 and 1999.

Table 4. FYs 1998-1999 Formulas Received And Rejected

	NBA Formulas		SDA Formulas		2-Year Totals	
	FY 1998	FY 1999	FY 1998	FY 1999	FY 1998	FY 1999
Received	4,978	5,452	2,331	1,925	7,309	7,377
Received with Samples	3,211	3,579	683	599	3,894	4,178
Samples Tested	2,184	2,435	275*	239*	2,459*	2,674*
Formulas Rejected	231	170	82	41	313	211
Formulas Rejected as Percent Of Received	4.6	3.1	3.5	2.1	4.3	2.9

* The SDA samples tested are estimated numbers by the Chief of the Non-beverage Section.

According to Federal Regulations (27 CFR 17.124), ATF may request a sample of a product whenever a manufacturer submits a NBA formula for review. However, ATF does not require manufacturers to submit samples for every formula. ATF generally requires samples when questions exist about quality control in

manufacturing or when certain products are involved. For example, the laboratory requires the herbal industry to submit samples. This is because the quality control procedures are not as defined in this industry as in the food and pharmaceutical industries. Also, companies manufacturing certain flavors are also required to submit samples. When samples are submitted, ATF may conduct two different tests: an alcohol test to verify the percentage of alcohol and a taste test[11] to ensure the product is unfit for beverage use.

According to the Chief of the Non-Beverage Section, he believes the reason for rejecting formulas in FYs 1998 and 1999 was because they were "fit for beverage purposes." Unless a product has a banned ingredient, ATF has very limited authority to reject the formula beyond its fitness to be consumed as a beverage.

The Section Chief said that the companies with the rejected formulas usually resubmit the formulas and, after making minor adjustments to influence the taste, the formulas are subsequently approved. The Section Chief also informed us that the data in Table 4 does not show the formulas returned to the submitters for resubmission to the laboratory for approval. He indicated that the total number of formulas returned for resubmission for NBA and SDA formulas was roughly 41 percent and 10.9 percent, respectively. Because this information was provided subsequent to our field work, we did not verify that this information was accurate.

Formulas Are Reviewed, Tested And Approved Regardless Of The Amount Of Product Produced Or Excise Taxes Paid

The laboratory analyzes each formula received, without regard to the quantity produced or the amount claimed for refund of excise tax. Each formula is analyzed to ensure the formula meets Federal government and other organizations' standards for product safety and effectiveness. In addition, if a sample is submitted, the sample may be analyzed for its alcohol level and taste-tested to ensure the product is unfit for beverage use.

The amount of revenue associated with a particular formula can be relatively small. For FY 1999, 473 manufacturers submitted 2,594 tax

[11] Laboratory personnel organize a taste panel consisting of a minimum 3 to a maximum of 20 people. The panel tastes the samples and decides whether the products are fit for beverage purposes.

returns for $292 million in excise tax drawback, or an average of $113,000 for each return. However, many of the returns involve much smaller quantities and excise tax amounts. We reviewed a summary listing of tax returns submitted to the National Revenue Center (NRC) in Cincinnati for FY 1999 and found that 63 entities, or 13 percent, submitted annual tax returns totaling less than $5,000. In addition, many of these returns represent the total refund for alcohol used in numerous formulas, meaning the excise tax associated with the individual formulas can be far less than $5,000.

We found that some companies submitted returns for as many as 200 different formulas involving very small quantities of alcohol. For example, one pharmaceutical company submitted two tax returns in FY 1999 totaling $1,442. On one return, the company had 12 different formulas; however, only 2 of the 12 formulas were subject to drawback. One of the formulas involved less than 1 proof gallon with a tax refund of less than $13.

Further, many of the products that were tested were herbal extract products which are often produced in small quantities and involve minimal amounts of alcohol. Information submitted by a trade association indicated that the majority of liquid homeopathic products manufactured in the U.S. are manufactured in 1-2 ounce sizes utilizing 20 percent alcohol. (There are a few larger sizes of liquid homeopathic medicines available, primarily in the form of cough syrups.) Therefore, most homeopathic medicines contain less than 0.5 ounce of alcohol per bottle. In 1999, an industry trade association indicated that the total excise tax from homeopathic drugs was less than $300,000.

According to the Chief of the Non-Beverage Section, laboratory personnel analyze formulas without knowing the annual amount of used alcohol or the amount of tax paid and refunded. ATF requires companies to submit forms containing formula information and the company may also include a sample of the product. Laboratory personnel review the formulas to ensure the numbers make sense and also may conduct a proof and/or taste test of the sample.

Minimal Adjustments Are Made To The Tax Returns By The NRC

We reviewed a sample of tax returns from FYs 1998-1999 and found that the manufacturers generally received the amount that was claimed on the return. According to NRC officials, they usually check to see if

the laboratory approved the formula, and whether the percentage of alcohol agreed with what the laboratory. ----------------------------------
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When the formula was not approved, the NRC would deduct the total amount of tax related to that particular formula. If the alcohol percentages were different, the NRC would penalize the manufacturer a maximum of $1,000 in accordance with ATF regulations. However, once the formulas were approved or amended, the amounts denied and penalized were often returned to the manufacturer.

ATF Tried To Reduce the Number of Formulas Submitted

In response to a request from the Flavor and Extract Manufacturers' Association (FEMA), ATF issued a notice to manufacturers of non-beverage (flavor) products. The notice contained a list of flavor ingredients that when added to alcohol would qualify the resulting products as non-beverage. To qualify, the manufacturers were required only to complete 5 of 16 items on the *ATF Form 5154.1*.

FEMA distributed the notice to its association members in April 2000. As of April 2001, only 13 companies used the new procedures to file 26 formulas with the laboratory. The Section Chief said that he initially estimated that a lot more companies would take advantage of the new policy. However, he believes that the policy needs to be better promoted. He mentioned that ATF could heighten the awareness of the new policy by discussing it in upcoming industry seminars and publishing it in industry circulars.

Recommendation

1. The Director, ATF, should review formula approval to determine if it can be made less burdensome on both the manufacturers and ATF, while not reducing the risk of using non-beverage alcohol for beverage purposes. For example, ATF could promote the use of flavor ingredients when added to alcohol would qualify the resulting products as non-beverage.

   Management Comment. ATF does not dispute the finding and will adopt the recommendation to do a comprehensive review of the process with an eye toward eliminating specific steps that do not add value and toward reducing the burden in general.

   The ATF laboratory has already internally proposed a new process of drawback approval. The proposed new process involves establishing standards of additives for non-beverage product classification and publishing this for industry use. This would be an ongoing process since it involves significantly large numbers of additives and development of analytical methodologies to confirm the levels of additives in drawback formulas. The proposed new process is significantly different than the current one; thus it would have to go through the official rulemaking process if ATF decides to pursue it.

   OIG Comment. We consider the recommendation to have a management decision. Final action is pending completion of the comprehensive review.

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We would like to extend our appreciation to ATF for the cooperation and courtesies extended to our staff during the review. If you have any questions, please contact me at (617) 223-8640 or a member of your staff may contact Dennis Deely, Audit Manager, at (856) 968-4907 x248. Major contributors to this report are listed in Appendix 3.

/s/
Donald P. Benson
Regional Inspector General for Audit

The objective of our audit was to evaluate the effectiveness of the Alcohol and Tobacco Laboratory beverage and non-beverage alcohol testing. Specifically, we wanted to assess whether (1) program personnel were using the laboratory tests on beverage samples; and, (2) work performed by laboratory personnel assigned to the non-beverage section was effective.

We performed our audit using ATF data from FYs 1998 and 1999. To accomplish our objectives, we interviewed officials from the ATF Alcohol and Tobacco Laboratories in Rockville, MD, and Walnut Creek, CA.; Market Compliance Branch at ATF Headquarters; Formula Section in the Alcohol Labeling and Formulation Branch at ATF Headquarters and inspectors at various field locations. We also interviewed personnel from the National Revenue Center in Cincinnati, OH.

To evaluate the use of testing on beverage samples, we selected samples from four ATF programs: Beverage Sampling, Compliance Inspections, Pre-Import Sampling under the Certificate of Label Approval program and consumer complaints. We reviewed laboratory test results obtained through the Beverage Sampling program for FYs 1998 and 1999, and evaluated the corrective actions ATF took when violations were found. Under Beverage Sampling, ATF inspectors purchase product samples from retail stores and send the samples to the laboratory for analysis.

We took a sample of test results from compliance inspections conducted at domestic producers during FYs 1998 and 1999 which resulted in violations. We requested that the Walnut Creek Laboratory provide all test results with violations during the months of May 1998 and March 1999. We then called the inspector who submitted the sample to determined why the inspection was performed, and what actions were performed as a result of the violation.

We reviewed samples submitted for pre-import testing to determine what actions were taken as a result of the violations that were found. Pre-import samples are submitted to the laboratory as part of the label approval process. These products represent products that have not yet been marketed in the United States.

Regarding the non-beverage area, we reviewed laboratory logs for formulas submitted to the laboratory in FY 1999 for non-beverage alcohol and specially denatured alcohol. Additionally, we obtained financial records from the National Revenue Center in Cincinnati, OH. These records summarized the number of tax returns submitted by companies for a drawback of their excise tax in FY 1999. It also contained the amount requested and the amount approved. We also requested information on samples submitted from inspections at non-beverage facilities.

We did not verify the number and type of laboratory tests. We also did not ensure that the testing was conducted in accordance with acceptable laboratory procedures. We did not review testing on tobacco products, which program personnel indicated only represented approximately 16 percent of the testing at the laboratory.

We conducted our audit between January 2000 and August 2000 in accordance with generally accepted government auditing standards.

DEPARTMENT OF THE TREASURY
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS
WASHINGTON, DC 20226

DIRECTOR

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MEMORANDUM TO: Regional Inspector General for Audit

FROM: Director

SUBJECT: Draft Audit Report on the Bureau of Alcohol, Tobacco and Firearms Alcohol and Tobacco Laboratories

This is in response to the draft report prepared by the Treasury Office of Inspector General (OIG) regarding the Bureau of Alcohol, Tobacco and Firearms (ATF) Alcohol and Tobacco Laboratories.

Finding 1. Beverage Alcohol Test Results Not Always Used

The draft report found that the ATF Laboratory was generally timely in analyzing and testing the alcohol samples provided by ATF program managers. However, program managers conducted limited follow-up of the violations found through laboratory testing for the Beverage Sampling Program; violations from samples submitted by inspectors following inspections were not always communicated to the companies; corrective actions were not always recommended and follow-up not performed; and violations found by the laboratory in samples taken from pre-import sampling under the Certificate of Label Approval (COLA) program generally resulted in ATF only issuing warning letters and no follow-up action was taken to ensure the violations were corrected.

The OIG attributes these findings to two factors: 1) Lack of clear guidelines about how the laboratory test results should be used; and 2) Program managers

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may not have considered the violations significant enough to warrant follow-up. If that were the case, the OIG believes ATF should assess the costs and benefits of performing these tests, and consider being more selective in requesting laboratory services under these programs.

Recommendation: The Director of ATF should conduct an overall assessment of its laboratory testing of alcoholic beverages. The assessment should include a determination of the cost and benefits of the various tests. Based on this assessment, the Director should determine whether to continue or modify the nature and level of testing.

ATF Response: ATF does not believe that an overall assessment of its laboratory testing is necessary. The Bureau considers the sampling of alcoholic beverages very valuable in meeting its consumer protection obligations. ATF does not dispute the finding that beverage alcohol test results were not always acted on. This lack of follow-up on sampling results is attributable to a lack of clear procedures and weak management controls, not because they are unimportant.

Finding 1 covered three areas in which ATF made very limited use of the sampling results. We will address each one separately.

Beverage Sampling Program:
On June 30, 1999, the Bureau disseminated written Alcohol Beverage Sampling Program Procedures. We agree that these procedures were not implemented as written. The Bureau is in the process of consolidating and formulizing all guidelines on action in response to laboratory findings and has set a target of January 1, 2002. The Market Compliance Branch will have all sample results in process acted on by October 1, 2001. Future lab results will be acted on within fifteen (15) calendar days.

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Samples Submitted by Inspectors/Follow-Up Not Performed:
In order to insure timely follow-up actions, the Bureau is instituting a monitoring process for samples submitted by inspectors that will provide for independent monitoring of test results by Market Compliance Branch. "Timely" is defined as notification to Field Operations by Market Compliance Branch within fifteen (15) calendar days of receiving a laboratory report. Field Operations will have sixty (60) days to secure additional samples and ninety (90) days to initiate an investigation as requested by Market Compliance Branch.

Pre-Import Sampling:
The Bureau views the pre-import testing of certain products as an important regulatory tool for imports, given the absence of access/oversight to foreign production facilities. In response to this finding the Bureau reviewed its procedures in responding to deficiencies found during pre-import sampling and has decided on modifications as follows.

Products found out of tolerance on fill or alcohol content, not affecting the class or type, will continue to be approved, without additional testing prior to importation. These products will be identified in notices sent to the field division where the importer is located, with a request for a field inspection/sampling scheduled for 3 to 6 months subsequent to the COLA approval.

Products with other deficiencies such as prohibited ingredients will not have COLA approval until a sample of a product meeting U.S. standards is submitted. Once the COLA is approved, the products will be referred for field inspection/sampling scheduled for 3 to 6 months subsequent to the COLA approval.

Action Due Date on Finding 1: Closed.

Regional Inspector General for Audit

Finding 2. Formula Approval Process for Non-Beverage Alcohol and Specially Denatured Alcohol Results in Few Rejections

Recommendation 1: The Director of ATF should review formula approval to determine if it can be made less burdensome on both the manufacturers and ATF, while minimizing the risk of using non-beverage alcohol for beverage purposes. For example, ATF could promote the use of flavor ingredients when added to alcohol, which would qualify the resulting products as non-beverage.

ATF Response: ATF does not dispute the finding and will adopt the recommendation to do a comprehensive review of the process with an eye toward eliminating specific steps that do not add value and toward reducing the burden in general.

In fact, the ATF Laboratory has already internally proposed a new process of drawback approval. [redacted]. The proposed new process is significantly different than the current one; thus it would have to go through the official rulemaking process if ATF decides to pursue it.

Action Due Date on Finding 1: September 30, 2002

Thank you for giving us the opportunity to respond to your draft review.

Bradley A. Buckles

Northeastern Region

Donald P. Benson, Regional Inspector General for Audit
Dennis F. Deely, Audit Manager
Barry M. Bruner, Auditor

The Department of the Treasury

Under Secretary of the Treasury for Enforcement
Office of Strategic Planning and Evaluations
Office of Accounting and Internal Control

Bureau of Alcohol, Tobacco and Firearms

Assistant Director, Science and Technology/ CIO
Assistant Director, Alcohol and Tobacco
Assistant Director, Field Operations
Assistant Director, Inspection

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