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## **TTB Industry Circular**

### **Voluntary Alcohol Beverage Recalls**

**To: Producers, Importers, Wholesalers, and Retailers of Alcohol Beverage Products, and Others Concerned**

#### ***(1) What is the purpose of this circular?***

The purpose of this circular is to provide the alcohol beverage industry with guidance and an explanation of the Alcohol and Tobacco Tax and Trade Bureau (TTB) policy on the voluntary recall of certain mislabeled or adulterated alcohol beverages (wines, malt beverages, and distilled spirits) from the marketplace. A recall is a voluntary action taken by an industry member who removes from the marketplace an alcohol beverage that TTB considers to be in violation of TTB regulations or which, after consultation with the Food and Drug Administration (FDA), TTB considers to be mislabeled because it is in violation of FDA administered laws or regulations regarding permitted substances and/or tolerances of ingredients in alcohol beverages. The recalling industry member will then destroy the product; re-label it, if appropriate, with corrected, approved labels before placing it back into interstate commerce; or take other appropriate corrective action.

This circular updates and supersedes Industry Circular 2010-6, dated September 10, 2010.

#### ***(2) What products are subject to this circular?***

The guidance in this circular applies to wine, malt beverages, or distilled spirits as defined in the Federal Alcohol Administration Act (FAA Act) that are mislabeled or adulterated. Low alcohol wines (containing less than 7 percent alcohol by volume) and non-malt or non-hops beers are not included in the definitions of wine, malt beverages or distilled spirits under the FAA Act and therefore recall of such products is not addressed in this circular. These products are subject to FDA's recall policies under title 21, Code of Federal Regulations (CFR) part 7.

Under the FAA Act, if you introduce alcohol beverages into interstate or foreign commerce or remove them from customs custody, you have an obligation to ensure that your products are labeled truthfully and in a manner that is not misleading, as required by title 27, United States Code (U.S.C.) section 205(e) and 27 CFR parts 4, 5 and 7, and that they are otherwise labeled in accordance with these provisions. Also, you have an obligation to ensure that these beverages are not adulterated, as defined in Section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 342, and FDA's implementing regulations.

#### ***(3) What is TTB's policy concerning alcohol beverage recalls?***

TTB does not have statutory authority to require an industry member to recall an adulterated or mislabeled alcohol beverage. However, in determining the appropriate sanction, TTB may consider in any case whether an industry member might choose to voluntarily detain or recall an adulterated or mislabeled product. Under the Internal Revenue Code of 1986 (IRC) TTB officers may detain any container that will be removed in violation of law (26 U.S.C. 5311). In addition, it is TTB's position that alcohol beverages found by FDA to be adulterated under the FD&C Act are considered mislabeled within the meaning of the FAA Act. Under the FAA Act mislabeled alcohol beverages, including adulterated products, may not be sold or shipped, delivered for sale or shipment, or otherwise introduced or received in interstate or foreign commerce by a producer, importer, wholesaler, or others subject to 27 U.S.C. 205(e). TTB may pursue action to suspend or to revoke the FAA Act Basic Permit of industry members who willfully violate the conditions of their permit with respect to mislabeled, adulterated products. See 27 U.S.C. 204(e). TTB also may seek an injunction or criminal prosecution by the Attorney General in the name of the United States, and any person convicted of a misdemeanor under section 203 or 205 of Title 27 can be fined up to \$1,000 per offense. TTB may enter into an offer in compromise covering the liability arising with respect to such violations in the sum of not more than \$500 for each offense. See 27 U.S.C. 207. In addition, FDA may take enforcement action (including seizure) where an alcohol beverage is in violation of FDA's statutory and regulatory authorities.

#### ***(4) How does TTB interact with other Federal agencies in handling alcohol beverage recalls?***

TTB operates under a [1987 Memorandum of Understanding \(MOU\)](#) with FDA that clarifies and delineates the enforcement responsibilities of each agency with respect to alcohol beverages that may be adulterated under the FD&C Act and establishes procedures for coordination between the two agencies. Under the terms of this MOU, TTB has primary responsibility for seeking and monitoring voluntary recalls of alcohol beverages that are adulterated under the FD&C Act and mislabeled under the FAA Act by reason of being adulterated.

The MOU with FDA also provides that when TTB learns or is advised that an alcohol beverage is or may be adulterated, TTB consults with FDA before proposing any voluntary recall action. Under the MOU, FDA will provide TTB with a written health hazard evaluation of each product involved in a recall situation or potential recall situation.

Upon receipt of FDA's health hazard evaluation indicating a definitive hazard, TTB will advise the responsible industry member as to an appropriate course of action, which might include a voluntary recall. Even if FDA concludes there is no adverse risk to health, TTB may still find that the product contains unauthorized substances and is, therefore, mislabeled in violation of section 105(e) of the FAA Act (27 U.S.C. 205 (e)).

Regarding adulteration involving pesticides, Section 408 of the FD&C Act, 21 U.S.C. 346a, authorizes the Environmental Protection Agency (EPA) to establish a tolerance or grant an exemption from the requirement of a tolerance for a pesticide chemical residue on or in foods (which include alcohol beverages). TTB analyzes alcohol beverage products to ensure that they do not contain pesticides in excess of the tolerances established by EPA. TTB also conducts appropriate analyses of alcohol beverage products to determine whether those products are adulterated with any other substances.

TTB-regulated industry members should also be aware of the reporting obligations outlined in the requirements of the FD&C Act regarding the "Reportable Food Registry," 21 U.S.C. 350f. FDA's Reportable Food Registry reporting requirements do apply to alcohol beverage industry members that are required to register with FDA under 21 U.S.C. 350d (generally, in this context, domestic or foreign facilities that manufacture, process, pack or hold alcohol beverages for consumption in the United States). Those requirements concern a "reportable food," which means "an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals." Additional information on these requirements can be found on FDA's website at [www.fda.gov](http://www.fda.gov).

#### ***(5) What are the types of voluntary actions to remove product from the market?***

A voluntary recall may be initiated by you or it may occur as a response to a request from TTB. A voluntary recall requested by TTB is normally limited to urgent health hazard situations or cases involving significant mislabeling by reason of adulteration. We direct these requests to the industry members who have primary responsibility for the manufacturing, importation, or marketing of the product.

#### ***(6) What procedures does TTB follow in the event of a recall?***

For each TTB-recommended voluntary recall, TTB will contact the affected industry member(s) in order to provide both a verbal and written notice of the requested action. TTB may contact you by telephone, email, or facsimile transmission for the sake of expediency, confirmation, and clarification. For each industry member-initiated recall, the affected industry member should contact the TTB Market Compliance Office at 202-453-2251 or by email at [market.compliance@ttb.gov](mailto:market.compliance@ttb.gov). TTB will request that you devise and inform us in writing of an appropriate recall strategy for removal of the product from the market, provide updates throughout the recall, and inform us of the final results of the recall. The targeted outcome is: removal of any mislabeled or adulterated product from the marketplace and, where health hazards may exist, return of those products from consumers.

TTB will work appropriately with FDA and other concerned Federal and State regulatory agencies. These agencies may include Alcohol Beverage Control Boards and Departments of Health, or equivalent organizations, in the States where the products subject to recall are distributed. TTB may also obtain samples of the product for laboratory analysis.

#### ***(7) What factors should industry members consider in developing a recall strategy?***

When developing your recall strategy, you should consider several factors. These factors may include the results of an FDA health hazard evaluation (if conducted), the type of product, the usage patterns of the product, the ease in identifying the product, the degree to which the product's non-compliance with the law is obvious to the consumer, and the degree to which the product remains in the marketplace. Further, your recall strategy should address the following elements regarding the conduct of the recall: the need for publicity, the scope of the recall, and a measurement of effectiveness. Depending on the circumstances, recalls may involve wholesalers, importers, distributors, retailers, and consumers. The scope of the recall is determined by the severity of the problem or the circumstance that requires a removal from commerce. A recall decision does not depend solely on the health risk of the product. Adulterated products and mislabeled products where no health hazard exists are still in violation of the law, and voluntary recall may still be appropriate.

#### ***(8) How does TTB handle alcohol beverage recalls for imported products?***

When TTB recommends a voluntary recall for an imported alcohol beverage, we will attempt to identify all importers who have imported the product into the United States. TTB will involve all those industry members known by us to have imported the subject adulterated or mislabeled product. TTB may request that U.S. Customs and Border Protection refuse entry of the identified products into the U.S. marketplace until we confirm that the products are not adulterated or mislabeled.

#### ***(9) How will TTB inform the industry and the public of alcohol beverage product recalls?***

TTB uses a variety of means to notify those who may be concerned about these issues. The scope of the announcement is dependent on the factual circumstances of the issue. We may issue appropriate and necessary press releases, website postings, notices, and warnings to the general public and trade associations for the purpose of alerting specific populations to

serious health hazards or other concerns. We strongly encourage the recalling industry member to issue a public announcement regarding the recall.

**(10) How will TTB judge the effectiveness of the recall?**

After an industry member initiates a product recall, TTB will assess both the progress and final outcome of the recall through voluntary effectiveness checks conducted by the industry member and appropriate TTB investigations and audits. The purpose of an effectiveness check is to verify that your recall notification letter was received by all affected customers (wholesalers, importers, distributors, retailers, or consumers) and that these customers read, understood, and followed the recall instructions. The effectiveness check will also verify that the recall reached the appropriate level in the distribution chain and that all products subject to the recall were removed from the marketplace. As noted above, TTB does not have the authority to require a voluntary recall. However, TTB will investigate appropriately to determine whether you have engaged in any violation of the FAA Act with respect to a mislabeled or adulterated product. Such an investigation may include an audit of the industry member to examine financial records and other documentation relating to the manufacture, removal, or sale of the subject product.

**(11) What types of documents will TTB review to verify recall effectiveness?**

TTB will request a final recall status report to verify the effectiveness of your voluntary recall. The reports requested will usually include the following information:

- Dates customers were notified and how they were notified, including a sample of the notification(s) sent;
- Number of customers notified;
- Number of customers responding;
- Any related consumer complaints or reports of adverse health effects received;
- Quantity of recalled product returned or accounted for, when this occurred, and final disposition of the recalled product;
- Details of your voluntary recall effectiveness checks; and,
- Procedures and safeguards put in place to prevent any recurrence of the issue.

**(12) What does success look like?**

Success is the appropriate and prompt removal of adulterated or mislabeled products from the marketplace. Obviously, the nature of the circumstances will determine the extent of this effort.

TTB will inform you when it has obtained sufficient factual information for appropriate termination of a voluntary recall. As part of this process, TTB will consult with other concerned agencies prior to the termination of a voluntary recall. TTB will also issue a press release to inform consumers and industry members of the termination of a voluntary recall in cases where a press release was issued by TTB announcing the recall. The successful completion of a voluntary recall does not preclude TTB from taking administrative action against the responsible industry member.

**(13) Questions?**

If you have any questions concerning this industry circular, please contact the Market Compliance Office at 202-453-2251 or by email at [market.compliance@ttb.gov](mailto:market.compliance@ttb.gov).

Date Signed: September 29, 2017

**Signed by John Manfreda**

John J. Manfreda  
Administrator

Alcohol and Tobacco Tax and Trade Bureau