DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 7 and 25

[TTB T.D.–21; Re: TTB Notice No. 4]

RIN 1513–AA12

Flavored Malt Beverage and Related Regulatory Amendments (2002R–044P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau adopt as a final rule certain proposed changes to the regulations concerning the production, taxation, composition, labeling, and advertising of beer and malt beverages.

This final rule permits the addition of flavors and other nonbeverage materials containing alcohol to beers and malt beverages, but, in general, limits the alcohol contribution from such flavors and other nonbeverage materials to not more than 49% of the alcohol content of the product. However, if a malt beverage contains more than 6% alcohol by volume, not more than 1.5% of the volume of the finished product may consist of alcohol derived from flavors and other nonbeverage ingredients that contain alcohol. This final rule also amends the regulations relating to the labeling and advertising of malt beverages, and adopts a formula requirement for beers.

We issue this final rule to clarify the status of flavored malt beverages under the provisions of the Internal Revenue Code of 1986 and the Federal Alcohol Administration Act related to the production, composition, taxation, labeling, and advertising of alcohol beverages. This final rule also will ensure that consumers are adequately informed about the identity of flavored malt beverages.

DATES: This rule is effective January 3, 2006.

FOR FURTHER INFORMATION CONTACT: Charles N. Bacon, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Procedures Division, P.O. Box 5056, Beverly Farms, MA 01915; telephone (978) 921–1840.

SUPPLEMENTARY INFORMATION:

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Notes to Readers

A. ATF–TTB Transition

Effective January 24, 2003, section 1111 of the Homeland Security Act of 2002 (Public Law 107–296, 116 Stat. 2135), divided the Bureau of Alcohol, Tobacco and Firearms (ATF) into two new agencies, the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury, and the Bureau of Alcohol, Tobacco, Firearms and Explosives in the Department of Justice. The regulation and taxation of alcohol beverages remains a function of the Department of the Treasury and is the responsibility of TTB. References to the former ATF and the new TTB in this document reflect the time frame, before or after January 24, 2003.

B. Use of Plain Language

In this document, ''we,'' ''our,'' and ''us'' refer to the Department of the Treasury and/or the Alcohol and Tobacco Tax and Trade Bureau (TTB). ''You,'' ''your,'' and similar words refer to members of the alcohol beverage industry and others to whom TTB regulations apply.

I. Background Information

Flavored malt beverages are brewery products that differ from traditional malt beverages such as beer, ale, lager, porter, stout, or malt liquor in several respects. Flavored malt beverages

exhibit little or no traditional beer or malt beverage character. Their flavor is derived primarily from added flavors rather than from malt and other materials used in fermentation. At the same time, flavored malt beverages are marketed in traditional beer-type bottles and cans and distributed to the alcohol beverage market through beer and malt beverage wholesalers, and their alcohol content is similar to other malt beverages—in the 4-6% alcohol by volume range.

Although flavored malt beverages are produced at breweries, their method of production differs significantly from the production of other malt beverages and beer. In producing flavored malt beverages, brewers brew a fermented base of beer from malt and other brewing materials. Brewers then treat this base using a variety of processes in order to remove malt beverage character from the base. For example, they remove the color, bitterness, and taste generally associated with beer, ale, porter, stout, and other malt beverages. This leaves a base product to which brewers add various flavors, which typically contain distilled spirits, to achieve the desired taste profile and alcohol level.

While the alcohol content of flavored malt beverages is similar to that of most traditional malt beverages, the alcohol in many of them is derived primarily from the distilled spirits component of the added flavors rather than from fermentation. A review of approved formulas showed that more than 99% of the alcohol in some flavored malt beverages was derived from added flavorings containing distilled spirits instead of from fermentation at the brewery.

Flavored malt beverages are sold under many proprietary names and include alcohol beverages such as alcoholic lemonades, alcoholic colas, cooler-type products, and other flavored alcohol beverages. In recent years, brewers have partnered with distilled spirits producers in order to label flavored malt beverages using prominent distilled spirits brand names.

In ATF Ruling 96–1 (ATF Quarterly Bulletin 1996–1, p. 49), our predecessor agency announced its intention to engage in rulemaking on the issue of whether it should consider the prohibition, restriction, or limitation of the use of flavor materials containing alcohol at any stage in the production of malt beverages. Pending rulemaking, the ruling held that for malt beverages with an alcohol content in excess of 6% alcohol by volume, a maximum of 1.5% alcohol by volume could be derived from alcohol flavoring materials. Six years later, in ATF Ruling 2002–2, ATF set forth guidance on the labeling and advertising of flavored malt beverages and again reiterated its intention to engage in rulemaking on the use of alcohol flavoring materials in the production of malt beverages.

In the interim, State regulatory and taxation agencies started to express concerns about the status of flavored malt beverages, and these agencies requested that ATF or TTB take action to clarify the status of these products as either malt beverages or distilled spirits.

In 2002, ATF examined the formulation of 114 alcohol beverage products labeled and marketed as flavored malt beverages. ATF undertook this study to find out how these products were produced, what ingredients were used, and from where the alcohol in them was derived. This study did not examine malt beverages labeled and marketed as flavored beers, flavored ales, and so forth (such as ''cherry beer'' or ''pumpkin ale'') since these types of malt beverages typically have the character of malt beverages and their alcohol is derived primarily from fermentation. The major results of the study are set forth in the tables below:

TABLE 1.—ALCOHOL DERIVED FROM ADDED ALCOHOL FLAVORING MATERIALS

Alcohol percentage derived from added alcohol favors	Number of flavored malt beverages
0–25%	4
26–0%	0
51–75%	≤5
76–100	105
Maximum alcohol derived from added alcohol flavors: 99.98%.	Total: 114

TABLE 2.—VOLUME OF BEER BASE PRESENT IN FLAVORED MALT BEVERAGES

Volume of flavored malt beverage derived from fermented beer base	Number of flavored malt beverages
0–25%	95
26–50%	4
51–75%	1
76–100%	14

ATF concluded that the great majority of the alcohol in most flavored malt beverages was not derived from fermentation of malt and grain. Instead, most of the alcohol in these products was derived from distilled spirits contained in added alcohol flavors. ATF found that over 75% of the alcohol in most of the flavored malt beverages studied was derived from alcohol flavoring materials and that in some cases this figure rose to more than 99%. In contrast, the alcohol derived from flavors constituted 50% or less of the overall alcohol in only 4 of the 114 products studied.

Based on the study's results, ATF also concluded that most flavored malt beverages contained very little actual beer base. Only 15 out of the 114 flavored malt beverages studied contained 51% or more by volume fermented beer; the remaining volume of those 15 products consisted of flavors, water, and other ingredients. Two of the flavored malt beverages studied contained only 1% fermented beer by volume.

II. TTB Notice No. 4

On March 24, 2003, we proposed a number of regulatory changes concerning beer and malt beverages in TTB Notice No. 4 (published in the **Federal Register** at 68 FR 14292; corrected at 68 FR 15119). Among other things, Notice No. 4 solicited comments on whether certain products marketed as flavored malt beverages should be classified as malt beverages or distilled spirits products under the Federal Alcohol Administration Act (FAA Act) and the Internal Revenue Code of 1986 (IRC). We recognized that the answer to this question would affect the rate of tax applicable to these products, the premises on which they may be produced, and the way that the products are labeled, advertised and marketed. Furthermore, their classification as malt beverages or as distilled spirits under Federal law could affect State oversight and control of these products, since many States follow the Federal classification of alcohol beverages.

Notice No. 4 included a proposal to limit the quantity of alcohol derived from added flavors or other ingredients containing alcohol to less than 0.5% alcohol by volume. The notice also requested comments on an alternative standard requiring that a malt beverage derive a minimum of 51% of its alcohol content from fermentation at the brewery, thus allowing no more than 49% of the alcohol content to be derived from added flavors containing alcohol.

As discussed below, Notice No. 4 also included proposed amendments to the regulations involving the filing of formulas, and the labeling and advertising of malt beverages.

III. Discussion of Specific Proposals in TTB Notice No. 4

A. Standard for Added Alcohol and Alcohol From Fermentation

In Notice No. 4, we proposed to delineate how much of the alcohol content of a beer or malt beverage must be derived from fermentation at the brewery, and how much of the product's alcohol content may be derived from alcohol added through the use of flavors and other ingredients containing alcohol.

Neither the IRC nor the FAA Act provides specific limits on the quantity of flavors that may be added to beer or malt beverages; nor does either statute set forth how much of the alcohol content of those products must result from fermentation at the brewery. While neither statute expressly sanctions the direct addition of distilled spirits or other alcohol to beer or malt beverages, TTB and its predecessor agencies, as set forth in ATF Rulings 96–1 and 2002–2, have historically allowed flavors, including flavors containing alcohol, to be added to these products.

In Notice No. 4, TTB suggested that the definition of ''beer'' in the IRC, which refers to beer, ale, porter, stout, and ''other similar fermented beverages,'' requires that a product derive a substantial portion of its alcohol from fermentation at a brewery since the definition does not contemplate a product that derives most of its alcohol content from distilled spirits. As the ATF study referred to above demonstrated, few products marketed as flavored malt beverages derive a substantial portion, or even a bare majority, of their alcohol content from fermentation.

We also stated that a similar standard should apply to the definition of a ''malt beverage'' under the FAA Act. The FAA Act defines a malt beverage as a product made from the fermentation of malted barley with the addition of hops. While the definition in the FAA Act allows for the addition to malt beverages of ''other wholesome food products'' such as flavors, we stated that we do not believe that Congress intended for these added materials to represent the dominant source of a product's alcohol content.

B. Proposed 0.5% Added Alcohol by Volume Standard for ''Beer'' Under the IRC

In Notice No. 4, TTB proposed adding to the regulations a new § 25.15 (27 CFR 25.15) that would have the effect of treating as a distilled spirits product any fermented product that contains 0.5% or more alcohol by volume derived from flavors, taxpaid wine, or other ingredients containing alcohol. As a consequence of the proposed new section, those products would be taxed and classified as distilled spirits. This proposed section also would allow the use of barley malt, malted grains other than barley, unmalted grains, sugars, syrups, molasses, honey, fruit, fruit juice, fruit concentrate, herbs, spices and other food materials in the production of a beer. It did not provide any standards for the use of these ingredients.

In Notice No. 4, TTB noted that this 0.5% alcohol standard had long been used to determine whether a beverage is considered an alcohol beverage. For example, many beverages, including juice, soft drinks, and soda, contain a small amount of alcohol derived from the use of flavoring materials containing distilled spirits. As long as the overall alcohol content of the product is below 0.5% alcohol by volume, these products are not considered alcohol beverages, and are not taxed as such. If the alcohol content of the a product reaches 0.5% alcohol by volume, the product would be subject to the tax imposed on distilled spirits products, since it would fall within the statutory definition of a distilled spirits product.

C. Proposed 0.5% Added Alcohol by Volume Standard for Malt Beverages Under the FAA Act

In Notice No. 4, TTB proposed adding to the regulations a new § 7.11 (27 CFR 7.11) that would classify a fermented product as a malt beverage only if it contains less than 0.5% alcohol by volume derived from flavors or other ingredients containing alcohol. This proposed section would also have explicitly permitted filtration or other processing to remove color, taste, aroma, bitterness, or other characteristics derived from fermentation. We specifically solicited comments on this proposed standard and on any other standard that might be consistent with the FAA Act definition of a malt beverage.

Notice No. 4 noted that the FAA Act's definition of ''malt beverage'' was intended to cover all products made by brewers at the time of the enactment of that Act in 1935. As already noted above, this definition requires that a malt beverage be made from the fermentation of malted barley with hops, with or without the addition of ''other wholesome food products.'' For years, brewers have used many substances, including starches, sugars, honey, fruits, flavors (including those containing alcohol), colors, and adjuncts to aid in fermentation, clarification, and preservation of malt beverages. TTB and its predecessor agencies have allowed these ingredients in malt beverage products.

TTB and its predecessor agencies have rarely examined the question of what constitutes ''wholesome food products'' under the FAA Act, other than to state that the ingredients added to malt beverages must be recognized as safe for food use by the Food and Drug Administration and must have some intended purpose in malt beverage production. We and our predecessor agencies have considered flavorings containing distilled spirits to be wholesome food products and have allowed their use in producing malt beverages.

The use of flavors containing distilled spirits can introduce a significant amount of distilled spirits into a malt beverage. Adding alcohol or distilled spirits in this fashion reduces the need to use fermented malt in the production of a malt beverage in order to attain alcohol content. When carried to extremes, this practice results in a product in which most of the alcohol content is derived from added flavors rather than from fermentation at a brewery.

Based on the above considerations, we stated in Notice No. 4 our belief that the definition of a malt beverage in the FAA Act supports limiting the amount of alcohol that is not ''made by the alcoholic fermentation * * * of malted barley with hops.'' Further, we stated our belief that labeling a beverage that derives most of its alcohol content from added alcohol flavors as a malt beverage is inherently misleading since consumers expect that malt beverages derive a significant portion of their alcohol content from fermentation of barley malt and other ingredients at the brewery.

D. Alternative 51/49 (Majority) Alcohol Standard

Although Notice No. 4 stated that both the IRC and the FAA Act would support a 0.5% added alcohol standard, it also stated that the IRC would support the issuance of a regulation requiring that a beer or malt beverage product must derive a majority of its alcohol content from fermentation at the brewery. Accordingly, TTB sought comments on both the 0.5% standard and a 51/49 standard, which would allow up to 49% of the alcohol in a beer or malt beverage to be derived from flavors or other materials containing alcohol.

E. Proposed Alcohol Content Labeling Statement for Flavored Malt Beverages

In Notice No. 4, TTB suggested that, due to the unique character of these new types of flavored malt beverages, many consumers have limited experience with them. At the same time, due to their label appearance and the use of the brand names of well-known distilled spirits products, TTB believed that consumers are likely to be confused as to the actual alcohol content of the products. TTB suggested that consumers are likely to assume that some flavored malt beverages are high in alcohol content like the distilled spirits products whose brand names they bear. Likewise, while other brands of flavored malt beverages are not labeled with distilled spirits brand names, their labeling or packaging, which often resembles that of nonalcoholic beverages such as juices, sodas, bottled water, and energy drinks, is likely to confuse consumers as to their identity as alcohol beverages.

To avoid consumer confusion over the alcohol content in flavored malt beverages, we proposed the addition of a new paragraph (a)(5) in § 7.22, (27 CFR 7.22), setting forth a mandatory requirement to state on the brand label the alcohol content of any malt beverage that contains any alcohol derived from added flavors or other ingredients containing alcohol. We suggested that this requirement would help consumers identify these products as alcohol beverages and would help consumers to understand that their alcohol content is similar to that of traditional malt beverages. This alcohol content labeling would also draw attention to any flavored malt beverages that might lie outside the customary 4 to 6% alcohol by volume range for malt beverages. For example, if a flavored malt beverage contained 10% alcohol by volume, alcohol content labeling would inform consumers about this important fact.

Since there is no provision in the TTB regulations that uniquely identifies flavored malt beverages, we proposed that the mandatory alcohol content labeling apply to any malt beverage that contains alcohol from a source other than fermentation at the brewery. For example, if a brewer adds a flavoring containing alcohol to a malt beverage, whether it is labeled as a flavored malt beverage, as a flavored beer or ale, or as a specialty malt beverage product, the requirement to display alcohol content on the brand label would apply. We proposed no changes to the form of the alcohol content statement, to the tolerances provided in 27 CFR 7.71, or to the type size requirements in 27 CFR 7.28.

F. Use of Distilled Spirits Terms in Malt Beverage Labeling and Advertising

Notice No. 4 pointed out that some newer flavored malt beverages use the names of well-known brands of distilled spirits as part of their own brand names. The labels of these flavored malt beverage brands are often designed to resemble the labels of the distilled spirits brand used in their names. In addition, when first introduced, some of these flavored malt beverages bore label statements referring to the class and type of distilled spirits used in producing the nonbeverage-flavoring component. For these reasons, a number of State regulatory and taxing authorities questioned the classification of flavored malt beverages and requested that we take action to clarify their status as either malt beverages or distilled spirits.

As previously noted, ATF Ruling 2002–2 clarified permissible labeling and advertising practices for flavored malt beverages, and gave brewers and importers labeling guidelines to prevent the misleading impression that flavored malt beverages are distilled spirits or contain distilled spirits. Notice No. 4 proposed to incorporate the holdings of the ruling in a new 27 CFR 7.29(a)(7) for labeling purposes and a new 27 CFR 7.54(a)(8) for advertising purposes. These proposed provisions would add to the malt beverage regulations language similar to that found in the FAA Act wine regulations regarding distilled spirits statements. The proposed language would prohibit labeling and advertising statements that imply that malt beverages are similar to distilled spirits or that malt beverage products are made with, or contain, distilled spirits.

The two new provisions in question would allow the use of a brand name of a distilled spirits product as the brand name of a malt beverage. However, the proposed provisions would have the effect of prohibiting the use of a distilled spirits brand name in any other malt beverage labeling or advertising context. The use of a cocktail name as a brand name or fanciful name would be permitted if the malt beverage's overall formulation, label, or advertisement did not present a misleading impression about the identity of the product.

G. Filing Formulas for Fermented Beverages

Notice No. 4 noted that the TTB regulations at 27 CFR 25.62 and 25.67 require brewers to file a statement of process with TTB's National Revenue Center in Cincinnati, Ohio, as part of the Brewer's Notice for any fermented beverage that the brewer intends to market under a name other than ''beer,'' ''lager,'' ''ale,'' ''porter,'' ''stout,'' or ''malt liquor.'' Under 27 CFR 25.76, a brewer must file an amended Brewer's Notice if there are changes to an approved statement of process. When a brewer files a statement of process with the National Revenue Center, a specialist at TTB's Advertising, Labeling and Formulation Division in Washington, DC, examines the proposed statement of process to ensure that authorized materials will be used, to determine the correct class and type, and to ensure that the fermented product may be made at a brewery.

Notice No. 4 proposed significant changes to the filing requirements described above. These changes included the removal of §§ 25.62(a)(7), 25.67 and 25.76 and the addition of new §§ 25.55 through 25.58 (27 CFR 25.55 through 25.58). These changes would:

- Replace the statement of process requirements found at §§ 25.62(a)(7) and 25.67 with a formula requirement;
- Describe more clearly the fermented products for which a formula is necessary;
- Require brewers to provide specific information about ingredients, processes, and alcohol content in formulas;
- Allow brewers to file formulas directly with the Advertising, Labeling and Formulation Division in Washington, DC;
- Permit brewers to produce certain fermented beverages solely for research and product development purposes without having to receive formula approval;
- Allow brewers to file formulas to cover production at multiple breweries; and
- Allow brewers to file superseding formulas.

Proposed § 25.55 would require the filing of a formula with TTB for specified products made at a brewery, including saké, flavored saké, and sparkling saké. A formula also would be required for products to which any coloring or natural or artificial flavors are added, or for any product to which fruits, herbs, spices or honey are added. This new section also would require the filing of a formula for any fermented product that undergoes special processing or filtration, or undergoes any other process not used in traditional brewing. The proposed § 25.55 text included examples of processes that would require the filing of a formula, including reverse osmosis, ion exchange treatments, filtration that changes the

character of beer or removes material from beer, concentration or reconstitution of beer, and freezing or superchilling of beer. However, the proposed Notice No. 4 text would not require filing a formula for traditional brewing processes such as pasteurization, filtration prior to bottling, filtration in lieu of pasteurization, centrifuging (for clarification), lagering, carbonation and the like.

Notice No. 4 also proposed more specific requirements for the information required in formulas, especially in the realm of flavoring materials and special processes. Proposed § 25.57 spelled out in more detail the information required in formulas, and included requirements found in ATF Rulings 94–3 (which concerned the production of ice beer), 96–1, and 2002–2. In keeping with the current practice of listing ranges of ingredients in statements of process, proposed § 25.57(a)(1) would permit brewers to indicate a ''reasonable range'' of ingredients used in formulas. However, in order to establish a useful limit, Notice No. 4 requested comments on how to define a ''reasonable range'' for the quantity of ingredients used in making fermented products. Also in keeping with current policy that permits using special processes in making fermented products, the proposed § 25.57 text specifically permitted such special processes, but required brewers to describe them in detail in their formulas.

As noted in Notice No. 4, § 25.67 requires brewers to file a statement of process prior to producing any fermented product at the brewery that is not to be marketed under a traditional designation. This regulation does not provide any exception permitting research or development of fermented products without a statement of process. With the removal of § 25.67, a brewer could produce certain fermented beverages for research and development purposes under proposed § 25.55(c)(2) without receiving formula approval; however, a brewer could not sell or market such products until receiving formula approval.

Proposed § 25.55(e) stated that previously approved statements of process would remain valid after adoption of the new regulation, provided that the finished product is in compliance with any new requirements relating to the definition of beer.

The proposed formula regulations did not specify any Government form to be used for their filing. TTB also solicited comments on whether the proposed regulations on the preparation and filing of formulas would be easier and less confusing than the present statement of process requirement.

H. Samples; Formulas and Samples for Imported Malt Beverages

Notice No. 4 also included a proposed new section, § 25.53 (27 CFR 25.53), specifically authorizing a TTB officer at any time to require the submission of samples. This section recognized TTB's authority to require a brewer to submit a sample of a beer or a material used in producing a beer. For example, we occasionally examine samples of beer or ingredients in connection with our review of statements of process or formulas and in order to determine the proper tax classification of fermented products.

Finally, Notice No. 4 also included a proposed amendment to § 7.31 (27 CFR 7.31) to reflect TTB's statutory authority to require an importer to submit a formula for a malt beverage, or a sample of a malt beverage or materials used in producing a malt beverage, in connection with the filing of a certificate of label approval on TTB Form 5100.31. This proposal recognized the fact that, occasionally, TTB has had to examine a statement of process or analyze samples of a malt beverage in order to determine the proper classification of a product, whether a particular product is a malt beverage, or whether a product is correctly labeled under the part 7 regulations.

I. Other Issues Raised in Notice No. 4

In addition to the very specific proposals made by Notice No. 4, TTB requested comments and information on a number of general topics relating to the production and labeling of flavored malt beverages.

TTB requested comments on the proposed 0.5% added alcohol standard for beer. Specifically, we solicited information regarding any studies, laboratory trials, or other empirical data that may have existed for added alcohol in flavored malt beverages. We also sought comments on how adoption of the proposed standard would affect the taste, shelf life, stability, or other characteristics of flavored malt beverages. In addition, we sought comments on whether production practices are available to produce flavored malt beverages with the desired product profile that would comply with the proposed standard. We also solicited comments relating to the effect of the proposed regulation on the viability of products currently on the market. Notice No. 4 further stated that we were particularly interested in comments addressing whether products on the market could be made under the proposed 0.5% added alcohol standard.

Finally, as previously noted, TTB requested comments on whether another standard, such as a standard requiring that a minimum of 51% of the alcohol in a malt beverage be derived from fermentation at the brewery (in other words, setting a maximum limit of 49% for the alcohol content derived from added flavors or other materials), would be more appropriate than the proposed 0.5% added alcohol standard. We asked for supporting data, facts, or studies to back up any suggestions or comments for different added alcohol standards. Since we recognized that any new standard would constitute a substantial change from existing regulations and policy, we also sought comments on the amount of time needed to comply with any new rule limiting the amount of alcohol that may be added to products taxed as beer. Notice No. 4 encouraged comments on the amount of time necessary to develop and implement new formulas for these products and the possible costs involved.

IV. Rulemaking History

Notice No. 4 provided for the submission of comments through June 23, 2003. At the request of the E. & J. Gallo Winery, on June 2, 2003, we published Notice No. 10 (68 FR 32698) to extend the period for the submission of comments for an additional 120 days, until October 21, 2003.

In Notice No. 4 we stated our intention to place all comments on the TTB Web site on the Internet. We stated that the names of commenters would be included in the posting of comments on our Web site, but that street addresses, telephone numbers, or e-mail addresses would be deleted on these postings. We did state that this information would appear on copies of comments available in the TTB reference library in Washington, DC.

Due to the large number of comments, we were unable to redact street address, telephone number, or e-mail address information from the comments we posted on our Web site. Redacting this information from the large number of comments received would have prevented us from posting comments on the Web site in a timely manner. Therefore, we issued TTB Notice No. 23 on December 2, 2003 (68 FR 67388). This notice advised the public of our inability to redact the information from comments posted on the Web site and provided an opportunity for commenters to request that we redact this information from their individual

comments if we received their request to do so by December 23, 2003.

V. Comments Received in Response to Notice No. 4

A. General Discussion of Comments

Before the close of the comment period, TTB received over 15,000 comments in response to Notice No. 4. Of these, over 14,000 consisted of variations on several form letters, which were submitted by mail, facsimile transmission, or e-mail.

In addition, we received over 1,000 comments after the close of the comment period. Due to the large volume of comments received in response to Notice No. 4, and because of the need to provide expeditious guidance to State regulatory agencies, the industry, and consumers on this issue, we determined that it was not practical to consider the late-filed comments.

Most of the comments focused on the proposed 0.5% standard or the 51/49 standard for beer and malt beverages. In particular, the ''form letter'' comments, which made up the vast majority of the comments, generally commented for or against the proposed rule, and either explicitly or implicitly commented on the standard for added alcohol. The hundreds of comments received from State legislators also focused primarily on this issue. While Notice No. 4 solicited comments on whether there was a different standard that would be appropriate, only a few comments addressed this question.

Furthermore, only a small percentage of the total comments focused on issues such as alcohol content statements or formula requirements. Accordingly, the following breakdown of comments focuses on the commenters' position on the proposed 0.5% standard.

B. Overview of Comments

In the following comment discussion, the abbreviations ''FMB'' and FMBs'' are used in place of ''flavored malt beverage(s).''

1. Form Letters

Of the over 14,000 form letter submissions referred to above, over 8,000 supported adoption of the proposed 0.5 percent standard and over 5,000 opposed adoption of that standard. The submissions in support of the proposed rule (or specifically in support of the 0.5 percent standard) break down as follows:

- Over 5,000 e-mail comments came from individuals who identified themselves as employees of one major U.S. brewer and its subsidiaries. These commenters stated that the proposed standard is the best way to maintain clear distinctions between beer and liquor (distilled spirits) and to preserve the flavored malt beverage category.
- Over 2,000 comments were received from beer distributors across the United States. Many of these commenters stated that the proposed rule is consistent with the historical interpretation of what constitutes beer and other malt beverages. They suggested that beer is a unique product that has been regulated and taxed differently from other alcohol beverages throughout our Nation's history. The commenters advocated adopting the proposed 0.5% standard in order to ensure the integrity of beer and the brewing process. They also stated that the proposed rule would help maintain an orderly marketplace and avoid costly and confusing disruptions in State licensing, taxation, and distribution policies, any of which would deal a blow to beer wholesalers.
- Approximately 900 comments were received from individuals who identified themselves as employees of another major brewer. These comments supported the proposed rule as a clarification that will ensure that if FMBs were sold as malt beverages, they would be made according to traditional brewing methods and practices. The commenters suggested that without the proposed rule, retailers and wholesalers would face a patchwork of individual State laws and regulations.
- Over 170 submissions came from beer consumers located primarily in two States. Many of these commenters stated that the proposed rule would provide a clear understanding to legislators, State and Federal regulators, and beer consumers as to what beer is and what beer is not.
- More than 50 employees of a domestic subsidiary of a foreign brewer expressed their support for the proposed rule. They suggested that the proposed rule would maintain an orderly marketplace, meet consumer expectations for consistent products, and help sustain the long-term development of the product category. These commenters suggested that the reformulated products would be consistent with State tax, license, and distribution laws, allowing wholesalers and retailers to continue their operations. Furthermore, they stated that without a standard, individual States would adopt their own regulations and create a patchwork of different standards.

The submissions in opposition to the 0.5 percent standard break down as follows:

- Over 4,000 e-mail submissions came from consumers of FMBs. These comments opposed the proposed rule and suggested that there was no need to amend the regulations. Many of the commenters stated that they like FMBs just the way they are and that the proposed changes will be expensive and will result in increased costs to consumers.
- Over 600 comments came from employees of a large producer of FMBs. These commenters opposed the proposed rule and suggested TTB instead adopt the ''51% compromise.'' The commenters suggested that compliance with the proposed standard would cost millions of dollars in new equipment purchases, reformulation of products, and development of new processes. They urged TTB to adopt regulations that promote fair competition and provide a level playing field, and they suggested the proposed rule would mark a dramatic change in how these products have been produced, marketed, and sold for 30 years. Finally, the commenters stated that the proposed rule could regulate FMBs out of the marketplace, depriving consumers of a drink they enjoy, costing millions in tax revenue, and resulting in the loss of thousands of jobs.
- Over 400 small retailers located across the United States expressed their opposition to the ''new regulations'' and ''rule changes.'' Many of these retailers asked TTB to reach a ''compromise'' that would allow FMBs to remain in existence. The commenters suggested that the regulatory changes would raise the price of FMBs, sabotage this category of products by making it impossible or costly to sell them, and adversely impact small businesses.
- More than 40 comments were received from employees of FMB distributors. These commenters opposed the 0.5 percent standard and urged TTB to adopt a ''more reasonable'' majority standard instead. The commenters focused on the potential impact of the proposed rule on the future of FMB producers and the businesses that rely on the viability of these products.

2. Other Comments

FMB Producers. We received comments from several major producers of FMBs. The Beer Institute submitted a comment in support of the proposed 0.5% standard, on behalf of Anheuser-Busch, Miller Brewing Company (''Miller''), and Coors Brewing Company (''Coors''). The Beer Institute stated that these three senior and sustaining members produce or import well over 75% of the beer and other malt beverages sold in the United States,

including many successful FMB brands. In addition, these three brewers each submitted individual comments in support of the proposed 0.5% standard.

These commenters argued that the proposed 0.5% standard is consistent with TTB's statutory authority and will preserve the integrity of the products known as beer or as malt beverages. More importantly, these commenters suggested that only a 0.5% standard would maintain an orderly marketplace and foreclose actions by individual States, which could adopt their own potentially differing and conflicting standards. Anheuser-Busch and Miller stated that they could take steps to reformulate their products within the 0.5% standard and, in fact, have produced FMBs that achieve the same taste and appearance as existing products.

The Flavored Malt Beverage Coalition (FMBC) submitted a comment on behalf of its members: City Brewing Company; Diageo North America, Inc.; High Falls Brewing Company; Mark Anthony Brands, Inc.; Pernod Ricard USA; Todhunter International; and United States Beverage LLC. The FMBC stated that, together, its members marketed and/or produced approximately 56% of the FMBs sold in the United States in 2002. The FMBC also stated that its members, as companies that collectively spent hundreds of millions of dollars to develop products now threatened by a change in Federal policy, have a particular interest in the outcome of the rulemaking.

The FMBC, and several of its individual members, questioned TTB's statutory authority to impose restrictions on the current practice but also stated that, as a matter of policy, they would support a final rule that adopts the 51/49 standard. Furthermore, these commenters raised a number of legal challenges to the basis for the proposed rule, and they argued that the proposed 0.5% standard was not supported by either the consumer protection rationale or the need to take action before the States do so.

Several of these commenters stressed the economic impact of the proposed rule. Many FMB producers suggested that the proposed 0.5% standard would require reformulation of popular FMB products, with a potentially adverse impact on consumer acceptance of those products. The FMBC submitted an economic study indicating that adoption of the proposed rule would have an adverse impact on the FMB industry, amounting to over $600 million over the next 4 years. Comments from a few small brewers that produce and bottle FMB products indicated that their survival would be in jeopardy under the proposed rule.

Brown-Forman Corporation (''Brown-Forman''), the producer of an FMB known as Jack Daniel's Country Cocktails, also commented in favor of the 51/49 standard. Finally, E. & J. Gallo Winery (Gallo), which produces 13 FMB products, submitted a comment in which it took no position on whether it preferred the 0.5% standard or the 51/49 standard.

Other Comments from the Beer Industry. The National Beer Wholesalers Association (NBWA) and the Brewer's Association of America (BAA) both commented in favor of the proposed 0.5% standard. TTB also received many comments from craft brewers, beer wholesalers, employees of the major brewers, and others in the beer industry supporting the proposed rule. Many of these comments suggested that FMBs are not beer or malt beverages as consumers understand these terms and that the proposed rule would preserve the integrity of the malt beverage category. Some brewers suggested that competition from FMB producers is hurting the beer industry.

Consumer/Taxpayer Groups. The Center for Science in the Public Interest (CSPI), the Pacific Institute for Research and Evaluation, and several other associations commented in favor of the proposed rule. CSPI stated that the use of popular, well-known distilled spirits brand names in the advertising and labeling of malt beverage products misleads consumers. CSPI also suggested that these ''alcopops'' are extremely popular with underage drinkers, and that since most ''alcopop'' products currently do not comply with the 0.5% standard, classifying and taxing them as distilled spirits products would help reduce youth access to such products by placing them in liquor stores in many States rather than in grocery and convenience stores.

The National Consumers League (NCL) commented against the 0.5% standard, stating that it opposed the perpetuation of policies that differentiate malt-based alcohol beverages from distilled alcohol beverages, and suggesting that ethyl alcohol is the same, regardless of whether it is in beer, wine, or distilled spirits. NCL agreed, however, that requiring compliance with a ''majority'' standard will ensure that an FMB actually contains malt, and in a significant concentration. While NCL questioned whether source of alcohol is in any way material to consumer choice, it concluded that FMB compliance with the majority rule would ensure that consumers are not deceived as to product content.

TTB also received comments opposing the proposed rule from taxpayer and citizen organizations. These commenters suggested that the proposed rule would limit consumer choice, decrease competition, and waste taxpayer dollars. The commenters stated that the Government should accommodate legitimate consumer, industry, and employment needs. They suggested that the majority standard would achieve these goals better than the proposed 0.5% standard.

State Regulatory Agencies and Lawmakers. TTB received comments from 31 State regulatory or tax agencies and one county liquor commission. Most of these comments specifically supported the proposed rule. The remaining comments generally supported the concept of a uniform standard for FMBs, without specifically supporting the proposed 0.5% standard. Two States simply provided information about their State laws, without taking a position on the standard. We also received comments in support of the proposed rule from three Governors, one Lieutenant Governor, and over 200 State legislators. A smaller number of State legislators commented in favor of the 51/49 standard.

Some comments that specifically favored the proposed rule suggested that, in many States, malt beverages containing distilled spirits would be classified as spirits rather than malt beverages. Several States indicated that if TTB does not take expeditious action on this issue, they would go ahead and issue their own standards. Other States, however, simply stressed the need for a uniform standard and urged TTB to take expeditious action to create a standard for FMBs.

Members of Congress. We received comments in favor of the proposed rule from nine members of the United States House of Representatives. We received comments in favor of the 51/49 (or majority) standard from 28 members of the House of Representatives and eight United States Senators.

Many of the members of Congress who commented in favor of the 51/49 standard expressed concern about the negative economic impact that the proposed rule would have on employers and jobs within their districts or States. Many of these comments noted that existing FMB products were formulated in reliance on the longstanding policies of our predecessor agency.

Miscellaneous comments. We received a comment from the Flavor and Extract Manufacturers Association of the U.S. (FEMA), the national trade

association of companies that create and manufacture flavors for use in a wide variety of products, including FMBs. FEMA urged TTB to reconsider the proposed 0.5% standard, stating that it would significantly restrict the amount of alcohol contributed to the finished product from flavors and thus make it technically impossible for flavor chemists to satisfy the consumer desire for the distinctive, fresh, fruity malt beverages currently being sold.

We received a few comments suggesting revisions to the system of taxing alcohol beverages as a way to take care of the classification issue posed by FMBs. These comments could not be adopted without legislative amendments to the IRC. Since the rest of the comments focused primarily on the two standards that we aired in Notice No. 4, the 0.5% standard and the 51/49 standard, our discussion of the comments will focus on those two standards.

A small number of commenters focused on the remaining issues raised for comment in Notice 4. While we received several comments from States and consumer groups in support of the proposed mandatory alcohol content labeling for FMBs, many comments from industry members suggested that FMBs were being unfairly singled out, and that any such requirement should apply to all malt beverages or to none. We also received a few comments in opposition to the proposed limitations on the use of distilled spirits terms in malt beverage labeling and advertising. Some of these commenters claimed that the proposed restrictions violated the First Amendment.

Finally, we received a small number of comments from brewers and brewery trade associations regarding the proposed new formula filing requirements. These commenters generally favored the new requirements, but they expressed concerns regarding certain aspects of the proposal and requested that TTB clarify some of the proposed formula requirements.

C. Summary of TTB Final Rule Decisions

After carefully analyzing the comments, which are discussed in greater detail below, we are adopting the proposals set forth in Notice No. 4 with certain important modifications. The final rule adopts the less stringent ''51/49 standard'' (allowing up to 49% of the alcohol content to come from flavors and other nonbeverage ingredients) for beers and malt beverages. We are providing affected industry members one year to reformulate their FMB products or otherwise conform to the standards adopted in the final rule. In reaching these decisions, we note that Executive Order 12866 provides that, when an agency determines that a regulation is the best available method of achieving an objective, it shall design its regulation in the most cost-effective manner to achieve that objective.

The comments on Notice No. 4 have persuaded us that implementation of the proposed 0.5% standard might impose economic burdens on a sector of the FMB industry and have adverse effects on the viability of small brewers who produce FMBs, as well as their ability to compete within the malt beverage industry.

We believe that adoption of the alternative ''51/49 standard'' for beers and malt beverages would achieve the important regulatory goals of protecting the revenue, ensuring that consumers have adequate information about the identity of FMB products, and establishing a Federal standard for such products, while at the same time reducing the compliance costs to the FMB industry. It is noteworthy that, with the exception of one producer that remained neutral on this issue, comments from the producers of FMBs all supported either the more restrictive 0.5% standard or the more liberal 51/49 standard. Thus, most of the FMB industry expressed support for creating some type of standard for FMBs that would set a limit on the alcohol derived from added flavors.

The final rule also adopts the other proposals aired in Notice 4, with certain modifications in response to the comments. We are adopting the proposed mandatory alcohol content labeling requirements, as we have concluded that this requirement will provide consumers important information about these FMBs. Since we specifically stated in Notice No. 4 that we were not proposing mandatory alcohol content labeling for all malt beverage products, comments advocating such a position were considered to be outside the scope of the current rulemaking. We may consider such a proposal in the future.

We are also adopting the labeling and advertising proposals, with modifications to respond to the First Amendment concerns raised by several commenters. As modified, the regulation will prohibit the use of labeling or advertising statements, designs, devices, or representations that tend to create a false or misleading impression that the malt beverage contains distilled spirits or is a distilled spirits product. These modifications clarify that we are only prohibiting labeling and advertising statements that are false or tend to mislead consumers.

Finally, we have modified the language of the formula regulations in response to several comments about whether the proposed requirements were overly burdensome. For example, we are no longer requiring formulas to disclose the alcohol content of the product at each interim stage of production. We have also clarified the language of these provisions in response to several technical comments.

VI. Comments on Whether the Rulemaking Is Necessary and Fair

In this section, we discuss some of the general issues raised by commenters regarding the need for engaging in rulemaking and the fairness of the proposed change in agency policy.

A. Is There a Need To Engage in Rulemaking on This Issue?

The first issue presented is whether there is a need to engage in rulemaking at all. Many commenters suggested that TTB should not amend its regulations in any manner, but should instead allow the continued production of FMBs according to current policy. Other commenters supported the idea of rulemaking on FMBs.

1. Comments Opposed to Rulemaking

As indicated above in the comment overview, TTB received over 4,000 e-mail comments that questioned the need for rulemaking on FMBs. These comments came from consumers who stated that they enjoyed drinking FMBs, and that they opposed the proposed regulation, which would mandate changes in the way those products were made. The commenters stated that they liked FMBs the way they are, that the changes would be expensive, and that consumers will end up paying more under the proposed rule.

Many of these commenters suggested that the Federal Government should not waste tax dollars on ''trivial'' issues such as how FMBs are made, and that companies should make changes that consumers want, not what the Government demands. Finally, many of these comments suggested that the Government should focus on bigger issues, such as job creation, improving the economy, and fighting terrorism. These comments did not directly address the 51/49 standard.

A few comments were also received from organizations representing taxpayer and citizen groups, including Americans for Tax Reform, the National Taxpayers Union, and Citizens Against Government Waste. One of these commenters stated that the proposed

rule would limit consumer choice, decrease competition, and waste taxpayer dollars. This commenter suggested that the Government should accommodate legitimate consumer, industry, and employment needs before engaging in rulemaking. Another commenter expressed concerns that the 0.5% standard would force either a significant tax increase and/or a change in the production process for FMBs. It should be noted that while these comments generally criticized the proposed rule, they expressed a preference for either the 51/49 standard or some compromise over the 0.5% standard.

2. Comments Supporting Rulemaking

TTB also received approximately 11,000 comments urging that TTB set a limit on the quantity of alcohol derived from added flavors in malt beverages. While these comments were divided over whether the limit should be set at the 51/49 standard or the proposed 0.5% standard, these commenters believed that it was important that TTB set a standard and clarify the classification of these products as malt beverages or distilled spirits. It should be noted that we received comments in support of setting a standard from the beer industry, producers of flavored malt beverages, consumers, members of Congress and other elected officials, and State regulatory agencies.

These commenters supported the setting of a uniform Federal standard for a variety of reasons. Some commenters expressed concern that current labels mislead consumers. Many consumers and brewers suggested that the Federal government has the responsibility to maintain a distinction between traditional beer products and distilled spirits, and that the line between these two well-established categories should not be blurred by allowing the production of malt beverages that derive most of their alcohol content from the distilled spirits components of added flavors.

Many commenters expressed concern that, in the absence of a Federal standard, the States would each set their own standards, leaving members of the beer industry facing a confusing patchwork of regulatory standards. Finally, of the FMB producers who commented on this issue, almost all supported action to set a standard to limit the quantity of alcohol derived from added flavors. While one major FMB producer expressed neutrality on the issue, the rest favored either the proposed 0.5% standard or the 51/49 standard.

3. TTB Response

We acknowledge that FMBs are a popular category of alcohol beverage and that many consumers enjoy drinking these products. We recognize the concerns of many consumers that proposed regulatory changes may increase the cost of these beverages, and we have given serious consideration to cost issues in drafting this final rule. We have also given serious consideration to the issues of decreased competition and consumer choice.

Nonetheless, after reviewing the thousands of comments received in response to this notice, we believe more strongly than ever that rulemaking on this issue is necessary. The overwhelming majority of the State regulatory agencies that commented on FMBs urged TTB to adopt a Federal standard for these products in order to avoid a patchwork of inconsistent State requirements. In addition, comments from the beer industry overwhelmingly favored the adoption of a Federal standard, including many commenters who pointed to the importance of maintaining a distinction between malt beverages, in which alcohol is derived from fermentation, and distilled spirits, in which alcohol is derived from distillation.

Treasury and TTB believe it is important, in order to protect both the revenue and the consumer, to set a limit on the use in FMBs of alcohol not derived from fermentation at the brewery and prevent the unlimited use of alcohol derived from distilled spirits in FMB production. Thus, we do not adopt the views of those commenters who urged that TTB take no action on this matter.

B. Fairness and Notice Issues

1. Comments Received

Many commenters argued that it is unfair for TTB to change a policy upon which brewers and importers have relied for several decades. These commenters made the following arguments:

- Since the 1950s, TTB and its predecessor agencies have required the review and approval of a statement of process (SOP) for any beer produced with flavors. By reviewing and approving SOPs for the various FMBs on the market today, TTB has accepted them as beer and malt beverages, and has endorsed the use of nonbeverage flavors up to the quantities indicated in the SOPs.
- Our predecessor agencies have officially recognized the use of flavoring materials in the production of malt beverages since the Internal Revenue Service issued Revenue Procedure 71–26 over 30 years ago.
- In 1980, ATF issued Industry Circular 80–3, which advised brewers that adjunct materials listed in the beer industry's Adjunct Report (later referred to as the Adjunct Reference Manual (ARM)), were suitable for use in beer and cereal beverages when used in accordance with the conditions described in the report. That Adjunct Report, as well as all subsequent editions of the ARM, lists ethyl alcohol as a permitted additive for use in flavoring beer, without any limitations.

Several commenters stated that they have relied on these policies to create beverages that consumers enjoy and that they have invested millions of dollars promoting those brands.

Some commenters argued that the industry had ample warning that TTB's predecessor agency was contemplating a limitation on the use of flavors containing alcohol in the production of beer and malt beverages. These commenters noted that in 1996 ATF notified the industry, through ATF Ruling 96–1, that rulemaking limiting the alcohol contribution from flavors in FMBs under 6% alc/vol was forthcoming. This ruling clearly stated that TTB would initiate future rulemaking to consider the prohibition, restriction, or limitation on alcohol derived from the distilled spirits components of added flavors, a statement that was reiterated in ATF Ruling 2002–2.

However, commenters who opposed the proposed 0.5% standard suggested that ATF's actions after 1996 sent mixed signals to the industry. For example, a U.S. Senator stated that although the Bureau in 1996 suggested that rulemaking ''in the near future'' might limit the use of flavors in such products, it abandoned that rulemaking project and did not even mention it in the unified regulatory agenda that every Federal agency must publish on a semi-annual basis. Another U.S. Senator noted that although the 1996 ruling mentioned rulemaking, no such rulemaking proposal appeared until 2003. The Senator suggested that:

> In the intervening 7-year time period, manufacturers have relied on the existing law and the Bureau's formula approvals to invest hundreds of millions of dollars in the formulation and marketing of new products. These investments have created hundreds of jobs and a vibrant fast-growing U.S. market sector in which tens of millions of cases of FMBs have already been sold. Without a reasonable public health or safety rationale, it does not seem prudent or fair to revise these rules dramatically at this stage of the game.

Accordingly, the Senator urged TTB to adopt the 51/49 standard, as it would ''accomplish the same goals and have a lesser impact on these products and the industry that produces them.''

Other members of Congress made similar comments. A letter signed by 26 members of the House of Representatives supported the ''majority'' standard, stating that over the past 5 years, ''hundreds of millions of dollars have been invested in the development of the FMB category. These investments, and the thousands of jobs created, were all made on the reliance of long-standing federal policy and rules.'' The letter suggested that Notice No. 4 intends to ''change the established rules mid-stream on those who have successfully created the category. This is especially troubling in that it threatens to stifle the only growth sector in the brewing industry over the last several years.''

Diageo stated that, in the summer of 2000, company officials met with ATF representatives and revealed Diageo's plans to enter the FMB market in the near future in reliance on existing policy. Diageo stated that company officials advised ATF that it would reconsider these plans if ATF planned to place new limits on the use of flavors in FMBs containing not more than 6% alc/vol. Diageo also stated that, after the meeting, ATF officials indicated that the agency did not plan to change existing policy towards FMB formulation. Diageo claims that, in reliance on those assurances, Diageo introduced Smirnoff Ice in December 2000.

The FMBC also stated that a number of its members had received assurances from ATF, in the summer of 2000, that ATF planned no change in policy towards the addition of alcohol to FMBs containing 6% alcohol by volume or less. The FMBC stated that it sought these assurances after an ATF official sent a letter indicating that the Bureau was considering rulemaking, which might limit the alcohol from added flavors to no more than 25% of the total alcohol content of the product.

A commenter pointed out that although ATF Ruling 96–1 stated that ATF would undertake rulemaking to limit alcohol from flavors in beer and malt beverages, ATF labeling and formula specialists never qualified approvals of statements of process or labels by stating that the approval was conditioned on future rulemaking. Instead, these commenters claimed that ATF continued to approve statements of process and labels without qualification. Another commenter stated that ATF personnel did not immediately implement the provisions in ATF Ruling 96–1 that require explicit ingredient listing and alcohol content information in statements of process, but instead delayed enforcement of these provisions until the issuance of ATF Ruling 2002–2 in 2002.

2. TTB Response

TTB agrees with the commenters who note that for many years ATF and its predecessors allowed brewers to use alcohol-flavoring ingredients, without limitation, when producing malt beverages. Our predecessor agencies approved statements of process and certificates of label approval for these products and, before 1996, never suggested that there was any limit on the use of flavoring materials in FMBs. Accordingly, we acknowledge that the FMB industry relied on existing policies in formulating these products.

It is important to note, however, that we know of no evidence that would suggest that producers of FMBs in the 1970s or 1980s were using nonbeverage flavors in their products at the high levels disclosed in the 2002 ATF study. To the best of our knowledge, the production of FMBs that derived the majority (and in some cases, up to 99%) of their alcohol content from added flavors is a trend that began in the 1990s. As the trend accelerated, ATF concluded that it was necessary to reevaluate the prior policy and consider the need for placing limits on the quantity of alcohol derived from added flavors. Furthermore, many State regulatory agencies began requesting that ATF create a Federal standard for the production of FMBs because of the confusion caused by the marketing and labeling of these products.

Agencies may change policies, as long as the agency follows the appropriate procedures under the Administrative Procedure Act. The Supreme Court has recognized that ''[r]egulatory agencies do not establish rules of conduct to last forever.'' (*See American Trucking Assns., Inc.* v. *Atchison, T. & S. F. R. Co.,* 387 U.S. 397, 416 (1967).) The Court has also stated that agencies must be given ample latitude to ''adapt their rules and policies to the demands of changing circumstances.'' (*See Permian Basin Area Rate Cases,* 390 U.S. 747, 784 (1968).) Furthermore, the Court has recognized that ''[a]n agency's view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis * * *.'' (*See Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 57 (1983), *quoting Greater Boston Television Corp.* v. *FCC,* 143 U. S. App. D. C. 383, 394, 444 F.2d 841, 852 (1970) (footnote omitted), *cert. denied,* 403 U.S. 923 (1971).)

New manufacturing processes and marketing trends created a need for TTB and our predecessor agency to reevaluate longstanding policies on the use of flavors containing alcohol in the production of beer and malt beverages. As the above-cited cases demonstrate, an agency may make changes in policy, as long as the interpretation of the applicable statutes and the rest of the administrative record reflects reasoned deliberation.

Finally, even if the agency in the two rulings referred to by the commenter had not given notice of its intention to engage in rulemaking on this issue, and even if the agency sent mixed signals on this issue prior to 2002, an agency is not precluded from engaging in rulemaking simply because it would change even a longstanding policy. By publishing a notice of proposed rulemaking and soliciting comments on this issue, we have clearly met the notice and comment requirements of the Administrative Procedure Act (APA). Notice No. 4 provided specific notice of the proposed changes to the industry and the public, and we provided the industry and the public almost 7 months to submit comments on those proposed changes.

As reflected in this discussion of comments, we have carefully considered the comments from all interested parties, and we have given full consideration to options that would minimize any adverse economic impact flowing from the rule and that would afford industry members an adequate period of time to reformulate their products, if necessary. In crafting a standard on the use of flavors containing alcohol in the production of FMBs, we have also taken into consideration past and current agency policy. Accordingly, we have taken fairness and equity into consideration in drafting the final rule.

VII. Regulatory Burden and Cost-Related Issues

One of the most important issues raised in the comments is the difference in regulatory burdens and costs associated with the proposed 0.5% standard and the 51/49 standard. Opponents of the proposed 0.5% standard gave more weight to this issue than did supporters of that standard. However, many commenters who would be directly impacted by the proposed 0.5% standard urged TTB to adopt the 51/49 standard instead because it would be less costly and because it would not distort competition in the FMB market.

The major issues raised by commenters on both sides of this question are summarized below.

A. Costs of Complying With the Proposed 0.5% Standard

1. Comments in Support of the 0.5% Standard

Many industry members who commented in support of the 0.5% standard downplayed the importance of economic issues. For example, the Beer Institute stated that the economic well being of certain sectors of the economy should not be a consideration in straightforward application of properly enacted Federal statutes. It also suggested that some of the comments were based on erroneous information that was provided to retailers, notably the false threat that FMBs will disappear from the marketplace if the proposed TTB standard is finally adopted. Instead, the Beer Institute suggested that these products would continue either as distilled spirits products or as reformulated FMBs.

Some individual FMB producers also suggested that the economic issues were not significant. Anheuser-Busch acknowledged that, as with any new process, there may be associated transition costs, and it stated that even the 51/49 standard would require process changes and associated transition costs for most producers. Anheuser-Busch commented that it expected the total cost impact across the company's system to be minimal, ranging between a small investment in capital and a net cost savings due to process and material changes. In either case, the brewer did not anticipate that the slight change in cost would impact FMB prices for its wholesalers, retailers or consumers.

Miller commented that there are costs that have been, and will be, incurred as a result of the proposed new standard; however, it accepted those costs as a part of doing business in a regulated industry. Neither brewer submitted an estimate of the costs they expected to incur; nor did they explain precisely how they would reformulate their products to minimize the cost of compliance.

Some supporters of the 0.5 percent standard commented that the standard would not adversely affect wholesalers or retailers, and that in fact, the standard will bring clarity to the marketplace and preserve the FMB category for wholesalers and retailers. Without a clear standard, these commenters believe that the States would take action and may ultimately classify these products as distilled spirits. Such reclassification would negatively affect wholesalers and retailers because in certain States they would no longer be able to sell these products.

2. Comments Opposed to the 0.5% Standard

Opponents of the proposed 0.5% standard submitted a great deal of data about the estimated economic impact of the proposed rule. The FMBC submitted an economic study indicating that adoption of the proposed rule would have an adverse impact on the FMB industry amounting to over $600 million over the next 4 years. Other commenters argued that the proposed 0.5% standard would have negative cost implications for the industry, the public, and the Federal Government, as set forth below.

Consumer Prices. Many commenters expressed concerns that the cost of FMB products would rise if the proposed rule were adopted. As previously noted, several thousand consumers commented against the proposed rule on various grounds, including the concern expressed by many that the 0.5% standard would result in higher prices for consumers.

Disruption to Existing Businesses. The FMBC commented that the proposed 0.5% standard would profoundly threaten the FMB business of its members. It stated that these companies had relied on longstanding Federal policies to create beverages that consumers enjoy and had invested millions of dollars in promoting these brands. The FMBC suggested that any change would disrupt and possibly damage the business of its members; however, they were willing to adjust to a majority standard. The FMBC argued that the proposed 0.5% standard presented a much more dire threat to the business investment of its members, without a sound policy justification behind it.

Research and Development Costs. Many commenters suggested that compliance with a new standard would force brewers to incur extensive upfront manufacturing costs for research and development to create new formulations for existing products. According to these commenters, the 0.5 percent standard would require most manufacturers to reformulate their existing products. They stated that reformulation would be quite costly in that it would require large amounts of capital to purchase new equipment, investment in expensive technologies and treatment processes, and to advertise the newly reformulated products.

Loss of Sales Due To Reformulation. Several FMB producers commented that even if they can reformulate their products to comply with the 0.5 percent standard, they believe they may not be able to achieve the same taste profile as their existing products. They indicate that this would cause them to lose customers, thereby reducing their sales and revenue.

ECS Study. The FMBC contracted with Economic Consulting Services, LLC (ECS) to conduct an economic assessment of the impact that both the 0.5 percent standard and the majority standard would have on the domestic industry. The ECS assessment relied on information available to the public as well as information it obtained by surveying the FMBC's members. Sales by the members of the FMBC comprise approximately 56 percent of the FMB market.

The ECS found that, for various reasons, the FMBC's members unanimously responded that they would choose to reformulate their products to comply with either standard rather than sell them as distilled spirits specialty products. They expected substantial costs associated with reformulating current products to comply with either standard. ECS estimated losses based on expected loss in volume, expected upfront capital costs, expected upfront research and development and test marketing costs, expected losses in operating income, and expected capital losses. ECS then extrapolated the data they obtained from FMBC members to the entire FMB industry based on market share data.

Specifically, the ECS estimated the cost to comply over the next four years to be:

COSTS TO COMPLY (IN MILLIONS) OVER 4 YEARS

Costs to	Majority standard	0.5% Standard
FMBC Members	186.2	340.5
Entire FMB Industry ..	332.5	608.1
Federal Taxes Foregone	139.1	291.8

ECS indicated that the 0.5 percent standard imposes significantly higher costs because it ''would drive several of the products off retailer shelves completely, denying the producers, distributors and retailers a source of business and profits and denying customers a product they have come to enjoy.''

Indirect Costs. Several commenters focused on the indirect costs associated with the proposed rule. For example,

some commenters suggested that Federal Government's revenue collections would suffer because the 0.5% standard would cause sales of FMB products to decline. Several FMB wholesale distributors and other commenters expressed concern that the 0.5 percent standard would cause existing FMBs to be reclassified as distilled spirits, with the result that wholesale distributors would no longer be permitted to distribute them in certain States. These commenters also noted that this reclassification would affect retailers because, in many States, only State stores can sell distilled spirits.

Effect on Small Businesses. Many commenters suggested that the proposed 0.5% standard would have adverse effects on small businesses. Some of these commenters suggested that the costs of complying with any new standard would hurt small companies the most since larger companies possess economy of scale advantages.

TTB received a few comments from companies that identified themselves as small brewers that would be adversely impacted by the proposed rule. It should be noted that, pursuant to the regulations issued by the Small Business Administration, a small brewer is one that has no more than 500 employees. (*See* 13 CFR 121.201). These commenters urged TTB to adopt the 51/49 standard. They suggested that the proposed rule would have a disproportionately large impact on small businesses because they are less able to adapt to the new technology necessary to comply with the proposed 0.5% standard.

Mark Anthony Brands (MAB), a member of the FMBC, is the national distributor and marketer of several popular FMB products. MAB and its production affiliate, Mark Anthony Brewing, Inc., contract with four U.S. co-packing facilities to produce its FMB products. [In this document, references to ''co-packing'' cover situations where one brewer produces and bottles for another brewer pursuant to a contract or where a brewer uses another brewer's premises under an alternating proprietor arrangement.] MAB suggested that TTB should abandon the 0.5% proposal in favor of the majority standard because the latter did not threaten the competitive viability of small companies like MAB and its co-packers. MAB suggested that the 0.5% standard would threaten the viability of the few regional breweries that currently co-pack FMB products for MAB and others.

City Brewing Company stated that it owns and operates a 5-million barrel capacity brewery in La Crosse, Wisconsin, which employs 350 people. The brewery was closed in 1999, but resumed operations in 2000 capitalized with funds contributed by employees and local investors. It adopted a contract-brewing business strategy because the beer brands formerly produced by the brewery were purchased and are now controlled by a major brewery. City Brewing Company stated that the consolidation of U.S. breweries had virtually eliminated all excess brewing capacity for beer marketers other than the largest U.S. brewers. The brewery stated that it has been profitable since resuming operation, but it expressed concerns that the proposed rule might result in a loss of business for FMB producers, which would have a significant negative impact on the brewery.

A small brewery in North Carolina, Carolina Beer & Beverage Company, stated that adoption of the 0.5% standard would have a ''profound adverse impact'' on both this brewery and similar small brewers. The brewery urged adoption of the majority standard instead. Carolina Beer & Beverage stated that 70% of its revenues are derived from FMBs, and it noted that it had invested significant amounts of capital and resources in order to produce FMBs that comply with longstanding Federal policies. This brewery suggested that if TTB adopted the 0.5% standard, it was unlikely that it could to maintain its competitiveness in the FMB industry and that such a standard could even threaten the company's ability to stay in business.

In addition, many distributors commented on the adverse impact of the 0.5% standard. For example, United States Beverage, a small distributor located in Connecticut, commented that it employs 85 people and that FMB products support over 70% of its revenues. This commenter stated that the proposed 0.5% standard would have ''devastating'' effects on the industry. United States Beverage also suggested that while reformulation might be only an inconvenience to the largest brewers, it would be an ''operational impossibility'' for a smaller brewer.

B. Effect on Current Products and New Product Development

In Notice No. 4, TTB sought comments relating to the effect of the proposed regulations on the viability of products currently on the market. We stated we were particularly interested in comments addressing whether products on the market could be made under the proposed standard. Additionally, we sought comments on how the adoption of the 0.5% added alcohol standard would affect taste, shelf life, stability, or other characteristics of these products. We also sought comments on whether production practices are available to produce FMBs with the desired product profile and still comply with the proposed standard. Finally, we sought comments as to whether another standard, such as the 51/49 standard, would be more appropriate for these products.

1. Comments Supporting the 0.5% Standard

Anheuser-Busch commented that it is capable of producing FMBs under the 0.5% standard and is preparing to do so. The brewer stated that its brew masters have already developed reformulated products that will be indistinguishable from the current FMB products they produce and sell. Anheuser-Busch indicated that these reformulated products would have the same clarity, aroma, and taste profile of their current products. Anheuser-Busch further stated that reformulation could be done and that no FMB producer should lead TTB to believe otherwise.

Miller also commented that its products could be produced under the proposed standard without compromising their taste or their high quality standards. Furthermore, the brewer indicated that it has successfully produced prototype products that comply with the 0.5% standard and has tested the acceptability of these products with expert tasters and others. These tests confirm that the reformulated product satisfies the taste profile of the original product.

Miller further stated that shelf life and product stability are not expected to be barriers to complying with the new standards. Miller stated that:

> Shelf life will be reduced to that of a traditional beer, i.e., approximately four months which is a significant reduction from the six to 12 month shelf life currently applicable to Flavored Malt Beverages produced today. Because it will be consistent with traditional beers, however, we do not anticipate shelf life or product stability to be an insurmountable problem with the reformulated products.

Other commenters stated that since certain brewers have already demonstrated their ability to produce FMBs in accordance with the 0.5% standard, they believe that these products will be available to wholesalers and retailers in all States with no interruption and no discernable taste differences.

Coors commented that the 0.5% standard ''is also fair because it does not prohibit any current product. Just because many of the current 'flavored

malt beverages' may need to be reclassified as distilled spirits does not mean that the TTB proposed regulation will 'kill the category,' as some might claim.'' Coors suggested that under the proposed rule, products containing 0.5% or more alcohol from the distilled spirits components of added flavors could continue to be produced, but would be regulated as distilled spirits products.

2. Comments Supporting the 51/49 Standard

While the major brewers claimed that product reformulation under the 0.5% standard would not be a problem, as previously noted in this preamble, other FMB producers suggested that this would have a significant impact on their businesses, resulting in higher costs for research and development, new equipment, and marketing, and the possibility of reduced sales due to consumer rejection of reformulated products.

Furthermore, several members of Congress expressed concerns about the costs of reformulation and the possible risks posed by such reformulations to the FMB industry. For example, one U.S. Senator stated:

> If the new formulation standards increase the costs of producing FMBs, and alter their taste such that consumers are reluctant to purchase them, the FMB market will decline. This decline in profitability will surely drive some FMB manufacturers out of the market, and reduce competition in the marketplace.

This Senator urged adoption of the 51/49 standard. Another Senator suggested that the proposed standard ''would likely change the taste and character of FMBs—products which have attained broad consumer loyalty. There is no doubt that this outcome would provide FMB's rivals with a distinct competitive advantage.''

Numerous State lawmakers opposed to the 0.5% standard commented that if TTB establishes the 0.5% standard, it would force FMB brewers to make costly changes to their current production processes. They indicated that TTB's adoption of the 0.5% standard would force FMB brewers to increase the amount of malted barley and other traditional ingredients used in an FMB, probably resulting in very differently tasting products.

As indicated earlier in this comment discussion, the Flavor and Extract Manufacturers Association of the United States (FEMA) urged TTB to reconsider the proposed 0.5% standard because it would significantly restrict the amount of alcohol contributed to the finished product from flavors, thus making it impossible for flavor chemists to satisfy the consumer desire for the distinctive FMBs currently sold.

FEMA noted that flavors contain ethyl alcohol because it is a safe, economical, and effective extraction medium for fruits, nuts, and botanicals, as well as a diluent for polar and non-polar flavor chemicals. FEMA also stated that fruit essences and distillates, which are used extensively in the creation of natural fruit flavors, contain an appreciable amount (up to 20–25%) of naturally occurring ethyl alcohol.

FEMA stated that, because of their composition, alcohol beverages require higher flavor loads to deliver pleasing characterizing flavors. It stated that while many non-alcoholic beverages use emulsions to deliver flavor systems, this is not possible in alcohol beverages because the destabilizing effect of the ethyl alcohol will produce precipitation and oil separation in the final beverage. According to FEMA, this means that the higher flavor level and the dependence on ethyl alcohol as the only reliable solvent makes it necessary to exceed the 0.5% limitation to manufacture acceptable and stable products.

FEMA noted that the ATF study referenced in Notice No. 4 found that most FMBs formulated their products in accordance with ATF Ruling 96–1. FEMA stated this has resulted in the evolution of beverages that deliver to the consumer a clean, pleasant flavor and that have a reasonable shelf life. FEMA further stated that producers have used various treatments to reduce the inherent bitterness and off-flavor characteristics associated with fermented malt beverages. FEMA suggested that if TTB limits the contribution of alcohol from flavors to less than 0.5%, that restriction would negatively impact the taste of FMBs and limit the shelf life of these products.

FEMA noted that malt-based beverages require a higher percentage of flavor addition than other alcohol beverages due to the more pronounced organoleptic properties of the malt base itself. Malt-based products have an aftertaste that is difficult to overcome. The aftertaste and malty off-characters tend to accentuate with increased exposure to heat. Limiting the amount of alcohol derived from flavor severely limits the opportunity to use vanilla, cocoa, coffee, and other botanical extracts that often require usage levels of 3% or higher in the finished products.

In conclusion, FEMA stated that limiting the contribution of alcohol content by flavors to less than 0.5% would change the overall taste profile of these products, and the consumer will ultimately receive a different tasting, less acceptable beverage. The change in flavor will be caused by a combination of increased malt base percentages and off-flavor contributed by the malt. FEMA stated that limiting either the ingredients that may be used in flavors or the alcohol contributions from flavors would make it impossible for manufacturers to continue producing many of the malt beverages being sold today and would severely limit the flavor industry's opportunity for new product development.

3. Neutral Comment

Finally, Gallo stated that it had conducted a study involving the aging of reformulated products under normal conditions to determine the impact of the proposed changes to the alcohol source standards on FMBs. Gallo studied two of its 13 FMB products, comparing their current formulation with both standards aired in Notice No. 4. Due to the limited time available, Gallo noted that it was only able to evaluate these products as they would age under normal shipping and storage conditions 3½ months after production.

After evaluating the results, Gallo determined that the study was inconclusive. According to Gallo, it appeared that the change in malt percentage impacted each product differently. Gallo concluded that ''[t]he indication is that all of our products must be studied individually to understand the full impact of the proposed change. There was no time to explore this issue in time for these comments.'' Gallo stated that, in light of the inconclusive results from the study, it took no position on the proposed definitions for beer and malt beverages.

Gallo did indicate that it plans to continue to produce and market FMBs under either of the standards aired for comment in Notice No. 4. However, it pointed out that either new standard would require Gallo to invest in new equipment to produce additional volumes of malt base. Either standard would also force Gallo to develop new malt fermentation techniques and production techniques to provide a malt base that results in products with a flavor and taste profile that meets current consumer expectations. This, Gallo noted, might require development of new technology and different equipment.

C. Effect on Competition

1. Comments in Support of the 0.5% Standard

Many small craft brewers expressed support for the 0.5% standard based on their view that the arrival of FMBs in

the marketplace has had a negative effect on sales of traditional malt beverage products. Some commenters suggested that TTB should adopt the 0.5% standard for added alcohol because this action would benefit small brewers who generally do not produce FMBs.

Many small brewers and their employees expressed their concern that the arrival of FMBs during the past years has weakened the brewing industry. They explained that over the past 25 years there has been a major revitalization of the brewing industry, with smaller brewers and brewpubs now found in every State and metropolitan area and in many small towns. They indicated that the number of microbreweries closing since the arrival of the newer FMBs has exceeded the number of microbreweries opening—reversing the trend and weakening the industry.

One small brewer stated that he expects to compete with other quality small brewers in the region, but would not like to see huge corporations with unlimited legal and marketing funds compete against him with products that are not real beer. Another small brewer commented that if he can make a wonderful tasting product with this standard, then the larger competitors could do it also. A third brewer indicated that the manner of FMB production explained in Notice No. 4 avoids many of the costs associated with the volume demands of beer production and storage. He indicated that he believes this results in an unfair competitive advantage over traditional and craft brewers.

2. Comments in Support of the 51/49 Standard

Many opponents of the 0.5% standard suggested that adoption of the standard would have an anti-competitive effect. For example, the FMBC suggested that support for the 0.5% standard appeared to come from the many industry members who, for competitive reasons, would benefit from the complete demise of the FMB category or would derive a competitive advantage from a 0.5% rule. The FMBC stated that the 0.5% standard, if adopted, would give a competitive advantage to some FMB producers at the expense of others. In support of this claim, the FMBC pointed out that America's largest brewer claimed that it could already produce FMBs meeting the 0.5% standard without compromising product taste or availability. The FMBC stated that this illustrates that, if adopted, the standard would adversely affect competition by forcing competitors to acquire technologies and capabilities similar to those apparently possessed today by the largest brewers. The FMBC added that the marketplace, not the Government, should determine the industry's winners and losers. The FMBC urged TTB to avoid crafting a rule that hands a competitive advantage to some FMB producers at the expense of others.

Mark Anthony Brands (MAB) stated that:

> [F]ederal policies favoring competition demand that TTB consider anticipated anti-competitive effects in choosing between policy alternatives and seek to adopt that alternative which promotes competitive outcomes. The 0.5% standard would favor larger companies, particularly America's (and the world's) largest brewers, and would therefore decrease competition in the FMB market segment. MAB accordingly urges TTB to reject the proposed 0.5% standard in favor of one that allows FMB producers to compete on a level playing field and supports future competition.

MAB suggested that Federal policy strongly favors marketplace competition and discourages the unhealthy concentration of market power in the hands of a few dominant players. MAB also argued that ensuring competition in the alcohol beverage industry played an important role in motivating Congress to enact the FAA Act, and it cited a provision of the legislative history of the FAA Act, which indicated that its promoters wanted to ''enable small units to get into the liquor industry.'' MAB also noted that the burdens of regulation fall disproportionately on small companies, citing a provision of the legislative history of the Regulatory Flexibility Act which recognized that even if actual regulatory costs are equal between competing large and small firms, small firms have fewer units of output over which to spread such costs and are thus unable to take advantage of the economies of scale.

As noted earlier in this comment discussion, MAB argued that TTB should abandon the 0.5% proposal in favor of the majority standard. MAB stated that the past two decades have seen the concentration of brewing capacity in the United States into a very small number of hands and that while America is home to over 1,400 breweries, the three largest brewers own the facilities responsible for producing over 90% of domestic beer and malt beverages. Noting that most other brewers are small ''micro'' and ''regional specialty'' operations that produce their own products, the commenter argued that these small brewers would not have the capacity to produce a successful new brand. MAB suggested that because of the costs of a new brewery, combined with the high failure rate of new products, production capacity presents a formidable barrier to entry to the U.S. beer market.

Accordingly, MAB stated that the ''few remaining 'old regional' brewers today represent the only realistic way to quickly access significant production capacity in the U.S.'' MAB argued that the demise of America's ''second-tier'' brewers over the past 10 years has taken vast amounts of brewing capacity off-line, and that a few old regional breweries, which currently co-pack FMB products for MAB and others, own the remaining excess U.S. brewing capacity. MAB concluded that a decline in FMB sales would ''likely'' cause these brewers to close their doors altogether and that this resulting loss of production capacity in the United States would add costs and drive jobs overseas.

MAB also suggested that the 0.5% standard represented a ''win-win'' scenario for the largest brewers if they indeed possess the technology to produce FMBs under that standard that achieve the same taste profile as existing products. MAB stated that this technology would allow them to dominate the FMB category with their products. On the other hand, if consumers reject FMBs produced under the 0.5% standard, MAB stated that ''the largest brewers will benefit because the elimination of the FMB category will protect their extensive investments in the production and distribution of traditional beer and malt beverage products.''

Several members of Congress indicated that the 0.5% standard seems designed to distort the existing market by providing an artificial competitive advantage for companies that currently dominate the domestic beer industry but that have introduced under-performing and less popular FMB products.

We also received a comment from the British Embassy suggesting that the proposed rule would place an unfair competitive disadvantage on companies based in the United Kingdom (U.K.), including the U.S. market leader, threatening jobs in the U.K. and the United States, as well as thousands of dollars in investment.

D. Effect on the Retail Licensing System and Overall Marketplace

1. Comments in Support of the 0.5% Standard

Many commenters stated that the 0.5% standard would ensure product integrity, preserve long standing distinctions imposed on beer, wine, and spirits, and provide a uniform and

consistent classification system on which States, wholesalers, retailers, and consumers can rely. They stated that, if adopted, the standard would help to maintain an orderly marketplace, meet consumer expectations for consistent products, and help sustain the long-term development of the FMB category.

According to several commenters, implementation of the 0.5% standard would avoid costly and confusing disruptions in State licensing, taxation, and distribution policies. Several retailers and wholesalers feared that any other standard could have significant consequences for the industry and for thousands of alcohol beverage licensees, most of which are small businesses. Without a clear standard, some commenters believed that the States would take action and may ultimately classify these products as distilled spirits. Such reclassification would negatively affect beer wholesalers and retailers because in certain States they would no longer be able to sell these products.

2. Comments in Support of the 51/49 Standard

In opposition to the 0.5% standard, several FMB wholesalers expressed concern that the standard would cause TTB to reclassify existing FMBs as distilled spirits. Some commenters expressed a fear that if TTB reclassifies these products, certain States will no longer permit beer wholesalers to distribute them. Some commenters pointed out that this reclassification would also affect retailers because in many States only State-operated stores can sell distilled spirits.

Many commenters, chiefly wholesalers and their employees, as well as employees of FMB producers, expressed the fear that they will lose their jobs if TTB approves the 0.5% standard. One industry association cautioned that approval of this standard would cost jobs in production facilities all across the country. Another commenter pointed out that thousands of businesses rely on sales of FMBs for revenue, from the product itself and from secondary sales. The commenter indicated that, if implemented, Notice No. 4 would threaten sales and put further pressure on small businesses already pushed to the brink.

Diageo explained that its products have generated numerous jobs throughout the country. Diageo noted that it not only employs numerous production and sales employees, but also generates work for numerous suppliers in areas such as glassware and packaging materials. Diageo stated that two of its facilities are involved in the production of FMBs and contract production has occurred at five non-Diageo facilities during the past three years.

A U.S. Senator commented that FMB bottling facilities provide jobs and millions in dollars to local economies through wages, taxes, services purchased, and other means. He stated that any regulation that threatens the market position of these products puts those jobs at risk. Other U.S. Senators commented that this proposal could have a profound and devastating impact on employees in their States and across the nation. Two U.S. Senators indicated that FMBs constitute a booming industry that has brought a direct benefit to their State, and they do not wish to see its growth and associated jobs curtailed in such an unnecessary fashion.

A wholesaler expressed concern over some small brewers' claims that the 0.5% standard will not harm America's small brewers. This commenter asserted that these small brewers have never produced an FMB product and have no intention of competing in the FMB category in the future. Since these small brewers have no stake in the outcome of this proposed rulemaking, their claims should not be considered as authoritative. Other commenters pointed out that it is not the job of TTB to favor one industry over another.

E. TTB Response

1. Regulatory Burdens and Costs Imposed by the Proposed Rule

When we issued Notice No. 4, we certified that the proposed rule would not have a significant impact on a substantial number of entities. We stated our belief that 10 or fewer qualified small breweries manufacture FMBs subject to the rule. We asked any small brewery that believed it would be significantly affected by this rule to let us know and tell us how it would affect them. We also certified that the proposed rule was not a significant regulatory action, as defined by Executive Order 12866, because it would not have an annual effect of $100 million or more on the United States economy.

After reviewing the comments, we have not changed our position on these matters. We do not believe that the proposed rule would have had a significant economic impact on small businesses, within the meaning of the Regulatory Flexibility Act. While we received many comments suggesting that there would be numerous indirect effects on wholesalers and retailers of FMBs, we received only a few comments from brewers that identified themselves as small businesses producing FMBs that would be adversely impacted by the proposed 0.5% standard.

Nor do we believe that the proposed rule would have been a significant regulatory action within the meaning of Executive Order 12866, notwithstanding the suggestion to the contrary in the ECS Study. The primary data for the analysis in that study comes from FMBC members. Because much of the economic data submitted by FMBC members is proprietary and confidential, TTB cannot verify the accuracy of the figures.

Furthermore, we are concerned that certain parameter assumptions and calculations in the ECS study are questionable and could lead to an overstatement of loss. For example, since the study separately included estimates of declines in Federal corporate tax revenue, it should have presented its estimates of declines in profits net of taxes. Under the 0.5% standard, ECS calculated that Federal corporate tax revenue would decline by $94 million in present value due to reduced profits for FMBC firms over the period 2004–2007. Accordingly, the expected after-tax decline in profits for FMBC firms would be $247 million rather than the $341 million decline in profits listed in the study. The study's use of discount rates of 20 and 30 percent to account for the increased uncertainty of future income appears to assume a large risk-premium. The treatment of capital expenditures is unclear, and the measurement of capital stock and capital losses is questionable.

Furthermore, there is a methodological flaw in deriving private and public loss totals because the ECS study looked at FMB operations in isolation, without accounting for the potential for increased sales of other types of alcohol beverages. For example, we do not agree that either the proposed 0.5% standard or the 51/49 standard would result in significant losses of Federal tax revenues as a result of lowered sales of FMBs. Even if the reformulation of popular FMB products results in lowered sales for these products, it does not necessarily follow that the Federal Government would lose tax revenues as a result. Because of changes in consumer preference and other factors, the relative market share of specific products often fluctuates. However, it is logical to assume that most of the FMB consumers who might abandon their favorite products as a result of changes in taste profile would substitute other alcohol beverages for them.

Thus, it is unlikely that any changes in the relative market share of FMB products would result in a significant net loss of the Federal excise taxes collected on alcohol beverages. Furthermore, because many FMB producers also manufacture other types of alcohol beverages, losses in sales of FMB products may be offset by increased sales of other types of alcohol beverages.

Finally, we do not believe that the economic impact on FMBC members can necessarily be extrapolated to the rest of the FMB industry based simply on market share. In fact, the FMBC, as well as other commenters opposed to the proposed 0.5% standard, have argued in this rulemaking proceeding that the 0.5% standard would benefit America's largest brewers at the expense of their competitors. The comments show that the expected costs of compliance vary from producer to producer. For example, as previously noted, Anheuser-Busch commented that it expected the total cost impact to be minimal and did not anticipate the ''slight change in cost'' to impact FMB prices for wholesalers, retailers, or consumers. Opponents of the 0.5% standard cannot argue with any consistency that the standard would unfairly benefit their competitors, while still maintaining that those competitors would suffer the same costs and losses as they would.

Nonetheless, after carefully considering all of the comments on this issue, TTB is persuaded that implementation of the proposed 0.5% standard might impose economic burdens on a sector of the FMB industry and adversely affect the viability of some small brewers who produce FMBs, as well as their ability to compete within the beer industry.

The comments indicated that while some brewers would be able to reformulate without incurring significant costs, many producers of FMBs believe that reformulation of their products to comply with a 0.5% standard would result in significant costs. The FMB producers that commented on this issue indicated that they would reformulate their products as FMBs rather than produce them as distilled spirits products. Accordingly, the costs associated with the 0.5% standard are not connected with the higher Federal excise tax imposed on distilled spirits products. Instead, these costs are brought about by the need to conduct research and development, and to invest in new equipment and technology necessary to produce FMBs that meet the 0.5% standard. Many FMB producers indicated that the costs of complying with a 51/49 standard would be significantly lower. Those FMB producers that commented in favor of the 0.5% standard did not specifically address the relative costs of the two standards, although one brewer noted that either standard would impose some costs.

In addition to the costs associated with producing new FMBs that met the new standards, many FMB producers expressed concerns that they would not be able to achieve the same taste profile under the proposed 0.5% standard, and that the 51/49 standard would afford them more flexibility in meeting the expectations of consumers in this area. These producers are concerned that if they attempt to reformulate their products in accordance with the 0.5% standard, consumers will not accept the reformulated products and product sales will go down, possibly resulting in the disappearance of some current FMB products from the marketplace.

A comment from FEMA supported this concern, noting that the 0.5% standard would make it impossible for manufacturers to continue producing many of the malt beverages being sold today and would severely limit the flavor industry's opportunity for new product development. We also find persuasive the comment from Gallo, which did not take a position on the 0.5% or 51/49 standard, but which noted the difficulty of predicting the impact of either standard on the taste profile and shelf life of FMB products.

Although the number of small brewers affected by this rule is not large, we note that several commenters indicated that there are fewer regional brewers with excess production capacity in the United States today than in the past. Many commenters indicated that the proposed 0.5% standard could have a significant impact on those regional brewers that co-pack FMBs for other companies. In particular, we are concerned that the economic impact of the proposed rule may be disproportionately borne by those small brewers who lack the economies of scale possessed by their larger competitors, and who would be less able to absorb the costs associated with reformulation of products in accordance with the more stringent 0.5% standard.

As a related matter, TTB is concerned that the proposed 0.5% rule might affect the ability of some small brewers to compete within the brewing industry. It should be noted that we do not agree with those comments that suggested that one of the purposes of the proposed rule was to protect either large or small brewers from competition with producers of FMBs. It is not TTB's intention in this rulemaking action to favor any one segment of the FMB or beer industry over another, to remove competition in the marketplace, or to destroy a particular category of malt beverages simply because it is preferred by many consumers over more traditional brewery products. Our statutory mission under the FAA Act is to promote fair competition within the malt beverage industry, not to favor one segment of the industry over another. Accordingly, the purpose of the final rule is to treat all segments of the beer and FMB industries in a fair and even fashion.

2. Options To Reduce Regulatory Burdens and Costs

Even if a rule is not a significant regulatory action, Executive Order 12866 requires us to design the regulation in the most cost-effective manner to achieve the regulatory objective.

We have considered several options to reduce the regulatory burdens and economic costs imposed by the proposed rule. One of those options is to exempt small businesses from the requirements of the rule. However, this option is not viable for several reasons. First, one of the primary purposes of the rule is to enhance consumer protection; this purpose would be defeated by an exemption for small businesses. Furthermore, some small brewers who produce FMBs do so under contract with larger companies, and allowing an exemption for these companies would raise significant fairness issues. Finally, and most important, since the IRC does not authorize such a difference in tax treatment for small producers of FMBs, we do not believe we have statutory authority to implement such an exemption by regulation.

A second option we considered was the delay of the effective date of the final rule in order to provide adequate time for the industry to make the necessary changes to product formulation. As discussed in more detail later in this document, we have delayed the implementation of the final rule for one year. We believe this one-year delayed effective date will provide ample time for the FMB industry to conform to the requirements of the final rule.

The final option we considered was adoption of the 51/49 standard instead of the 0.5% standard. Based on the information in the rulemaking record, we have concluded that compliance with the 51/49 standard will be significantly less burdensome and costly than compliance with the 0.5% standard. Furthermore, based on the

comments, it appears that adoption of the 51/49 standard would not adversely affect the ability of small brewers to compete in the FMB marketplace and would reduce the impact of the changes needed to reformulate existing products to comply with the final rule.

As we considered the comments and weighed the relative merits of the 0.5% standard and the 51/49 standard, we also considered the issues of costs and other regulatory burdens. As shown in the remainder of this document, we have tried to address these issues at each step, so that our final rule will achieve the goals of this rulemaking process—protecting the revenue, ensuring that FMB labels provide the consumer with adequate information about the identity of the product and do not mislead consumers, and setting a Federal standard for the use of added alcohol flavors in malt beverage products—while minimizing unnecessary costs and other regulatory burdens on the affected industry.

For these and other reasons set forth later in this document, we have concluded that we should adopt the 51/49 standard for beers under the IRC and for malt beverages under the FAA Act. TTB believes that by allowing FMBs to comply with the less stringent 51/49 standard rather than the proposed 0.5% standard, we meet the goals of this rulemaking proceeding and, at the same time, lessen the potential economic costs and other regulatory burdens imposed on members of the FMB industry. The other reasons for adopting the 51/49 standard are set forth elsewhere in this preamble.

VIII. The 0.5% Standard vs. the 51/49 Standard—Other Issues

A. Comments in Favor of the 0.5% Standard

1. Consistency With the IRC and the FAA Act

Many commenters found support for the proposed 0.5% standard in the IRC provisions establishing 0.5% as a dividing point between products subject to tax under the IRC and those that are not subject to tax. For example, the Beer Institute noted that the IRC ''clearly provides the Secretary with broad authority to issue and enforce regulations, to classify products for tax purposes, and to establish a workable administrative system to collect taxes.'' The Beer Institute stated that classifying intoxicating liquors based on the 0.5% cutoff has a long history, dating back to 1902 and continuing through Prohibition. Miller commented that the ''use of what could be characterized as a *de minimis* threshold such as 0.5% is a common sense approach to the regulation of alcohol beverages considering that small amounts of alcohol are present in many other beverage products such as juice, soft drinks, soda, and non-alcoholic beers made by brewers.''

Several commenters noted that the IRC and FAA Act definitions of ''beer'' and ''malt beverage,'' respectively, contemplate that the alcohol content in those products must be derived from fermentation, not from added distilled spirits. Coors argued that while some may argue that there is a difference between combining distilled spirits ''directly'' with a malt base and doing so ''indirectly'' through the addition of flavors, it believed that ''this is a distinction without a difference. Congress clearly intended to classify any alcoholic beverage that contains a mixture or dilution of distilled spirits as 'distilled spirits.' ''

Several brewers commented that neither law nor good policy supported the 51/49 standard. Coors suggested that while the proposed 0.5% standard allowed the addition of a *de minimis* amount of flavors, a 51/49 rule went beyond the allowance of a *de minimis* quantity of flavors. Anheuser-Busch stated that neither the FAA Act nor the IRC provided a basis for TTB to adopt the 51/49 standard, arguing that ''[t]he difference of only a couple of drops between a product that is 'mostly' a beer versus 'mostly' a distilled spirit would make a mockery of the law, public policy and the many years of distinction between malt beverages and distilled spirits.''

2. Consumer Deception or Confusion

Many commenters supported the proposed 0.5% standard based on the premise that it would reduce consumer confusion. These commenters included consumers, State senators and representatives, beer distributors, merchandisers, Members of Congress, State governors, State ABC commissions, breweries, national associations, State licensing and taxing authorities, State coalitions, and industry members.

As indicated in the comment overview, several thousand commenters stated that the establishment of a 0.5 percent standard would eliminate consumer confusion, preserve the integrity of the beer category, or provide beer consumers with a clear understanding of the product. Many commenters suggested that it was important to define the difference between beer and other alcohol beverages, such as distilled spirits. For example, we received thousands of comments suggesting that the proposed 0.5% standard was the best way to maintain ''clear distinctions between beer and liquor.''

Many commenters agreed that TTB has a responsibility to protect consumers through accurate labeling, to ensure that products labeled as ''flavored malt beverages'' are truly products that have alcohol obtained by the fermentation of malt. Others believed the proposed rule would promote consistency in consumer expectations, clarify Federal public policy, and end any confusion that may linger from the past or that may arise from alternative proposals.

Several commenters suggested that, in the absence of a national standard, States would enact differing standards under which the same product may be sold as a ''beer'' in one State and as a ''distilled spirits'' product in another State. The commenters suggested that these inconsistent standards would confuse consumers.

Many commenters focused on industry and consumer understanding of the terms ''beer'' and ''malt beverage.'' For example, the Brewers' Association of America (BAA), a 62-year-old trade association representing the interests of more than 1,400 small American breweries, submitted a comment in support of the 0.5% standard. The BAA stated:

> The perception of the general public is that beer is a beverage with malt flavor and hop bitterness, flavor and aroma. Many small brewers currently produce flavored malt beverages that have these characteristics. The products currently classified as FMBs and recently analyzed by TTB display none of these characteristics, and should not be considered or taxed as beer.

Many commenters stated that many FMBs do not meet the traditional definition of beer or ale and thus blur the line between spirits-based beverages and traditional beers and ales. Others argued that the consumer does not expect beer to contain added distilled alcohol from outside sources. Some suggested that it was deceptive to characterize FMBs as malt beverages since many FMBs do not resemble or taste like beer.

3. Preserving the Integrity of Beer

Many commenters stated that beer and malt beverages are unique beverages with a unique history. We received thousands of comments from the beer industry urging TTB to maintain this distinction by adopting the 0.5% standard. These commenters noted that Federal and State governments have historically regulated and taxed beer and malt beverages differently from

distilled spirits. These commenters suggested that the 0.5% standard was the only way to maintain the integrity of beer and the brewing process.

Many commenters were of the opinion that the 0.5 percent standard will ensure that FMBs are produced as traditional malt beverages using traditional brewing methods and processes. A large number of commenters stated that the classification of FMBs as beer threatens beer culture in the United States. In this regard, they pointed out that beer has unique attributes as a beverage—including malt-flavor, hop-bitterness, and aroma. Many of these commenters argued that the integrity of beer and the brewing process must be preserved.

Some commenters suggested that beer and FMBs are produced differently and should be categorized separately in the alcohol beverage market. Many commenters pointed to the history of alcohol beverages in the United States as evidence of the longstanding distinction between malt beverages and distilled spirits. They stated that these differences are well defined by the taxation structures at the State and Federal levels and these differences should be maintained.

B. Comments in Favor of the 51/49 Standard

1. TTB's Statutory Authority Under the IRC and the FAA Act

Several FMB producers suggested that TTB lacks statutory authority to impose a 0.5% limit on the use of alcohol derived from flavoring materials in the production of FMBs. It should be noted that while these commenters also believe TTB lacks authority to impose any limits on the use of alcohol derived from flavoring materials in the production of malt beverages, they nonetheless supported the 51/49 option as a matter of policy.

Authority Under the IRC. Several commenters stated that the current definition of the term ''beer'' in the IRC, at 26 U.S.C. 5052, gives brewers substantial discretion in formulating their products and places no limits on the use of nonbeverage flavors in products taxed as beer. They noted that prior IRC provisions included restrictions on producing a beverage from nonbeverage articles such as flavors, and they suggested that the current IRC's silence on the issue represents a deliberate choice by Congress not to restrict flavor use in the production of beer. Furthermore, the comments noted that the statutory definitions of beer and malt beverages do not specify any minimum amount of alcohol to be derived from fermentation. The FMBC suggested that the IRC places a practical limit on the use of flavors because of the unpleasant taste of nonbeverage flavors. The FMBC and Diageo both argued that IRC section 5001(a)(2) does not apply to products containing nonbeverage drawback flavors, and that it instead only applies to products containing distilled spirits on which tax has not been paid or determined.

Authority Under the FAA Act. Many commenters also noted that the FAA Act does not place limits on the use of flavors in a malt beverage but instead explicitly authorizes the use of ''wholesome food products'' in malt beverage production (*see* 27 U.S.C. 211(a)(7)). Furthermore, the comments suggested that since the Volstead Act explicitly restricted the use of nonbeverage flavors to make a beverage, the silence of the FAA Act indicates a deliberate choice by Congress to allow the unlimited use of flavoring materials in malt beverage production.

2. Standard Best Supported by Law

Many commenters suggested that if TTB has statutory authority to impose a limit under the IRC or the FAA Act, the 0.5% standard has no basis in Federal law; rather, the 51/49 standard is the proper standard. These commenters pointed out that in Notice No. 4, TTB indicated that IRC section 5052 also would support the issuance of a regulation requiring that a beer or malt beverage must directly derive a majority of its alcohol content from fermentation. The commenters argued that since both the FAA Act and the IRC would support such a standard, TTB did not provide sufficient reasons why it proposed the much stricter 0.5% standard.

3. IRC Regulatory Policy

Many commenters suggested that the 51/49 standard would actually protect the revenue by placing a meaningful limit on the addition of alcohol flavorings to FMBs in a manner consistent with TTB's regulatory policy. For example, one commenter argued that the 0.5% standard is punitive and has no basis in recent TTB policy. This commenter suggested that ATF Ruling 96–1 actually weakened the case for the 0.5% standard since the ruling permits the addition of up to 1.5% alc/vol derived from flavors in beer and malt beverages over 6.0% alc/vol. The commenter stated that in view of this ruling, TTB has failed to present evidence why a far stricter standard, 0.5%, should be used for the definitions of beer and malt beverages.

Some commenters stated that the proposed 0.5% standard would arbitrarily impose a more rigorous standard on FMBs and beer than TTB imposes on other alcohol beverages. The commenters allege, as examples of this disparity in treatment:

- There is no regulatory restriction on the amount of alcohol flavorings used in wine specialty products;
- Fortified wine has less stringent standards for the addition of distilled spirits to the wine base than the proposed 0.5% standard;
- Distilled spirits products may contain up to 50% wine on a proof gallon basis;
- Certain wines may be labeled with a varietal designation if 51% of the grapes are of the labeled grape variety; and
- A TTB regulation, 27 CFR 5.22(b), requires bourbon whiskey to be produced from a fermented mash of not less than 51 percent corn. The other 49 percent may come from any other grain.

Additionally, a number of commenters argued that TTB's general policy on beer ingredients, allowing as little as 25% of the fermentable ingredients to be from malted barley, is significantly more lenient than the proposed 0.5% standard. Some commenters further noted that to label a product ''beer,'' 50 percent of the fermentable base must be a grain. Accordingly, these commenters argued that the 51/49 standard was more consistent with TTB's regulatory policies than the 0.5% standard.

4. Burden of Establishing Consumer Deception

In support of their position against the proposed 0.5% standard, FMBC, as well as several FMB producers, argued that TTB failed to meet its burden of establishing that consumer deception or confusion results from use of the term ''malt beverage'' on the label of a product that derives most of its alcohol from added flavors. These commenters suggested that TTB must first produce evidence to back up its assertion that use of the term ''malt beverage'' on a label leads consumers to believe that a significant portion of the product's alcohol derives from fermentation of barley malt and other ingredients at the brewery, and must secondly demonstrate that the consumer confusion it asserts is material in that it actually affects consumers' purchasing decisions.

FMBC suggested that TTB had not met either of those burdens in Notice No. 4. This commenter argued that the notice contained no evidence of consumer confusion, cited to no

consumer survey, and did not point to a single consumer complaint about the alcohol source in FMBs. FMBC suggested that a final rule could not cure this deficiency as the APA requires TTB to provide the public an opportunity to comment on the basis of new regulations. FMBC also stated that Federal courts today virtually require survey evidence to back up a claim of consumer confusion; mere assertions of administrative expertise, without more, would not carry TTB's evidentiary burden.

Finally, FMBC suggested that TTB bears an even heavier evidentiary burden since Notice No. 4's assertion of confusion directly contradicts its predecessor's pronouncements on the same subject. FMBC pointed out that when TTB's predecessor agency, ATF, decided not to pursue further rulemaking on the use of cocktail names on labels of malt beverage coolers, it concluded, in a letter dated November 17, 1997, as follows:

> Evidence introduced indicates that flavored malt beverages are viewed by consumers as coolers or low alcohol refreshers, and not as a distilled spirits product. Evidence introduced also indicates that the presence of distilled spirits or any similarity of these products to a distilled spirits drink is not a criteria in their selection by consumers.

Accordingly, FMBC, like many other commenters, suggested that TTB's statement in the preamble to Notice No. 4 was inconsistent with the conclusion of its predecessor agency, reached just 6 years before, that consumers did not care about the alcohol source of malt beverage products. The commenters noted that ATF had reached this conclusion after soliciting public comments on the use of cocktail names in the labeling of malt beverages, and that its conclusion was consistent with consumer surveys submitted by malt beverage producers in that rulemaking proceeding.

5. Consumer Survey Conducted by the Luntz Research Companies

MAB retained the Luntz Research Companies (''Luntz'') to survey consumer beliefs about the alcohol source in FMBs, and to ascertain whether any of these beliefs were material to FMB purchasing decisions. Luntz conducted 600 face-to-face interviews of FMB consumers in 3 metropolitan areas—Baltimore, Chicago, and San Diego. The purpose of the survey was to determine if the term ''malt beverage'' led consumers to believe erroneously that the alcohol in an FMB comes from a fermentation process and whether consumer beliefs about the source of alcohol in FMBs were likely to influence the purchasing decisions of consumers.

To determine if the term ''malt beverage'' confused consumers, the research group provided respondents with a bottle of the FMB ''Mike's Hard Lemonade.'' The term ''malt beverage'' appeared prominently on the front label. The survey asked the respondents to look at the bottle and to state if they believed the alcohol came from a distillation or fermentation process, or if they had no belief about the product's alcohol source. The results were as follows:

[In percent]

No belief about the source of alcohol	80
Alcohol comes from a distillation process	11
Alcohol comes from a fermentation process	9

As noted in the table, the Luntz survey found that four out of five FMB consumers had no belief about the alcohol source in an FMB product after examining a bottle of a well-known FMB product prominently labeled as a ''malt beverage.'' Consumers who had a belief about the alcohol source roughly split into those who believed that it contained alcohol from fermentation and those who believed that it contained alcohol from distillation. Of the 9% of the respondents (54 out of 600) who believed the product derived its alcohol from fermentation, approximately 2% (14 out of 600) based this belief on the product's labeling as a malt beverage. MAB asserted that the case law requires a level of confusion far greater than 2% in order to find the existence of consumer confusion in the marketplace.

To determine whether the source of alcohol in FMBs affected purchasing decisions, the survey asked respondents to name the top two most important reasons why they drink FMBs. The results were as follows:

[In percent]

Taste/Flavor	52
New/Different/Not Beer	28
Convenience/Availability	13
Refreshing/Thirst Quenching	12
Easy to Drink/No Alcohol Taste	12
Females Like Them	9
Effect of Alcohol	6
Friends/Family Drink It	7
Given to Me/Bought For Me	5

The survey noted that not one of the 600 respondents stated that the source of alcohol was an important reason for choosing an FMB.

The survey then provided the respondents with a list of nine reasons why someone would choose an FMB, providing as one of the reasons whether the alcohol comes from the fermentation or distillation process. The respondents were asked to choose their top three reasons. The results were as follows:

[In percent]

The Taste	81
Alcohol Strength	47
Convenience	42
Cost	32
What My Friends/Family/Co-Workers are Drinking	32
Advertising and Marketing	21
The Design of the Packaging and Bottle	9
The Image I Want to Portray to People	8
Whether the Alcohol Comes from a Fermentation or Distillation Process	0.2

MAB suggested that the Luntz survey demonstrates that alcohol source is totally immaterial to the purchasing decisions of FMB consumers. When asked for their top two reasons for choosing an FMB, not a single respondent gave alcohol source as a reason. Indeed, taste-related responses topped consumers' criteria for selection, followed by the FMB's difference from beer and its convenience. Even when presented with a list of 9 reasons for selecting an FMB that included alcohol source, just one respondent chose alcohol source as a reason for selecting an FMB. MAB suggested that this evidence conclusively demonstrates that alcohol source is not material to consumers' purchasing decisions, and that to label an FMB as a ''malt beverage'' is not misleading as a matter of law.

6. Standard That Best Prevents Consumer Deception

Some commenters suggested that adoption of the 51/49 standard would better prevent consumer deception than implementation of the proposed 0.5% standard. The FMBC suggested that if TTB was concerned about consumer confusion, it had failed to bear its burden of establishing why the 0.5% standard prevents consumer deception better than a majority or 51/49% standard. As noted earlier in the comment overview, the National Consumers League (NCL) made a similar comment, noting that requiring that the product derive a majority of its alcohol content from malt fermentation would assure that an FMB actually contains a significant concentration of malt. The NCL also questioned whether source of alcohol was in any way material to consumer choice, and urged more complete labeling information on alcohol beverage containers.

As noted earlier in this comment discussion, several commenters pointed out that TTB and its predecessor agency had adopted ''majority'' or ''predominance'' standards for other products. These commenters noted that wine can constitute up to 50% of a distilled spirits product; thus, nonbeverage flavors should be able to contribute up to half (or 49%) of the alcohol content of a malt beverage product.

7. Preserving the Integrity of Beer

The FMBC noted that several supporters of the 0.5% standard cast themselves as defenders of ''traditional'' and ''age-old'' production techniques, but suggested that the brewing industry ''long ago departed from the brewing methods employed at the time current federal and state alcohol control laws were enacted.'' The FMBC suggested that several techniques currently used by brewers are not specifically authorized by law such as the use of high-tech enzymes to enhance fermentation, the use of ''high-gravity'' brewing to produce a high-alcohol product to which water is added just before packaging to make beer, new fermentation techniques that have pushed the upper strength limit of beer to 25% alcohol by volume, and the thousands of adjuncts authorized by the ARM.

The FMBC argued that ''tradition'' arguments play upon the real differences in taste and appearance between conventional beers and FMBs. However, the FMBC asserted that Federal policy long ago abandoned any taste, aroma, or color criterion for products classified as beer or malt beverages. Finally, the FMBC noted that supporters of the 0.5% standard claim that brewers can produce, under the 0.5% standard, FMBs that look and taste exactly like FMBs on the market today. Thus, claimed the FMBC, ''in a wonderfully ironic twist, supporters of the 0.5% standards wrap themselves in the banner of brewing tradition while championing a rule that will accelerate the development and deployment of high-technology processes necessary to produce an FMB under the Notice 4 standard.''

C. TTB Response

1. Statutory Authority

In the preamble to Notice No. 4, TTB set forth, in great detail, its authority to engage in rulemaking to place limits on the use of alcohol derived from flavoring materials in the production of malt beverages. After carefully considering the comments to the contrary, we have concluded that we have authority, under both the IRC and the FAA Act, to issue regulations that establish those limits.

Statutory Definitions. Fermentation is the process by which yeast converts sugar into alcohol and carbon dioxide. Both the definition of ''beer'' under IRC section 5052 and the definition of ''malt beverage'' under the FAA Act focus on fermentation as the source of the alcohol in these products.

The study conducted by ATF in 2002 established that for many FMB products, the major source of alcohol was distilled alcohol rather than fermented alcohol. The results of this study raised the question: Should a product that derives the majority (in some cases up to 99%) of its alcohol from the distilled spirits components of added flavors qualify as a ''beer'' under the IRC, and as a ''malt beverage'' under the FAA Act? TTB concluded that Congress never intended to allow such products to qualify as beers or malt beverages. At the same time, neither statutory definition explicitly excludes beverages that contain alcohol in addition to that produced during their fermentation. Accordingly, we proposed a regulation that would allow only less than 0.5% alcohol by volume derived from flavors, and we also sought comments on an alternative proposal that would require that at least 51% of the alcohol in a beer or malt beverage must be derived from fermentation at the brewery.

After carefully considering the comments on this issue, as well as the statutes that provide us with authority to issue regulations on standards for beer and malt beverages, we have concluded that we have statutory authority to limit the alcohol that may be added to ''beers'' under the IRC, and to ''malt beverages'' under the FAA Act, and to ensure that they derive most of their alcohol from fermentation at a brewery rather than from the distilled spirits components of added flavors.

Authority Under the IRC. TTB does not agree with those commenters who suggested that malt beverages may contain unlimited quantities of distilled alcohol from added flavors without falling under the statutory definition of a distilled spirit. One commenter argued that the provisions of IRC section 5001(a)(2) apply only to products containing distilled spirits on which the tax has not been paid. Because the distilled spirits used in nonbeverage drawback products are tax determined or taxpaid, the commenter argued that this section does not apply to products containing flavors.

TTB does not agree with this interpretation of the IRC. Section 5001(a)(2) provides as follows:

> (2) *Products containing distilled spirits.* All products of distillation, by whatever name known, which contain distilled spirits, on which the tax imposed by law has not been paid, and any alcoholic ingredient added to such products, shall be considered and taxed as distilled spirits.

The commenter misreads this section by suggesting that the critical issue is whether the distilled spirits contained in the product have been taxpaid. Instead, the statute clearly imposes a tax on all products of distillation that contain distilled spirits, as long as the tax imposed by law on the finished product has not been paid.

This provision of the IRC must be read in conjunction with other IRC requirements. Subject to certain exceptions not relevant here, a person who manufactures, mixes, or otherwise processes distilled spirits is a processor within the meaning of IRC section 5002(a)(5). The definition of a ''processor'' does not revolve around whether the distilled spirits in question are taxpaid or not, and neither does the imposition of tax under section 5001(a)(2). The critical issue is not whether the original distilled spirits used in the product were taxpaid; instead, the issue is whether the final product has been taxpaid as a distilled spirits product.

Furthermore, IRC section 5002(a)(8) defines the term ''distilled spirits'' to mean ''that substance known as ethyl alcohol, ethanol, or spirits of wine in any form (including all dilutions and mixtures thereof from whatever source or by whatever process produced).'' The application of this definition does not depend upon whether the spirits are taxpaid or not.

TTB also believes that those commenters who questioned TTB's authority under the IRC are overlooking our broad authority over the production of flavoring materials under the nonbeverage drawback provisions of the IRC. This authority includes the ability to ensure that nonbeverage flavors are not being misused as the primary source of alcohol in beverage products such as malt beverages.

Pursuant to section 5132 of the IRC (26 U.S.C. 5132), the Secretary has authority to issue ''rules and regulations * * * to secure the Treasury against frauds.'' This authority is not new, and it has been used in the past to issue regulations placing a 2½ percent limit on the quantity of nonbeverage drawback flavors used in the production of distilled spirits products. (*See* T.D. 5573.) Congress recognized this

regulatory limit when it enacted section 5010 of the IRC in 1980, limiting the quantity of flavors eligible for a tax credit in distilled spirits products to 2½ percent. Our broad authority to limit the use of drawback flavors in the production of alcoholic beverages also allows us to place limits on the use of such flavors in the production of beer.

Authority Under the FAA Act. The FAA Act also gives the Secretary of the Treasury authority to issue regulations to prevent deception in the labeling and advertising of malt beverages and to ensure that labels provide consumers with adequate information about the identity and quality of malt beverages. (*See* 27 U.S.C. 205(e).) One of the questions raised by this rulemaking process is whether the term ''malt beverage'' is an accurate description of a product that derives up to 99% of its alcohol from the distilled spirits components of added flavors. Our authority under the FAA Act requires us to issue regulations setting forth standards for terms such as ''malt beverage'' to ensure that use of this designation on alcohol beverage labels does not mislead consumers but instead provides consumers with adequate information about the identity and quality of the product.

Accordingly, TTB has concluded that it has authority, under both the IRC and the FAA Act, to set limits on the quantity of non-fermented alcohol, derived from added flavors, that is used in the production of flavored malt beverages.

2. Which Standard Is Better Supported Under the IRC?

In Notice No. 4, we stated that we believed that the IRC would support either the proposed 0.5% standard or the alternate 51/49 standard. After carefully examining the comments, we have concluded that valid arguments may be made in favor of both standards.

The primary argument in favor of the 0.5% standard is that it establishes a *de minimis* standard for the addition to beer of flavors containing alcohol. Essentially, the use of this a standard treats beers in the same way that soft drinks and other non-alcoholic products are treated; they may contain less than 0.5% added alcohol from flavors.

The arguments against the 0.5% standard are both practical and statutory. We are not starting from a blank slate; instead, we are facing a marketplace in which many of the most popular FMB products derive the vast majority of their alcohol content from added flavors. The policies of TTB and its predecessor agencies have allowed this practice for years. We have allowed the use of non-beverage flavors in the production of beer, wine, and distilled spirits. The IRC does not require us to adopt a 0.5% standard. Accordingly, companies that have invested millions of dollars in reliance on the existing policy argued that if TTB has discretion to implement either standard, the Bureau should choose the standard that imposes the least burden on FMB producers.

After carefully considering the comments, we agree with those commenters who stated that TTB has some discretion in this area. Beers subject to taxation under the IRC are not nonalcoholic beverages like soft drinks; thus, the 0.5% limit on added alcohol in nonalcoholic products does not apply to beers, which are already being taxed under the IRC. However, our authority under the IRC includes the authority to set standards for the production of beer and for the use of nonbeverage flavors in beer production, to ensure that the revenue is adequately protected.

3. Which Interpretation Is Consistent With Our Regulatory Policy and Practice?

After careful consideration of the comments, we have concluded that it is necessary, for purposes of implementing the relevant statutes, to adopt a limit on the use of alcohol derived from flavoring materials in the production of beer. As explained below, we believe that the 51/49 standard interprets the statutes as issue in a way most consistent with our regulatory policy on revenue classification issues.

The unlimited use of flavors containing alcohol in the production of FMBs poses a threat to the revenue. Once FMBs start deriving 51%, or 75%, or even 99% of their alcohol content from the distilled spirits components of added flavors, it can be argued that these products are properly classified as distilled spirits rather than as beers. As previously noted, the IRC definitions of these terms make it clear that beers are products of fermentation, and distilled spirits are generally products of distillation. The tax rate on beer is significantly lower than the tax rate on distilled spirits. Accordingly, allowing such products to be produced at a brewery and taxpaid as beers rather than distilled spirits renders meaningless the distinction between distilled spirits products and beers.

Clearly, a standard must be established in order to avoid the current situation whereby a product deriving as much as 99% of its alcohol content from the distilled alcohol component in added flavors is classified, and taxpaid, as a beer. Furthermore, if we do not adopt a limit on the use of added flavors containing alcohol, it is very possible that producers will find new ways to take advantage of this policy, by producing at breweries more and more products that used to be produced at distilled spirits plants. Accordingly, we believe that, at a minimum, the alcohol derived from added flavors and other nonbeverage ingredients must be restricted to less than half the alcohol content of the finished FMB product.

We are persuaded by the comments that suggested that the proposed 0.5% limit was not the appropriate standard, notwithstanding its historical use to distinguish alcohol beverages from non-alcoholic beverage products, because we are dealing here with a taxable commodity—beer—not a nonalcoholic beverage such as a soda or juice. In other words, when we use the 0.5% limitation to limit the use of alcohol from flavorings in nonalcoholic beverages, we are drawing a line between products that are subject to tax under Chapter 51 of the IRC and those that are not. However, FMBs are clearly subject to tax under Chapter 51; the only question is whether they are appropriately taxed as beers or distilled spirits.

While either the proposed 0.5% standard or the 51/49 standard would be consistent with the statutory language, we have concluded that the 51/49 limit is more consistent with TTB regulatory policy and practice. As previously noted, the revenue issue posed is how to ensure that we maintain a meaningful distinction between beer and distilled spirits under the IRC. Because the statute does not provide us with specific guidance on this issue, we are guided by our regulatory policy on similar classification issues.

With regard to those commenters who argued that the proposed limits on the use of alcoholic flavorings in the production of beer are inconsistent with our treatment of wines under the IRC, and who suggested that the regulations do not place limits on the use of flavors containing alcohol in the production of wine, we believe that these statements are not entirely accurate. In the first place, it should be noted that the statutes and regulations governing the production of wine under the IRC differ significantly from the statutes and regulations governing the production of beer under the IRC. While the IRC does not specifically authorize the direct addition of distilled spirits to beer, it does specifically authorize the addition of wine spirits to wines. (*See* 26 U.S.C. 5373.) Thus, many wines contain distilled alcohol from wine spirits.

Secondly, the IRC regulations governing the production of wine do place limits on the use of essences containing spirits. In particular, the regulations provide that where an essence contains spirits, use of the essence may not increase the volume of the wine more than 10 percent nor its alcohol content more than four percent by volume. (*See* 27 CFR 24.85.) Thus, the regulations do place limitations on the use of essences containing spirits in the production of wine. As previously noted, there is a 2½% limit on the use of drawback flavors eligible for credit in the production of distilled spirits products under 26 U.S.C. 5010.

TTB believes that because of the different statutory provisions, our treatment of the use of flavors in wines and distilled spirits does not provide clear guidance as to how to limit the use of alcohol derived from flavors in beer production. However, we believe that a more analogous regulatory provision concerns the use of wine in distilled spirits products. Regulations issued under both the FAA Act and the IRC define the term ''distilled spirits'' to exclude mixtures of distilled spirits and wine, bottled at 48 degrees proof or less, if the mixture contains more than 50 percent wine on a proof gallon basis. (*See* 27 CFR 5.11 and 19.11.) This longstanding distinction signifies the intent to distinguish between two categories of taxable alcohol beverages, wine and distilled spirits, based on a predominance standard.

4. Reasons for Adoption of the 51/49 Standard Under the IRC Regulations

After carefully considering the record, TTB has concluded that the 51/49 standard is most consistent with our regulatory policy on revenue classification issues. Accordingly, we are adopting the 51/49 standard in the regulations setting forth the standards, under the IRC, for addition of flavoring materials that contain alcohol to beer.

As noted previously, TTB has determined that the adoption of the 0.5% standard for all beers under the IRC would impose additional economic costs and regulatory burdens on the beer industry. Since we have concluded, after careful analysis of the record, that either interpretation is allowed under the relevant statutes, we are adopting the alternative that is less costly to the industry, and imposes fewer regulatory burdens.

It should be emphasized that adoption of this standard reflects a decision on a tax classification issue, and will in no way reduce the tax liability of brewers that utilize the maximum amount of flavors in the FMBs that they produce. Brewers will pay the same tax rate on beer regardless of whether the beer derives 10% or 49% of its alcohol content from added flavors. Because beer is taxed on a volume basis, a brewer derives no tax advantage by increasing the flavors content of the product to the maximum allowed by the regulations. Thus, the 51/49 standard will accord maximum flexibility to the industry in formulating their products according to the taste preferences of their consumers, without jeopardizing the revenue.

Accordingly, TTB is amending the proposed regulation in 27 CFR 25.15 to provide that flavors and other nonbeverage ingredients containing alcohol may contribute no more than 49% of the overall alcohol content of the finished beer.

5. FAA Act, Consumer Deception

After carefully considering all the comments on this issue, TTB has concluded that current FMB labels do not provide consumers with adequate information about the product. For this reason, we have decided to set new standards for use of the designation ''malt beverage'' on labels.

TTB concludes that the term ''malt beverage'' does not accurately describe a product that derives up to 99% of its alcohol content from the distilled spirits components of nonbeverage flavoring materials. However, it is important to stress that this in no way means that producers of FMBs currently on the market have intentionally misled consumers by using this term on labels. Instead, these producers have relied on the policies of TTB and our predecessor agency. Accordingly, the focus of TTB is on which standard for FMBs will best achieve our statutory mandate of ensuring that malt beverage labels adequately inform consumers about the identity of the product.

Consistency With 1997 Decision on Cocktail Names. We do not believe that our predecessor agency's 1997 decision not to pursue further rulemaking on the use of cocktail names in the labeling or advertising of malt beverages precludes us from making this decision. In the first place, we recognize that we are changing longstanding policy with regard to the labeling of FMB products; that is why we engaged in notice and comment rulemaking before implementing this change. Secondly, the proposed and final rules are consistent in many respects with ATF's 1997 decision about cocktail names. As set forth later in this document, the regulations in this final rule continue to allow the use of a cocktail name as a brand name or fanciful name of a malt beverage, provided that the overall label does not present a misleading impression about the identity of the product.

Consumer Survey Conducted by the Luntz Companies. We have carefully reviewed the results of the consumer study conducted by Luntz. The commenter that submitted this study argues that it establishes two essential points: alcohol source is immaterial to consumers, and consumers are not confused about the source of alcohol in an FMB product. We disagree.

First, we will address the materiality issue. Other commenters have raised this issue as well, noting that in 1997 our predecessor agency concluded that there was evidence indicating that similarity to distilled spirits products was not a major factor in consumers' purchasing decisions with regard to FMB products. A major producer of FMB products has submitted new consumer evidence, the Luntz survey, which purports to establish that the source of alcohol in an FMB is not a material factor in a consumer's decision to purchase the product. Accordingly, several commenters have argued that TTB can justify action based on consumer deception only if consumers are being misled in a material fashion.

TTB does not agree that the Luntz survey conclusively establishes that consumers do not care whether the product is a result of fermentation or distillation. Furthermore, we do not agree that we are required to conduct consumer surveys to find out if alcohol source is a material issue to consumers before setting standards that distinguish malt beverages from distilled spirits products.

Since the enactment of the FAA Act in 1935, we and our predecessor agencies have issued regulations setting class and type designations or standards of identity for wines, distilled spirits, and malt beverages. These standards of identity are largely based on industry and consumer understanding of the meaning of certain terms. The FAA Act provides us with authority to issue labeling regulations that will prevent consumer deception *and* provide the consumers with adequate information about the identity and quality of the product. (*See* 27 U.S.C. 205(e).)

The FAA Act provides for three broad categories of alcohol beverages: distilled spirits, wines, and malt beverages. The classification of a product within one of these categories is the most fundamental decision that must be made before the product can be properly labeled or advertised under the Act. To say that consumers do not care whether the alcohol in a product comes from

fermentation or distillation is equivalent to saying that consumers do not care whether the product is a distilled spirits product or a malt beverage. Yet, our most basic responsibility under the FAA Act labeling provisions is to provide the consumer with adequate information about the identity of the product. There can be no question that the starting point of this responsibility is informing the consumer whether the beverage is a wine, malt beverage, or distilled spirits product.

In *Federal Security Administrator* v. *Quaker Oats Co.,* 318 U.S. 218 (1943), the Supreme Court upheld revised standards of identity for ''farina'' and ''enriched farina'' under the Federal Food, Drug and Cosmetic Act. A manufacturer had challenged these standards, alleging that under the revised standards, its product, previously marketed as farina enriched with Vitamin D, would qualify as neither farina nor enriched farina. The Court of Appeals found that the Administrator's findings as to probable consumer confusion in the absence of prescribed standards of identity were speculative and conjectural, in the absence of evidence that the respondent's product had in fact confused or misled anyone. The Supreme Court overturned this decision, stressing the deferential nature of its review of the Administrator's decision. The Supreme Court rejected the argument that the Administrator relied on speculative and conjectural testimony as to whether the marketing of products that do not conform to standards of identity would tend to confuse and mislead consumers, finding that:

> The exercise of the administrative rule-making power necessarily looks to the future. The statute requires the Administrator to adopt standards of identity [which], in his judgment, ''will'' promote honesty and fair dealing in the interest of consumers. Acting within his statutory authority he is required to establish standards which will guard against the probable future effects of present trends. (*See* 318 U.S. at 228.)

Similarly, our authority under the FAA Act requires us to prescribe labeling regulations that will ensure that consumers are adequately informed as to the identity and quality of alcohol beverages.

Although the *Quaker Oats* case deals with the Federal Food, Drug and Cosmetic Act (FD&C Act), rather than the FAA Act, many of the Court's observations about the FD&C Act are equally applicable to the FAA Act. For example, the Court noted that ''the text and the legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling.'' (*See* 318 U.S. at 230.) The Court held that ''provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other.'' (*See* 318 U.S. at 230–231.) In the same way, regardless of whether we have consumer surveys establishing that consumers care whether a product derives its alcohol from distilled spirits or beer, it is our responsibility to ensure that the label truthfully and adequately describes the contents of the product. In order to do this, we must establish basic standards for use of the terms ''distilled spirits'' and ''malt beverage'' on alcohol beverage labels.

The second issue addressed by the Luntz survey is whether current labels mislead consumers, and whether they provide adequate information about the identity of the product. MAB argues that consumers are not confused about the source of alcohol based on the fact that of the 20 percent of consumers that had a belief about the source of alcohol, less than half believed that the alcohol came from fermentation, and slightly more than half believed that it came from distillation. TTB draws very different conclusions from this survey.

The survey was conducted for a ''hard lemonade'' product labeled as a ''flavored malt beverage.'' Yet 80% of the respondents, after reading the label, had no belief whatsoever as to whether the product was derived from fermented alcohol or distilled alcohol. This would seem to indicate that the vast majority of the respondents were very confused as to the classification of this FMB product.

Because the vast majority—80%—of the respondents had no belief on this issue whatsoever, and the remaining respondents were almost evenly divided on the question, the survey clearly does not establish that current FMB labels provide consumers with adequate information about the identity of the product. Indeed, the only thing that is clear from the results of the survey is that, of the 600 FMB consumers that participated in the survey, only a very small percentage (11%) recognized that the alcohol in the product might come from distillation rather than fermentation. Thus, to the extent that the survey's results establish anything at all, they would appear to resoundingly support the conclusion that there is significant confusion among FMB consumers about the identity of these products.

As previously noted, TTB does not agree that it needs to conduct a consumer survey to establish standards for the use of labeling terms based on consumer and industry understanding of the terms. As the U.S. Court of Appeals for the D.C. Circuit has recognized, ''while consumer surveys conducted by independent experts may arguably constitute the best way to establish consumer understanding and preference * * * such surveys are not the exclusive form of probative evidence of public perception.'' (*See FTC* v. *Brown & Williamson Tobacco Corp.,* 778 F.2d 35, 41 (D.C. Cir. 1985).) Our conclusion in this matter is bolstered by comments from beer and malt beverage industry members urging us to preserve the integrity of the beer and malt beverage classifications by establishing limits on the use of flavors containing alcohol.

Based on the above analysis, TTB concludes that current FMB labels may mislead or confuse consumers by labeling as ''malt beverages'' products that derive up to 99% of their alcohol content from added flavors rather than from fermentation at the brewery. We believe that our statutory mandate to prevent consumer deception, and to ensure that alcohol beverage labels provide consumers with adequate information about the identity of the product, support an amendment to the regulations that would limit the quantity of alcohol derived from flavors in a malt beverage product.

6. Reasons for Adopting the 51/49 Standard for FMBs

After careful consideration of the record, we have decided to adopt the 51/49 standard for malt beverages under the FAA Act. We agree with those commenters who suggested that the 51/49 standard is consistent with certain other limits in our FAA Act labeling regulations. *See,* for example, 27 CFR 5.11 (the definition of the term ''distilled spirits'' excludes mixtures containing wine, bottled at 48° proof or less, if the mixture contains more than 50 percent wine on a proof gallon basis) and 27 CFR 5.22(b)(1)(i) (the standard of identity for ''bourbon whisky'' provides, among other things, that it must be produced from a mash of not less than 51 percent corn). We believe the 51/49 standard will adequately inform consumers about the identity of the product. Furthermore, as noted previously, adoption of the 51/49 standard for FMBs will minimize economic costs and regulatory burdens placed on members of the FMB industry.

IX. State Concerns

As noted in the preamble to Notice No. 4, one of our concerns in this rulemaking process has been to provide a Federal standard for the guidance of State regulatory agencies. Several State regulatory and taxation agencies expressed concerns to TTB about FMBs and requested that TTB take action to clarify their status as either malt beverages or distilled spirits. Many States have urged us to define FMBs and establish regulatory limits on the addition of alcohol to beer and malt beverages through the use of flavors. In the absence of such a Federal definition and regulation, several States have said that they will develop their own definitions for FMBs.

TTB received more than 650 comments addressing the creation of a Federal standard for beer or malt beverages or addressing Federal-State relationship issues. Thirty-one State liquor control boards, revenue departments, or other State agencies having jurisdiction over alcohol beverages, as well as one county liquor commission, submitted comments. Twenty-four of these comments supported the proposed rule. Of the remaining 8 comments, 6 supported the concept of a uniform standard for flavored malt beverages and 2 provided information about State laws without expressing an opinion on the TTB proposals.

We also received comments in support of the proposed rule from three Governors, one Lieutenant Governor, and many State legislators. A smaller number of State legislators commented in favor of the 51/49 standard.

A. Comments by State Regulatory Agencies

1. Federal Leadership Role

Several State regulatory agencies commented that it was only in the last year that they became aware of the actual composition of flavored malt beverages and that is up to TTB to establish a national standard. Some stated that a Federal definition for beer and malt beverages would ease the burden on State regulators by providing a uniform definition.

Several of these agencies also commented that individual State governments do not have the time or resources necessary to establish definitions of beer or malt beverages, or to properly identify new alcohol beverages. They suggested that the Federal Government has these resources. For example, the Delaware Alcoholic Beverage Control Commissioner noted that ''[i]f a national standard for these beverages is established, state legislatures and administrators can make an informed decision as to whether it is in the state's interest to comply with or deviate from the national standard.'' The Washington State Liquor Control Board commented that ''[a]ddressing these issues at the federal level will ensure consistency and preclude the various states from having to create separate regulations.''

2. Need for Expeditious Action

Many States urged TTB to resolve the issue expeditiously. For example, the Superintendent of the Idaho Liquor Dispensary did not express support for either the 0.5% standard or the 51/49 standard, but urged TTB ''to take action to reach a decision on a standard.'' The Director of Minnesota's Alcohol and Gambling Enforcement Division also did not express a preference for either standard but noted that the introduction of FMBs into the marketplace ''has been a complicated and confusing situation for regulators as well as the consuming public'' and stated that the Federal efforts to establish a uniform national standard were of great importance to the State. The Director of Oklahoma's Alcoholic Beverage Laws Enforcement Commission expressed his appreciation of Federal efforts to clarify issues concerning FMBs.

3. Importance of Consistent Federal Standard

Many States noted the importance of a consistent Federal standard. For example, the Director of the Montana Department of Revenue supported the proposed 0.5% standard, noting that Montana, ''like many other states, believe[s] it could be detrimental to both regulatory agencies and the industry if there are inconsistent classifications of these products in different states.''

4. States That Follow the Federal Standard

Many commenters stated that State governments have traditionally followed Federal policy in the taxation, licensing, and distribution of alcohol beverages. For example, the Kentucky Alcoholic Beverage Control Board stated that the ''Board has long felt that this standard should be set by the Federal Regulatory Authorities, not the individual states. Such Policy consistency is important because while states enjoy regulatory power over alcohol, most follow federal regulatory guidelines.''

Some comments from States indicated that they would follow the Federal standard regardless of what decision is reached by TTB. For example, a comment from the California Department of Alcoholic Beverage Control indicated that California had ''always deferred to your agency's professional expertise concerning the classification of alcoholic beverages into one of three primary categories: beer, wine, or distilled spirits'' and it intended to continue deferring to TTB's classification of FMBs. A comment from the Comptroller of Maryland and its Alcohol and Tobacco Tax Division supported the proposed 0.5% standard but stated that Maryland ''adopts federal standards with respect to labeling and content of alcoholic beverages'' and thus was ''prepared to apply whatever standards your agency ultimately determines to be most appropriate.''

5. Possibility of Unilateral State Actions To Classify FMBs

Several State agencies commented that without prompt action by TTB, it would be necessary for them to undertake this regulatory activity on their own. For example, Maine's Department of Public Safety Liquor Licensing Division commented that if TTB delays or fails to adopt the proposed 0.5% standard, many States ''will find the need to act under their independent authority to determine the alcohol beverage category, label disclosures, tax, necessary wholesale and retail license requirements in order to continue the selling of these products in their state.''

Some States have already begun regulatory proceedings on this issue. The Nebraska Liquor Control Commission commented that it has already determined that FMBs containing more than 0.5% alcohol derived from distillation should be classified as distilled spirits, and has set a deadline for industry compliance with this standard. The Tennessee Alcoholic Beverage Commission commented that it had already conducted administrative proceedings on the classification issue and that it believed that TTB's proposed 0.5% standard would be consistent with the position taken at its hearing. The issuance of an order in this matter is awaiting the TTB final rule.

Other States commented that they would defer action pending completion of the TTB rulemaking proceedings. A comment from the Virginia Department of Alcoholic Beverage Control noted that while Virginia had accepted Federal classification of products in the past, under State law a product containing alcohol from spirits and beer is classified as a distilled spirits product, even if the majority of the alcohol is contributed by beer. The commenter suggested that TTB's recent study revealed that most FMBs were

incorrectly classified in Virginia, and stated that the Department was delaying action pending the outcome of the TTB rulemaking.

A comment from the Massachusetts Alcoholic Beverages Control Commission expressed support for the proposed 0.5% standard, stating that the Commission ''in the past has substantially deferred to federal standards concerning the identity of a specific product, but the information that has come to light recently during the review and discussion of FMB is troubling to the Commission.'' This commenter indicated that Massachusetts is deferring taking any action pending completion of the TTB rulemaking process.

6. Tax Issues

Some State agencies focused on the taxation aspects of the proposed 0.5% standard, suggesting that taxing FMBs as distilled spirits would have positive revenue effects. For example, a comment from the Maryland Comptroller and Alcohol and Tobacco Tax Division suggested that it seemed ''inherently unfair to tax a product as a 'malt beverage' when the majority of the alcohol by volume contained in the product is from distilled spirits (flavoring or otherwise).'' Delaware's Office of Alcoholic Beverage Control Commissioner commented in support of the proposed regulation and stated that its concerns were not with distribution, but with ''the tax issue and the substantial reduction in the rate paid for beer * * * versus the rate paid for 'low spirits' * * *. Obviously, the amount of money in controversy is large for the State, the industry, and the consumers.''

7. Consumer Deception

Several State agencies focused on the issue of consumer confusion or deception. For example, a comment from Florida's Division of Alcoholic Beverages and Tobacco supported the 0.5% standard as a ''positive step toward providing consumer information and avoiding confusion.'' A comment from Kentucky's Alcoholic Beverage Control Board stated that the proposed 0.5% standard ''maintains the clear distinction between malt beverages and distilled spirits that were becoming blurred in the minds of many regulators, including Kentucky.'' The Oregon Liquor Control Commission stated that while FMBs were made in breweries, distributed through beer distribution channels, and taxed as beer, they discovered that ''their alcohol is mainly or completely from distilled spirits sources, and their appearance and taste usually do not resemble beer. Customers, along with regulators, have been unsure what this hybrid product really is.''

8. State Law Issues

In Notice No. 4, TTB solicited comments on whether States would have to enact new legislation if TTB amended its regulations to establish either the 0.5% standard or the 51/49 standard. Some States advised that the proposed 0.5% standard would not require amendments to State law, but they did not address the issue of whether a different standard would be inconsistent with State law. For example, the Oklahoma Alcoholic Beverage Laws Enforcement Commission advised that under Oklahoma's constitution, alcohol beverages were taxed and regulated based on whether the alcohol content of the product exceeds 3.2%, regardless of whether the alcohol content is derived from brewing or distilling.

A comment from the Georgia Department of Revenue advised that the proposed 0.5% standard would most likely cause the State to enact new legislation, because Georgia's alcoholic beverage code did not anticipate such products. However, this comment noted that, regardless of the standard, it might be necessary for the State to enact legislation in order to bring clarity to the issues of taxation and distribution.

Only a few States indicated that adoption of a standard other than the 0.5% standard would be inconsistent with State law. A comment from the Virginia Department of Alcoholic Beverage Control stated that while adoption of the proposed 0.5% standard would be consistent with State law, any standard allowing a higher percentage of alcohol from a source other than the brewing process would create a potential conflict with current State law, which classifies products containing mixtures of beer and distilled spirits as distilled spirits products, regardless of whether the majority of the alcohol is contributed by the beer. The Arkansas Alcoholic Beverage Control Division indicated that if TTB allowed the use of distilled spirits products as a flavoring agent, legislative changes would be required in Arkansas if this product was to be sold by beer-only permittees.

B. Other Comments in Support of the 0.5% Standard

Hundreds of brewery employees submitted comments stating that without the proposed 0.5% standard, brewers, wholesalers and retailers may face a patchwork of individual State laws and regulations, where the same product may ultimately be sold as ''beer'' in one State and as ''hard liquor'' in another. These comments suggested that this was already happening in Nebraska and will almost certainly happen in other States as well. Other commenters pointed out that such different standards could result in subjecting a product to two entirely different sets of laws and regulations regarding production, distribution, place of sales, labeling, and advertising. Many commenters stated that this discrepancy would jeopardize nationwide marketing and distribution efforts by industry members.

A State lawmaker commented that clear definitions of alcohol beverages are important for the State legislative process. Without definitions, the State legislatures cannot study and act on beverage alcohol issues in an educated and professional manner.

Several members of the beer industry supported the 0.5% standard as being most likely to resolve the concerns of State administrators. For example, the Beer Institute commented that the 0.5% standard is the best option to maintain consistency among existing Federal and State statutes and regulations. While noting that State officials must utilize their respective definitions of alcohol beverages, the Beer Institute suggested that almost all of the States that have reviewed the issue can reconcile their statutes and regulations with the TTB proposal, but that this is not true of alternative standards.

The Beer Institute suggested that implementation of an alternative standard would:

> unravel the consensus and relative stability that have been achieved to date with respect to state statutes and regulations. The alternative discussed in Notice No. 4, a standard permitting a 51–49% blend of malt beverage and distilled alcohol would require many changes in existing state tax and regulatory systems or even worse, a return to state-federal conflicts and inconsistent regulation.

Anheuser-Busch predicted that:

> there will be complete disorder in the nationwide marketplace if FMBs are permitted to contain 49 percent distilled spirits alcohol under federal law, yet most states would only permit 0.5% spirit alcohol. A patchwork of states regulating identical products as distilled spirits in most states, and as beer in others, would cause havoc and tremendous consumer confusion.

As one example of the confusion that could be caused by differing State classifications of the same product, the brewer noted that television advertisements regularly cross State lines.

Anheuser-Busch also suggested that while the 51/49 standard is nowhere to

be found in State laws, many State laws incorporate a 0.5% alcohol by volume threshold in their definitions of malt beverages and distilled spirits; accordingly, adoption of the alternative 51/49 standard by TTB would be disruptive to the system of State laws. The brewer suggested there is no basis to support the alternative standard in existing State laws, and that such action would create a conflict between Federal and State law. Additionally, Anheuser-Busch stated that such Federal action would trigger disruptive State action since many States would no longer follow TTB guidance, but would instead have to develop and/or enforce their own 0.5% standard, ''effectively ending federal leadership on the most important alcohol regulation issues.''

Coors commented that the 0.5% proposal is consistent with TTB's role under the 21st Amendment and noted that it is the only approach or proposal consistent with the vast majority of the different State laws. Accordingly, Coors suggested that the 0.5% proposal ''thus fulfills TTB's role as a leader of the states' regulatory and tax collecting organizations.'' Coors acknowledged that ''[e]xamples of differences in the regulation of malt beverages at the state level do exist,'' but suggested that ''only the TTB proposed regulation provides comity to the states and a marketplace free from disruption * * *.'' Miller suggested that, given the support of the States for the proposed 0.5% standard and the reality of the FAA Act's penultimate provision, ''considering other standards would be detrimental to the creation of a uniform standard.''

C. Other Comments in Support of the 51/49 Standard

Supporters of the 51/49 standard challenged those comments that suggested that only the proposed 0.5% standard would meet the needs of the States and result in a uniform Federal standard. These commenters argued that while a national standard would be beneficial, TTB has provided no evidence in Notice No. 4 as to why the proposed 0.5% standard is the only way to accomplish this goal. Several commenters stated there is no reason to assume the proposed 0.5% standard for added alcohol is the only standard supported by the various State authorities.

The FMBC noted that Federal law remains independent of State law and that the views of State officials are not binding on TTB. The FMBC stated that while it commended TTB for seeking to craft a national standard to respond to State concerns, TTB should not regulate to the ''least common denominator'' and elevate the opinions of a few State regulators above other considerations it must weigh.

The FMBC further stated that all States today classify FMBs as ''beer,'' ''malt beverages,'' or an equivalent statutory term. The FMBC suggested that while definitions vary from State to State, many resemble in material respects one of the two Federal definitions. Like these Federal statutes, State statutes are silent on the issue of how much alcohol nonbeverage flavors can contribute to a malt beverage or beer. Accordingly, the FMBC argued that even assuming that this silence could support the imposition of limits on the use of flavors, it would allow State regulators to adopt either a majority standard, a 0.5% standard, or some other standard.

The FMBC also challenged the characterization by other commenters of State laws on this issue. The FMBC noted that some supporters of the 0.5% standard suggest that the presence of a 0.5% alcohol by volume threshold in many State statutes requires those states to limit the alcohol contribution of flavors to that *de minimis* amount. However, the FMBC pointed out that these thresholds do not address the formulation of products but instead constitute a threshold that divides taxable alcohol beverages from products containing alcohol that are not subject to taxation. The FMBC stated that it was aware of no State statute that sets 0.5%—or any other figure—as the mandatory limit on the amount of alcohol that flavors or other alcohol sources can contribute to a malt beverage. The FMBC also noted that if such an interpretation prevailed, many States would have to reclassify wines that derive alcohol from flavors or spirits.

The FMBC argued that while some States have expressed support for Notice No. 4, none to date had indicated that they could not accept a majority standard. Finally, the FMBC stated that in 2002, the Joint Committee of the States (a body that represents the interest of alcohol regulators from both the ''control'' and ''open'' States) voted to recommend that States support a position that more than 50% of the volume of a finished FMB come from the product's beer/malt beverage base. The FMBC suggested that such a standard would be more lenient than the majority standard that FMBC can accept.

D. TTB Response

We agree with those commenters who suggested that the originally proposed 0.5% standard would give States guidance in classifying FMBs. However, we have concluded that the 51/49 standard would achieve the same goal, with less cost to the industry, as discussed earlier in this document. We agree with those commenters who suggested that the 51/49 standard will achieve our regulatory goal of establishing a uniform standard that provides a meaningful distinction between FMBs and distilled spirits products.

It is noteworthy that, while most of the comments from State regulatory agencies supported the proposed rule, only a few of these comments specifically opposed the majority standard. Several State regulatory agencies did not specifically support either standard, but simply supported TTB's action in trying to resolve this difficult issue by setting a uniform standard.

Furthermore, while a few States suggested that any standard other than 0.5% would be inconsistent with their State laws or regulations, none of these comments pointed to laws that specifically restricted the use of alcohol derived from nonbeverage flavors in FMB production. Like Federal law, many State laws use 0.5% alcohol by volume as the dividing point between products subject to tax and other regulations, and those that are not. Similarly, some State laws classify mixtures of beer and distilled spirits as distilled spirits products. However, we are not aware of any current State statutes that specifically regulate flavor use in FMB production, although at least two States have apparently initiated administrative procedures to establish such a policy.

Several States have indicated that they will not follow TTB's lead if we adopt an alternative to the 0.5% standard. Other States have indicated that they will follow the Federal standard, regardless of what it is. TTB's role is to provide Federal leadership on this issue. However, it is up to the States to decide whether they want to follow Federal standards or not.

Clearly, many brewers are concerned over facing a multitude of different State laws and regulations. Pursuant to the 21st Amendment, States have significant authority to regulate the sale and distribution of alcohol beverages within their borders. Under the penultimate clause of the FAA Act, Federal labeling and advertising regulations apply to malt beverages only to the extent that the State has adopted similar requirements for malt beverages sold within the State. Accordingly, brewers, wholesalers and retailers must

follow State laws on these issues, regardless of what standard TTB adopts.

We recognize that our adoption of the 51/49 standard may mean that some States will adopt a standard that differs from the Federal standard. However, as many commenters noted, State requirements on alcohol beverage classification issues already vary from State to State. We do not believe that the adoption of a different standard by some States will cause major problems to the beer industry; in any case, it is beyond TTB's authority to control what the States choose to do on this issue. We would note, however, that although TTB is adopting the 51/49 standard for FMBs, brewers are free to adopt the stricter 0.5% standard for their own FMB products, thus ensuring compliance with those State laws and regulations that are amended to incorporate this standard. Finally, by adopting a one-year effective date provision for this final rule, we hope to provide States with an adequate period of time in which to decide whether they wish to follow the Federal rule or not, and to make any corresponding changes in their own laws or policies.

X. Mandatory Alcohol Content Labeling for FMBs

TTB received 31 comments expressing opinions about the proposed mandatory alcohol content labeling for flavored malt beverages. Five commenters were brewers, six were from State licensing or regulatory agencies, seven were from interest groups, six were from individuals, and smaller numbers were from other sources. Although we received thousands of form letters supporting the Notice No. 4 proposals, none of these letters specifically addressed alcohol content labeling.

A. Comments Supporting the Proposal

Miller supported the proposed alcohol content labeling requirement for FMBs and other malt beverages that derive any alcohol from added ingredients. Miller's comment stated that it would oppose a requirement to label all malt beverages with an alcohol content statement. Miller also commented that the regulations should provide flexibility by allowing the alcohol statement on any label rather than on the brand label (front label) as proposed. Miller commented that allowing the alcohol content statement on any label is consistent with other mandatory labeling requirements such as the Government warning label, and that the proposed placement on the brand label is unnecessary since there is no empirical evidence concerning consumer confusion over the alcohol content of FMBs.

Two State liquor authorities supported the Notice No. 4 proposal to require alcohol content labeling on FMBs and other malt beverages that derive alcohol content from sources other than the brewing process. They agreed that this alcohol content labeling is necessary because of the similarity of some FMB labels to distilled spirits labels and because of the need to distinguish FMBs from non-alcohol products. Both States cited the importance to consumers of having alcohol content information available on malt beverage labels.

B. Other Comments

Several commenters opined that the proposed alcohol labeling requirement should not be restricted to FMBs and other products containing added alcohol but should apply to all malt beverages. These commenters generally stated that there was no reason to single out FMBs for mandatory alcohol content labeling. Diageo commented that Notice No. 4 provides no basis for requiring alcohol content statements only on the labels of malt beverages that derive alcohol from added flavors or other ingredients. Diageo stated that the intended alcohol content labeling bears no relationship to its cited justification in Notice No. 4, where TTB stated that consumers may believe either that spirits-branded malt beverages contain the same high alcohol content as distilled spirits or that other FMBs may contain no alcohol due to their unconventional appearance. As an example of the contradictory policy this requirement would cause, Diageo asserted that the regulations would not require alcohol content labeling on a product with a distilled spirits brand name such as ''Jack Daniels Pilsner'' but would require alcohol content labeling on a traditional malt beverage product made with alcohol flavoring materials like ''Strawberry Blonde Ale.'' Diageo further stated that they have placed alcohol content on labels of their FMBs since 2000.

Brown-Forman also commented that TTB has no basis for treating FMBs differently from other malt beverages. Brown-Forman argued that alcohol content labeling is important consumer information that should be required for all malt beverages. Gallo also supported extending alcohol content labeling to all malt beverages but requested that it be optional because of labeling prohibitions in Oklahoma and New York State.

The FMBC commented that alcohol content is important consumer information and that all of their member companies place that labeling on their FMBs. This trade association noted that although nearly all FMBs fall within a 5.0 to 5.5 percent alcohol by volume range, so-called traditional malt beverages contain between 4% and 25% alcohol by volume, a much wider range, making alcohol content labeling more meaningful for so-called traditional malt beverages than for FMBs. Since most malt beverage labels do not contain alcohol content information, the FMBC claims that consumers are less informed and more confused about the alcohol content of other malt beverages. The FMBC therefore urged TTB to require alcohol content labeling on all malt beverages.

CSPI similarly urged TTB to adopt alcohol content labeling for all malt beverages, stating that there is no reason to require such labeling only for FMBs and other malternative-type products, but not for all malt beverages. Another consumer organization, the NCL, also supported mandatory alcohol labeling for all malt beverages. The NCL stated, ''Mandatory labeling will provide consumers with the information they need to make better, more informed choices about alcoholic beverage consumption.''

Anheuser-Busch opposed the proposal to require alcohol content labeling on FMBs and other malt beverages containing alcohol from added ingredients. Anheuser-Busch stated that consumers do not assume malt beverages with distilled spirits brand names are higher in alcohol content, noting also that most FMBs already have alcohol content labeling. Anheuser-Busch further stated that any alcohol content labeling should be at the discretion of the brewer and should not be applied to only one kind of malt beverage.

C. TTB Response

The intent of TTB's proposal for alcohol content labeling was to provide this important information to consumers who may not be familiar with FMBs, or who may be misled by distilled spirits brand labels into believing that their alcohol content is higher than of other malt beverages. For the reasons outlined in the preamble to Notice No. 4, TTB is adopting the amendment to § 7.22(a) to require alcohol content labeling on the brand labels of malt beverages that derive any amount of alcohol from flavors or other ingredients containing alcohol. TTB believes this requirement will provide consumers with better information about these malt beverage products and will help prevent consumer confusion over their identity. Moreover, this requirement applies to

the addition of flavors or other nonbeverage materials containing alcohol at any step in the production process. At the same time, we are modifying the new § 7.22(a)(5) text to exclude from this requirement the use of hop extract that contains alcohol since hops are an essential ingredient in the production of malt beverages. It should be noted, however, that TTB will count any alcohol contained in added hop extract toward the 49% limitation under the 51/49 standard.

TTB notes that the final rule text, like the proposed rule text, does not separate FMBs that derive a substantial portion (up to 49%) of their alcohol content from added flavors from those traditional malt beverages that contain small amounts of added alcohol from flavors. Thus, this alcohol content labeling requirement applies to flavored beers, flavored ales, and so forth that are produced using alcohol flavorings.

While many comments supported alcohol content labeling for all malt beverages, TTB is unable to issue such a broad regulation at this time. In Notice No. 4, we specifically stated that we were not proposing to require alcohol content statements on all malt beverage containers at that time. Thus, we have not aired this issue for comment. We also believe that such a requirement represents a significant departure from past labeling requirements that, until the addition of § 7.71 in 1993, actually prohibited the placement of alcohol content statements on malt beverage labels (unless required by State law), due to the prohibition within the FAA Act (this prohibition was found to be unconstitutional in *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476 (1995)). Thus, while we are not unsympathetic to the comments suggesting mandatory alcohol content labeling for all malt beverages, we are not in a position to implement such a rule without notice and public comment. We also note that we have received several petitions from various consumer and public interest groups for additional labeling information on alcohol beverage containers, including alcohol content labeling. TTB intends to pursue these labeling issues in future rulemaking.

TTB acknowledges Gallo's comment regarding two States' prohibition of alcohol content statements on malt beverage labels. Pursuant to the penultimate paragraph of the FAA Act, the labeling requirements of the FAA Act apply only to the extent that State law imposes similar requirements on malt beverages sold within the State. Thus, brewers have to comply with the labeling laws of the State in which the malt beverages are being sold.

We recognize that brewers may be required to print different labels for malt beverages intended for sale in those States in which alcohol content statements on malt beverage labels are prohibited. However, TTB does not believe this is a sufficient reason not to adopt mandatory alcohol content labeling statements for malt beverages that derive alcohol from flavors or other ingredients. Brewers have always been required to conform labels to State requirements when those requirements conflict with part 7 requirements under the FAA Act.

With regard to the requirement that the alcohol content statement appear on the brand label, we have concluded that consumers are more likely to notice the statement if it appears on the brand label. Furthermore, this requirement is consistent with the regulations applicable to the mandatory alcohol content statements for wine (*see* 27 CFR 4.32(a)(3) and distilled spirits (*see* 27 CFR 5.32(a)(3)).

XI. Use of Distilled Spirits Terms on Labels and in Advertisements

A. Comments Received

TTB received 10 comments addressing the proposed limitations on the use of distilled spirits terms in malt beverage labeling and advertising. Three of these comments came from brewers, two were from State licensing and regulatory agencies, and the rest were from other sources. The majority of the comments favored limiting the use of distilled spirits terms on FMBs.

Several brewers requested assurances that the policy in ATF Ruling 2002–2, allowing the use of distilled spirits brand names on FMBs, will continue. They commented that industry members have made large investments in the labeling and advertising of these distilled spirits brand names based on existing government policies.

Several commenters believed the proposed language of §§ 7.29 and 7.54 is vague, and they requested clearer language that directly addresses TTB's stated purpose. The Washington Legal Foundation, a nonprofit public interest law and policy center, submitted a comment in opposition to the proposed language, asserting that the regulation would not accommodate the First Amendment rights of malt beverage industry members to make truthful statements about their products.

One commenter pointed out that the use of certain non-misleading statements would be prohibited by the proposed limitations on the use of distilled spirits terms on FMBs. This commenter cites a statement of ''having the color of dark rum'' as a truthful statement that describes the color of an FMB product but which would be prohibited. Another commenter cited the example of ''Beer aged in Bourbon Barrels'' as a truthful, informative statement that would similarly be prohibited by the proposed regulations.

B. TTB Response

We are incorporating the general holdings of ATF Ruling 2002–2 into §§ 7.29 and 7.54. However, in response to the comments received on this issue, we are modifying the language of the regulation to clarify that the regulation prohibits only those labeling and advertising representations that tend to create a false or misleading impression that the malt beverage contains distilled spirits or is a distilled spirits product. In addition, we are keeping ''safe harbor'' provisions in §§ 7.29 and 7.54 that incorporate the specific practices that we do not consider misleading.

The proposed language in §§ 7.29 and 7.54 was patterned after the existing language in 27 CFR part 4, Labeling and Advertising of Wine. In response to the issues raised by the commenters, we are revising these sections to clarify that we are not banning truthful and non-misleading speech about malt beverage products. Instead, we are incorporating the holdings of ATF Ruling 2002–2, which were intended to ensure that labeling and advertising statements comparing FMBs to distilled spirits products do not mislead consumers.

ATF Ruling 2002–2 noted the existence of a recent trend in the marketing of FMBs. Brewers and importers had begun to associate FMBs with well-known brands of distilled spirits, by using distilled spirits brand names as the brand names for FMB products; by using labeling and packaging that resemble the labeling and packaging of well-known distilled spirits brands; and by the use of specific distilled spirits terms in describing flavorings added to malt beverages. The ruling noted that these products were drawing media attention, in part because of the impression given that these FMBs are made with distilled spirits or contain distilled spirits. Certain FMBs were using labels that used distilled spirits brand names or distilled spirits class and type designations to describe a flavor element as part of the statement of composition on the label. For example, these labels used a distilled spirits brand name, and then stated ''Flavored malt beverage made with natural flavors containing vodka'' or ''Flavored malt beverage with natural flavors containing

genuine [Distilled Spirits Brand Name].''

The ruling held that such statements were misleading. The labels create the misleading impression that the product is made with, or contains, distilled spirits. In fact, however, distilled spirits used to manufacture flavors lose their class and type when blended with other ingredients to make a flavor extract. Thus, it is misleading to represent that the malt beverage contains a particular class or type of distilled spirits, such as vodka, rum or tequila. Furthermore, this kind of labeling created the misleading impression that the product contained distilled spirits, or in fact was a distilled spirits product.

Accordingly, the purpose of the ruling was to set forth specific labeling and advertising statements that would be considered misleading. The ruling held that the use of a brand name of a distilled spirits product as the brand name of a malt beverage was not in itself misleading. However, the use of a distilled spirits term found in the standards of identity in 27 CFR part 5 (such as whisky, rum, vodka, brandy, gin, and so forth) as the brand name for a malt beverage or as part of the statement of composition or as the fanciful name of a malt beverage, is misleading. The use of a cocktail term as the fanciful name of a malt beverage would not be considered misleading if the overall labeling and advertising does not create a misleading impression about the identity of the product.

TTB still takes the view that the use of a distilled spirits brand name as the brand name of an FMB is not inherently misleading. Furthermore, we do not believe that the use of a cocktail name as part of a fanciful name of an FMB is always misleading, as long as the remaining labeling and advertising of the product do not create a misleading impression as to the identity of the product. We are not changing our position with respect to these issues.

In response to the concerns voiced by the commenters, we are changing the wording of the amendments to §§ 7.29 and 7.54 contained in the proposed rule. Instead of the specific prohibitions proposed in those sections, we are adding the following to the prohibited statements with respect to labeling and advertising of malt beverages:

> Any statement, design, device, or representation that tends to create a false or misleading impression that the malt beverage contains distilled spirits or is a distilled spirits product.

Because this language prohibits only labeling and advertising statements that are false and misleading, it does not infringe upon the First Amendment rights of producers and importers of FMBs. Information on alcohol beverage labels is considered commercial speech. (*See Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 481 (1995).) The First Amendment protects commercial speech only if that speech concerns lawful activity and is not false or misleading. (*See Central Hudson Gas & Electric Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557, 563–564 (1980).) Similarly, our statutory authority under the FAA Act is to ensure that labels provide consumers with adequate information as to the quality and identity of malt beverages, and to ensure that labels and advertisements for such products do not tend to mislead consumers. (*See* 27 U.S.C. 205(e) and (f).) It is not TTB's intention to prohibit any labeling or advertising statements that are truthful and non-misleading.

The final rule regulatory texts incorporate the proposal to prohibit the types of references to distilled spirits brand names and class and type designations in FMB statements of compositions that were addressed in ATF Ruling 2002–2. However, those texts will allow truthful non-misleading statements that may draw similarities between the taste or character of a malt beverage and the taste or character of a distilled spirits product, but that do not imply in a false or misleading fashion that the product contains distilled spirits or is a distilled spirits product. Moreover, this general prohibition will not prohibit truthful and non-misleading statements such as ''beer aged in whiskey barrels'', provided that such a statement is not in the context of implying that the FMB contains whisky as the result of the aging process. Finally, this standard will not prohibit the use of cocktail terms as a brand name or fanciful name on malt beverage labels or in advertising provided the use of those terms does not draw a misleading comparison between the two types of alcohol beverages. To the extent that labeling or advertising comparisons between malt beverages and distilled spirits are false or misleading in a manner that is not covered by these new regulations, they would fall under the general prohibition on the use of false or misleading statements in the labeling or advertising of malt beverages. (*See* 27 CFR 7.29(a)(1) and 7.54(a)(1).)

ATF Ruling 2002–2 held that certain labeling and advertising practices by themselves are not misleading if their use does not give a misleading impression about the malt beverage. The ruling specifically held that the use of a brand name of a distilled spirits product as the brand name of a malt beverage is not in itself misleading. The ruling further held that the use of a cocktail term as the brand name or fanciful name of a malt beverage is not misleading if there is no misleading impression about the identity of the product, based on the overall labeling and advertising of the product.

Consistent with the proposed rule, and in response to the comments that specifically request affirmation that the use of distilled spirits brand names will be permitted, we are incorporating these ''safe harbor'' provisions from the ruling into §§ 7.29 and 7.54. We are reconfiguring the text as three subparagraphs in § 7.29(a)(7) and § 7.54(a)(8). Subparagraph (i) permits the truthful statement of alcohol content in labeling and advertising in conformity with existing requirements in § 7.71. Subparagraph (ii) in each case permits the use of a distilled spirits brand name as the brand name of a malt beverage provided the overall label or advertisement does not present a misleading impression about the identity of the product. Similarly, subparagraph (iii) permits the use of a cocktail name as the brand name or fanciful name of a malt beverage, with the same proviso.

XII. New Formula Requirements

TTB received a small number of comments from brewers and brewery trade associations on the proposed new formula filing requirements that would replace the existing statement of process. These commenters generally favored the new formula filing requirements, but they expressed concerns regarding certain aspects of the proposal and requested that TTB clarify some of the proposed formula requirements.

A. Fermented Products Requiring Formulas Under § 25.55

1. Comments Received

Several brewers and brewing industry trade associations commented on the proposed requirements that would trigger the filing of a formula by a brewer. These commenters requested that we more clearly communicate which fermented products require filing formulas.

One brewer stated that because of the wording of the proposal, it appears that most fermented products would require a formula. A brewery trade association argued that the requirement to file formulas showing special processing is so broad that the proposal would require brewers to file formulas for most products. This association noted that many traditional malt beverages contain

fruits, herbs, spices, or honey and that the proposed requirement to file a formula for fermented products containing any of these ingredients would greatly increase the number of products for which a formula is required. The association further alleged that products containing some of these types of ingredients are considered traditional malt beverages or beer and that, therefore, filing formulas for them would simply increase the number of formulas filed without assisting TTB in classifying them for tax purposes. One brewer and one trade association suggested adding a paragraph to the formula requirements in § 25.55 to state that a formula is not required when processes or ingredients are used in the production of traditional beers.

One brewer commented that proposed § 25.55 requires a formula when honey is used but does not specifically require a formula when maple syrup is added to beer. Further, this brewer commented that TTB should rewrite § 25.55 in the final rule to require formulas only for beer made with the use of processes or ingredients that the TTB Administrator has not declared as standard brewing processes or ingredients. TTB would then implement this regulation by periodically publishing a list of processes or ingredients declared to be traditional and therefore not requiring the filing of a formula for their use in beer production.

2. TTB Response

The formula requirement proposed in § 25.55 would replace the statement of process now required by § 25.67. The existing section currently requires brewers to file a statement of process whenever they propose to produce a fermented product not marketed as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor.'' As several commenters noted, some traditional malt beverage products are made with added flavors but are marketed under those traditional designations and not as flavored or specialty products. Because of the present wording in § 25.67, which uses the marketing designation as the filing criterion, some brewers may not file a statement of process for some fermented products that contain flavors or other materials. While these fermented products do not require a statement of process under § 25.67, the proposed regulation would require a formula and perhaps additional labeling for these traditional fermented products.

The intent of this proposal was not to require a statement of process or formula for additional kinds of fermented products. Rather, it was intended to clarify which fermented products require the filing of a formula. Thus, in this final rule document, we have changed § 25.55 in order to state more clearly when a brewer must file and receive approval of a formula in order to produce a fermented product. We have added a provision to this section that allows a brewer to request information on whether a formula is required in specific instances. Additionally we have amended this section to make it clear that TTB approval of a formula is required prior to using it to produce a fermented product.

Paragraph (a) of § 25.55 lists processes, materials, or specific types of fermented products that will require a brewer to file a formula. Paragraph (a)(1) contains the general rule to file a formula for a fermented product that is produced using certain processes. Based on the comments to Notice No. 4, which indicated that the term ''special processing'' is so broad that formulas would be required for most fermented products, we have changed the criteria in § 25.55(a)(1) that trigger filing a formula. Section 25.55(a)(1) now requires filing a formula for the use of any process, filtration, or other method of manufacture that is not generally recognized as a traditional process in the production of a fermented beverage designated as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor.'' We have also removed the language from this proposed section that would have used a change in the character of beer or the removal of material from beer as a criterion for the filing of a formula since it is impossible to quantify these standards. Thus, under § 25.55(a)(1), the sole criterion for filing a formula for a process depends on whether or not the process is traditionally used in producing fermented products designated as beer, ale, and so forth.

Non-traditional processes such as ion exchange treatment, reverse osmosis, concentration of beer, separation of beer into different components, and filtration to substantially change the color, flavor, or character of beer are processes that require the filing of a formula. These processes are those specifically included in proposed § 25.55(a)(1) as requiring filing a formula. We note that these are only examples, and the exclusion of a process from this listing does not mean that its use in making a fermented product would not require the filing of a formula.

Conversely, processes such as pasteurization, filtration prior to bottling, filtration in lieu of pasteurization, centrifuging for clarity, lagering, carbonation, blending, and so forth are clearly traditional and their use does not require a formula. Subparagraph, (a)(1)(ii) of § 25.55 lists examples of these processes. These processes were listed in the preamble to Notice No. 4 as examples of traditional processes not requiring a formula. Other processes exist that are considered traditional and will not require filing a formula.

Subparagraph (a)(1)(iii) of § 25.55 provides that brewers may request a determination from us as to whether a particular process used in producing beer will require a formula. Procedures for requesting this determination are contained in new paragraph (f) of § 25.55.

Paragraphs 25.55(a)(2) through (a)(5) list the other instances when a formula is required to produce a fermented product. These correspond to those formula requirements in proposed § 25.55(a).

Paragraph (a)(3) requires brewers to file formulas when they use coloring or natural or artificial flavors in producing a fermented product. Paragraph (a)(4) requires brewers to file a formula for any fermented product to which fruit, fruit juice, fruit concentrate, herbs, spices, honey, maple syrup, or other food materials are added. In response to the above comments regarding the production of traditional brewery products to which certain flavors or other material are added without filing a statement of process, we have added a reference to § 25.55(f). This section permits brewers to request a determination from us as to whether a particular ingredient used in producing beer will require a formula.

3. New Procedural Requirements

New paragraph (f)(1) of § 25.55 authorizes TTB to determine whether the use of a particular process or a particular ingredient will require the filing of a formula. Under § 25.55(f)(2), a brewer may request a determination on whether the use of a proposed process or a proposed ingredient will require the filing of a formula. Paragraph (f)(2)(i) sets forth the information that a brewer must submit to TTB in order to request a determination as to whether a formula is required when using a particular process. For use of a proposed process, the brewer must submit a full description of the process, evidence of whether the process is generally recognized as a traditional process in the production of fermented beverages designated as beer, ale, and so forth, and an explanation of the intended effect of the process.

Similarly, a brewer may request an exemption from the formula filing

requirement under § 25.55(a)(3) and (a)(4) when certain flavors or other ingredients are used in a fermented product. Under § 25.55(f)(2)(ii), a brewer must submit information about the proposed ingredient, including a description of the ingredient, evidence establishing that the proposed ingredient is generally recognized as a traditional ingredient in the production of a fermented beverage designated as beer, ale, and so forth, and what effect the use of the proposed ingredient has on the fermented product. However, there is no exemption from the formula requirement in § 25.55(a)(2) with respect to the use of flavors and other ingredients containing alcohol, because this information is essential for purposes of administering the 51/49 standard.

As suggested by the comments, there may be many fermented beverages produced and marketed under the traditional designations of ''beer,'' ''ale,'' and so forth that contain flavors or other ingredients and which are produced without statements of process. The information submitted by brewers under paragraph (f) will allow us to evaluate whether or not these fermented products made with flavors or other ingredients should be subject to the formula approval and possible additional labeling provisions. TTB will give consideration to the past usage of those flavors or other ingredients and to whether the fermented products are considered to be traditional products that are entitled to be marketed as ''beer,'' ''ale,'' and so forth without formula approval and without additional labeling information. As part of our evaluation, we will take into consideration the class and type regulations in § 7.24(a) that require that statements of class and type conform to the designation of the product as known to the trade. Additionally, § 7.24(e) requires products designated as ''ale,'' ''porter''' or ''stout'' to be produced without the use of coloring or flavoring materials (other than those recognized in standard brewing practices). We will consider these criteria when evaluating a request for a determination on the use of flavors or other materials in producing fermented products without obtaining a formula approval.

With respect to the use of processes, we recognize that the listings in § 25.55(a)(1)(i) are not complete and that brewers may propose to use new processes in the production of fermented beverages. Thus, a request to TTB under paragraph (f) of § 25.55 will permit us to determine, for example, whether a process may constitute distillation, and whether a proposed process is appropriate for the production of a fermented beverage that is to be sold under a traditional designation such as ''beer'' or ''ale''.

We will maintain on the TTB Web site a list of new processes and ingredients determined by TTB under § 25.55(f) to require, or not to require, the filing of a formula.

B. Standards for Formula Approval

1. Comments Received

The FMBC and one FMB producer commented that proposed § 25.15(a) gives brewers a wide variety of ingredients for producing beer. The FMBC agreed that the statutory definition of beer permits the use of a wide range of fermentable materials at the brewery and that this listing of ingredients reflects existing TTB policy. However, both commenters stated that the proposed formula regulations provide no standard for using these materials in producing beer. The FMBC commented that proposed § 25.15(a) appears to blur the distinction between beer and wine since TTB taxes as wine products made primarily from honey, fruit, fruit juice, and fruit concentrate, which are all materials listed in proposed § 25.15(a). These commenters requested that TTB provide to the industry regulatory standards to as to when the use of honey, fruit, and other materials would result in classification of a product as a wine. As an example of a suggested standard, these commenters cited TTB's unofficial policy that half of the fermentable material in a beer must be derived from barley malt and other fermentable grains. These commenters suggested that incorporating this policy of ingredient use in the regulations would provide brewers with necessary guidance in determining what fermented products qualify as a beer, especially when other fermentable ingredients such as honey or fruit are used.

The FMBC further commented that although Notice No. 4 stated that one use of the formula submission is for TTB to evaluate whether a certain process constitutes distillation, the actual proposed formula regulations do not contain any standards that could be used for this purpose. The FMBC stated that without such regulatory guidelines, producers would be uncertain whether a proposed process constitutes distillation and, further, that this lack of a standard will lead to arbitrary and uneven decision-making. The FMBC therefore requested that TTB seek comments on proposed regulations containing both criteria for distillation and criteria that TTB will use in evaluating beer produced by special processes.

2. TTB Response

TTB has not incorporated in this final rule its informal administrative policy regarding the percentage of fermentable materials in a beer that must be grain-based because we did not air this issue for comment in Notice No. 4. However, we agree with the FMBC that the proposed regulatory text did not adequately distinguish between fermentable materials and fermentable adjuncts. The term ''beer'' is defined in section 5052(a) of the IRC as:

> beer, ale, porter, stout, and other similar fermented beverages (including saké or similar products) of any name or description containing one-half of 1 percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from any substitute therefor.

In 1889, the Commissioner of Internal Revenue stated that the term ''substitute for malt'' included rice, grain of any kind other than malt, sugar, bran, glucose, and molasses.

The comment from the FMBC rightly pointed out that the proposed language of new § 25.15(a) seemed to authorize unlimited use of materials such as honey and fruit as substitutes for malt. This was not our intention. Accordingly, we have revised the language in paragraph (a) of proposed § 25.15. The first and second sentences of paragraph (a) address the basic brewing materials, and we have revised this list to conform the substitutes for malt to those specifically listed in the Internal Revenue Commissioner's letter in 1889. Accordingly, § 25.15(a) lists the following materials as the only permissible substitutes for malt: rice, grain of any kind, bran, glucose, sugar, and molasses. We note the term ''grain of any kind'' includes both malted and unmalted grains.

The third sentence of paragraph (a) lists other materials that may be used in brewing but that are not considered basic brewing ingredients as contemplated by the IRC. Extensive use of those other materials in fermentation could yield a fermented product that might be considered wine rather than beer; thus, the revised text distinguishes between those materials that we categorize as ''adjuncts'' and the basic brewing materials covered by the first two sentences of § 25.15(a).

In the absence of a regulatory standard, TTB will continue to rely on its current administrative guideline, which requires at least 50% of the fermentable material in an IRC ''beer'' to be one or more of the following: barley

malt, other malted grains, unmalted grains, rice, bran, sugars, or molasses. Brewers may use the other materials listed in the third sentence of § 25.15(a) as fermentable adjuncts in the production of a beer at a brewery. We will consider the comments summarized above as suggestions for future amendments of the part 25 regulations, and we may address this issue in the near future in connection with the planned revision of the part 25 brewery regulations.

With regard to the FMBC comment requesting regulatory standards for distillation and for the evaluation of other processes in producing beer, TTB notes that Notice No. 4 did not propose to adopt either of those standards. Moreover, determinations of whether distillation has occurred are highly technical matters. The determination often depends on laboratory examination of the process and the materials produced. Therefore, we believe that it is preferable to continue to examine processes on a case-by-case basis. However, we will consider these comments as suggestions for future regulatory amendments.

C. Alcohol Information in Formulas

1. Comment Received

One brewer commented that since Notice No. 4 proposed limits on the amount of alcohol that can be added to fermented beverages through the use of flavors and other ingredients containing alcohol, it was unnecessary to require detailed information about those ingredients in formula submissions. This commenter stated that since the proposal would limit the amount of added alcohol, the detailed information in proposed § 25.57 is not needed and should not be required.

Another brewer expressed its concern about the requirement to state maximum volumes of flavoring materials in formulas. This brewer commented that they need significant flexibility in the amounts and types of flavorings to accommodate price changes or acceptability of ingredients in foreign countries. Furthermore, they may use two or more flavors alternatively in a formulation. Although, on examination, the use of the maximum amounts of each flavor listed would appear to exceed overall added alcohol limitations, this brewer stated this is not the intention of using or listing alternative flavors in a formula. Thus, this brewer requested that TTB add a provision in § 25.57 specifying that the amount of alcohol contributed by all of the flavoring material in a formulation will not exceed the overall limit established by § 25.15.

This brewer also commented that the requirement to state the alcohol content of the fermented product at each step in production is overly restrictive. This requirement, according to the commenter, would eliminate streamlining of operations, forcing production by batches rather than in-line blending and other methods. The commenter therefore suggested requiring a single statement for alcohol content at the final stage of production.

2. TTB Response

TTB will continue to require information about individual flavors and other ingredients in fermented beverages, not only for tax classification purposes under the IRC, but also for labeling purposes under the FAA Act. Thus, we are retaining the requirement in § 25.57 to provide information about separate flavors and other ingredients. Additionally, we need to know at what stage in production flavorings are added since this information impacts the classification and labeling of the fermented product. Thus, we have amended § 25.57(a)(2) to require brewers to state the point of production'during, before, or after fermentation'that flavors are added.

We do agree that brewers need flexibility to use alternate ingredients in producing fermented beverages and that brewers should not be required to file new or amended formulas every time they make slight changes in the use of flavors or in the ratio of certain flavors used in a product. Nevertheless, we again emphasize that the proposed formula requirements are intended to clarify existing statement of process requirements and are not intended to impose new requirements on brewers.

It is our intention to permit the use of alternate or optional flavors in producing fermented products, and, to this end, we have added the following sentence at the end of proposed § 25.57(a)(1): ''You may include optional ingredients in a formula if they do not impact the labeling or identity of the finished product.'' We have also clarified our position on alcohol content contributed by alternative flavors and other nonbeverage ingredients containing alcohol in a formula by adding the following sentences at the end of § 25.57(a)(3)(iv): ''You are not required to list the alcohol contribution of individual flavors and other nonbeverage ingredients containing alcohol. You may state the total alcohol contribution from these ingredients to the finished product.'' We believe the addition of these sentences to § 25.57 will make it clear that the use of alternative ingredients is permitted and that it is not necessary to list the alcohol contribution of each individual ingredient in the formula.

We also have removed the proposed requirement in § 25.57(c) for listing in a formula the alcohol content of a fermented beverage at every step in production. We agree with the commenter that this requirement is burdensome and not useful in evaluating a formula. This paragraph now requires listing only the alcohol content of the fermented product after fermentation and the alcohol content of the finished product.

D. Reasonable Range of Ingredients

1. Comment Received

Only one commenter addressed TTB's request for comments on how to define a ''reasonable range'' of ingredients used in formulas in § 25.57(a)(1). This commenter, Diageo, recommended that TTB prescribe specific ranges for various ingredients. For ''major ingredients'' or those composing more than 3% of a product's total weight or volume, Diageo recommended that the range should vary by no more than 30% over or under the actual amount used in production. For ''minor'' ingredients that represent less than 3% of the product's weight or volume, this comment recommended the reasonable range could vary by up to 200% of the actual quantity used.

2. TTB Response

TTB is still seeking broad industry input on what constitutes a ''reasonable range'' of ingredients in a formula. Since only one commenter responded to this question, we do not believe we have enough information to take final rule action on its meaning. Thus, we are not defining ''reasonable range'' of ingredients for purposes of § 25.57(a)(1), and have removed the word ''reasonable'' from this provision.

TTB will continue to permit brewers who submit formulas to indicate a range of ingredients. A range of ingredients may not be so large as to change the tax classification of a fermented beverage or to change the designation of the fermented beverage. For example, a formula for a ''wheat beer'' cannot indicate a range of fermentable ingredients of 5 to 95% wheat malt since a minimum of 25% wheat malt is required for a beer to have this designation. We will evaluate formulas submitted by brewers, and make a case-by-case determination whether the range of ingredients indicated in a formula is appropriate. We note that,

under § 25.57(e), we will have authority to request additional information from brewers when we evaluate a formula.

We intend to revisit the question of what constitutes a ''reasonable'' range in the future through rulemaking or other appropriate procedure.

E. Formula Confidentiality

1. Comments Received

One brewer expressed a strong concern regarding the need for formula confidentiality. Another commenter stated that formula protection from public disclosure is a very important issue in the competitive market. Another brewer commented that the confidentiality issue for formulas should be resolved in the final rule as a separate regulation.

2. TTB Response

TTB agrees that formulas filed by brewers, like statements of process, are confidential and are not generally subject to public disclosure. To the extent that formulas are filed under the requirements of part 25, they are classified as ''return information'' subject to the disclosure restrictions of 26 U.S.C. 6103. Furthermore, formulas filed under either part 7 or part 25 are treated as confidential business information under the Freedom of Information Act, 5 U.S.C. 552(b)(4), and are thus exempt from that statute's mandatory disclosure provisions. Finally, TTB has always treated statements of process and formulas as trade secrets subject to the disclosure restrictions of 18 U.S.C. 1905.

At this time, TTB is not adopting the suggestion of the commenter who advocated placement of confidentiality provisions in the formula regulations in part 25 and part 7. At present, we believe that the existing TTB and Treasury disclosure regulations adequately address the protection of this type of data. Furthermore, it would not be an efficient use of government resources to address this issue for beer formulas, without addressing the similar issues presented by formulas for wine and distilled spirits products. Finally, before adopting such regulations, it would be preferable to specifically air the proposal for comments from the public and affected industry members. Notice No. 4 did not contain any such proposal.

Accordingly, TTB will consider these comments as suggestions for future rulemaking actions. In the interim, submitters of formulas required under parts 7 and 25 should accept our assurances that TTB will comply with all applicable statutory and regulatory restrictions on the disclosure of that proprietary information.

F. Standard Form for Formulas

1. Comments Received

Three commenters suggested that TTB should develop a standardized form for formulas and that industry members should be able to provide input on the development of the form. One brewer commented that TTB should develop a formula form for FMBs that is similar to the form used for flavored wine products. Another brewer requested that TTB develop a unique formula form that is unlike the formula form for wine.

2. TTB Response

At this time, TTB declines to adopt a standard formula form for part 25 purposes, but we will consider developing a standardized form for formulas in the future. We may consider combining a formula form for beer with the form used for wine in order to achieve standardization, and we will consider comments or suggestions from industry members and the public in developing any form for beer formulas. In the meantime, brewers may continue to prepare their formulas for fermented products on their own letterhead stationary.

G. Formula Proceedings

1. Comments Received

A brewer commented on the statement in § 25.55 that a formula remains in effect until surrendered or superseded by a new formula or until TTB cancels or revokes it. This commenter noted that no formal or informal procedure is given in the regulation that would apply to the cancellation or revocation of a formula. This commenter stated that any attempt to revoke a formula without proper procedures would raise serious due process issues. The commenter requested inclusion of those procedural safeguards and that they be at least similar to the procedural safeguards afforded certificate of label approval revocations.

2. TTB Response

In 1999, ATF issued regulations setting forth procedures for the revocation of approved labels in 27 CFR part 13, Labeling Proceedings. Although we have not prescribed specific procedures for the revocation of formulas in the regulations, it has been our policy to afford formula holders due process by giving them advance notice, and an opportunity to respond, before revoking the formula. An exception, of course, applies to the extent that the revocation is by operation of law or regulation. In those cases, it is the new law or regulation that requires the revocation of the formula, and TTB has no choice but to comply with the requirements of the law or regulation.

This issue was not specifically aired for comment in Notice No. 4. Accordingly, we are treating the single comment that we did receive on the issue as a suggestion for future rulemaking. Pending the issuance of regulations specifically addressing this issue, we will continue to provide due process to formula holders by applying procedures similar to those set forth in part 13 to any cancellation or revocation of an approved formula.

H. Placement in the CFR

1. Comments Received

One brewer noted that the proposed formula requirements appear in part 25, which applies to domestic beers, but not in part 7, which applies to all malt beverages. This brewer stated that the formula requirement should apply equally to domestic and imported products and should therefore be placed in part 7.

2. TTB Response

Placement of the formula requirement in part 25 is deliberate. This action implements TTB's existing statutory authority permitting it to request certain information from domestic brewers. Many domestic brewers do not operate in interstate commerce and do not obtain certificates of label approval for their products because they are not packaged but rather are sold from tanks at the tavern on brewery premises. The formula provisions must apply to these brewers as well as brewers who obtain certificates of label approval since the same requirements exist regarding the classification of fermented products and the appropriate use of ingredients. Thus, we must include the formula requirements in part 25 in order to apply them to all brewers, regardless of their size or the method of distribution of their products.

TTB has no statutory authority to require foreign producers to submit formulas. In the case of imported malt beverages, our authority to require formula information applies to U.S importers rather than to foreign brewers. Thus, this final rule document adopts the proposal to add a new paragraph to § 7.31 to reflect this authority. This provision recognizes TTB's authority to request formula or sample information from an importer in conjunction with the filing of a certificate of label approval for a malt beverage. We believe

we can obtain adequate information about an imported malt beverage under this new provision to determine the class and type of an imported malt beverage and to resolve any ingredient or labeling issues that may arise during a certificate of label approval submission.

XIII. Other Issues Raised by Commenters

A number of commenters raised issues regarding FMBs that were not directly addressed in Notice No. 4, and thus are outside the scope of this rulemaking document. However, TTB wishes to comment on some of these issues and may consider some of them to be appropriate for future rulemaking on beer or malt beverages.

A. Information Quality Act

1. Comment Received

A law firm representing a major FMB producer filed a request under the Information Quality Act (IQA) for correction of TTB's statement in Notice No. 4 that existing FMB labels may confuse and mislead consumers as to both the source and amount of alcohol in these beverages, arguing that Notice No. 4 did not provide any supporting data for these assertions. In response to this request, TTB stated that it would treat the letter as a comment to the proposed rule.

2. TTB Response

Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Public Law 106–554, directed the Office of Management and Budget (OMB) to issue, by September 30, 2001, government-wide guidelines that ''provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies.'' On September 28, 2001, OMB issued guidelines; revised final guidelines were published on February 22, 2002. (*See* 67 FR 8452.)

The law also requires Federal agencies to issue their own implementing guidelines, including administrative mechanisms that allow affected persons to seek and obtain correction of information maintained and disseminated by the agency, where such information does not comply with the OMB Guidelines. Finally, the law requires agencies to report periodically to OMB on the number and nature of complaints received by the agency, and how such complaints were handled.

In compliance with these requirements, both the Department of the Treasury and our predecessor agency, ATF, published guidelines on information quality. (See ''Subdivision of Treasury Information Technology (IT) Manual,'' Ch. 14: Information Quality (''Treasury Guidelines''), and ''Process for Requesting Correction of Information Disseminated by the Bureau of Alcohol, Tobacco and Firearms' (''ATF Guidelines'').) Both the Treasury and ATF Guidelines stress that the guidelines are not legally enforceable, and do not affect any otherwise available judicial review of agency action. Pursuant to the provisions of the Homeland Security Act of 2002, and Treasury Order No. 120–01 (Revised), published on January 24, 2003, ATF's orders still apply to TTB until superseded or revised. Accordingly, TTB continues to rely upon the published procedures of ATF, as well as the published procedures of the Department of the Treasury, in responding to requests for correction of information under the IQA.

Section 14.5.3(C) of the Treasury guidelines provides that in most cases, absent unusual circumstances, requests for correction of information contained in a notice of proposed rulemaking should be addressed through the rulemaking process. TTB found that there were no unusual circumstances in this case, and there was no evidence that the requester had a reasonable likelihood of suffering actual harm if the issue was not resolved before the issuance of the final rule on FMBs. Accordingly, we advised the requester that we would treat the letter as a comment on the proposed rule, and that the final rule would address the issues raised in the letter.

The issues raised by this comment are addressed elsewhere in this preamble. As we stated, TTB remains of the opinion that it is inherently misleading to label as FMBs products that derive up to 99% of their alcohol content from the distilled spirits components of added flavors and other nonbeverage products. As stated earlier in this preamble, we have determined that both the FAA Act and the IRC provide us with authority to define the terms ''malt beverage'' and ''beer'' in order to set limits on the use of alcohol from added flavors and in order to ensure that the majority of the alcohol is derived from fermentation at the brewery.

As already pointed out in this preamble, we have also concluded that we are not required to conduct consumer surveys every time we define a labeling term applicable to alcohol beverages. In this rulemaking proceeding, we have considered all the data presented by the commenters, including the consumer surveys previously conducted on this issue, as well as a new consumer survey submitted by another FMB producer. It is our conclusion that the evidence establishes that current labels may mislead consumers and that they do not provide adequate information about the identity of these products. As we specifically stated in this document, we are not concluding that FMB producers intentionally misled consumers; instead, these producers appear to have relied on the policies of TTB and its predecessor agencies in labeling and classifying these products.

However, we have also concluded that the term ''malt beverage'' may tend to mislead consumers when applied to a product deriving the majority of its alcohol content from the spirits components of added flavors and other nonbeverage ingredients. We have also concluded that such a term does not provide adequate information to consumers about the identity of such a product. Accordingly, the final rule limits use of the labeling term ''malt beverage'' to products that derive at least 51% of their alcohol content from fermentation at the brewery. We are confident that the data in support of the final rule comply with the requirements of the IQA.

B. ''Alcohol is Alcohol''

1. Comment Received

In its comment, the National Consumer League (NCL) stated, ''alcohol is alcohol, regardless of source.'' The NCL suggested that, from a consumer standpoint, only the actual alcohol content in a product matters and not the source of that alcohol. This commenter stated that most single servings of alcohol beverages contain roughly an equal amount of alcohol, a fact of which many consumers are unaware. Further, this commenter cited experts who agree that all types of alcohol beverages are functionally equivalent on a serving-to-serving basis and that no differences exist between hard liquor and beer.

Because of the ''alcohol is alcohol'' argument, NCL opposed the proposed rule because it perpetuates the differences between different types of alcohol beverages and would continue to accord alcohol beverages different regulatory status based on their source of alcohol. This commenter suggested there is no scientific or public policy to support these distinctions. As previously noted, NCL did state that there was greater merit to the majority standard, as it ''may reduce the

potential for consumers to be misled or confused,'' and that compliance with the majority standard ''will assure that consumers are not deceived as to product content.''

2. TTB Response

TTB acknowledges that, depending on the alcohol content of the product, single servings of different types of alcohol beverages may contain roughly the same amount of ethyl alcohol and that the ethyl alcohol found in these is chemically the same substance. However, longstanding Federal and State laws recognize very significant differences between distilled spirits, wine, and beer or malt beverages for production, tax, labeling, advertising, and distribution purposes. Thus, to the extent that the NCL comment suggests that Federal law should ignore these distinctions, it lies outside the scope of the proposals made in Notice No. 4 and would require significant statutory changes.

C. Marketing of FMBs to Underage Drinkers

1. Comments Received

A number of commenters, including many individuals and several public interest organizations, commented that FMBs should be treated as distilled spirits. These commenters claimed that FMBs are designed for the youth market due to their taste and the way in which they are marketed. Further, these commenters stated that the introduction of FMBs has substantially increased distilled spirits brand awareness and loyalty among young people. Some commenters claimed this is a deliberate strategy on the part of producers.

One commenter suggested that TTB should take action against producers and collect distilled spirits taxes on products marketed as malt beverages. CSPI requested that TTB classify FMBs as distilled spirits in order to reduce youth access to them by limiting the range of outlets where they can be sold. An individual commenter suggested that TTB undertake any action that would make FMBs more expensive in order to reduce their availability to underage youth.

CSPI further commented that its own data found that both teens and adults think that so-called ''alcopop'' products such as FMBs, which have the brand names of distilled spirits products, are more like liquor than beer or wine. Some commenters suggested that these products are particularly appealing to underage consumers and noted that these products are marketed on television and are widely available in convenience and grocery stores. Several commenters argued that convenience and grocery stores are more conducive to underage sales than are State-licensed retailers selling distilled spirits, and they supported classifying FMBs as distilled spirits products so that their distribution would be more strictly regulated in most States. Other commenters expressed various concerns about the public health consequences of alcohol abuse.

On the other hand, some commenters pointed to the recent study conducted by the Federal Trade Commission (FTC). (*See* ''Alcohol Marketing and Advertising: A Report to Congress,'' Sept. 2003.) The FTC's report noted that it had previously reviewed this issue in response to a complaint by CSPI, and it had found no evidence of intent to target minors with the FMB products, packaging, or advertising. Furthermore, after reviewing the consumer survey evidence submitted by CSPI in support of the proposition that FMBs were predominantly popular with minors, the FTC concluded that flaws in the survey's methodology limited the ability to draw conclusions from the survey data.

The FTC reviewed this issue again in response to a request by Congress to study the impact on underage consumers of the significant expansion of ads for flavored malt beverages. The FTC's investigation again found no evidence of targeting underage consumers in the marketing of FMBs. However, the report recognized that ad content that appeals to new legal drinkers, as well as the sweet taste of FMBs, may be attractive to minors, and the FTC urged the industry to exercise significant caution when introducing new alcohol beverage products, to ensure that they are not marketed to an underage audience. (*See* ''Alcohol Marketing and Advertising: A Report to Congress,'' September 2003, p.22.)

2. TTB Response

As stated in Notice No. 4, we do not believe that the use of distilled spirits brand names or cocktail names on FMB labels is inherently misleading. We recognize that many commenters believe that these names confuse consumers as to the identity of the products. However, if a product is clearly labeled with a designation such as ''malt beverage with natural flavors,'' we believe that the use of a distilled spirits brand name on the label does not mislead consumers. Accordingly, we are not adopting the suggestion that we prohibit the use of distilled spirits brand names or cocktail names in the labeling or advertising of FMBs. However, we will continue to consider labels and advertisements on a case-by-case basis, to determine if the overall presentation misleads consumers as to the identity of the product.

We note that not a single FMB producer indicated an intention to produce FMBs that would be classified as distilled spirits products under either the proposed 0.5% standard or the 51/49 standard we are adopting. Thus, under either standard, FMBs would continue to be produced as malt beverages rather than distilled spirits.

We recognize the concerns of many commenters that FMBs may be particularly attractive to young drinkers. The public health issue posed by underage consumption of alcohol beverages is significant. In September of 2003, the National Research Council and Institute of Medicine of the National Academies released a report to Congress on underage drinking, in which it found that the societal cost of underage drinking has been estimated at $53 billion, including $19 billion from traffic crashes and $29 billion from violent crime. (*See* ''Reducing Underage Drinking: A Collective Responsibility.'') The report calls for a comprehensive prevention strategy to create and sustain a broad societal commitment to reduce underage drinking.

TTB appreciates the importance of these prevention efforts. However, many of the issues that are of concern to the commenters in this regard are beyond the scope of our authority. For example, the FAA Act does not prohibit the advertisement of distilled spirits products on television; voluntary industry codes in the broadcasting and distilled spirits industries govern this matter. Furthermore, it is the States that decide whether products such as FMBs are sold in liquor stores or grocery stores. As previously noted, the rulemaking record indicates that producers of FMBs will reformulate their products so that they will continue to be classified as malt beverages under Federal law, regardless of whether we adopt the 0.5% standard or the 51/49 standard. Thus, we do not conclude that adoption of the 0.5% standard would result in the reclassification, under Federal law, of FMBs as distilled spirits products.

Our mandate is to ensure the proper classification of FMBs under the IRC and the FAA Act, and to ensure that these alcohol beverages are labeled and advertised in a manner that does not mislead consumers. We do not believe that the concerns of those commenters who wish to reduce underage alcohol consumption, important as they are, are directly addressed by this rulemaking.

D. More Explicit Labeling of FMBs

1. Comments Received

Several commenters requested that TTB implement more specific labeling for FMBs, including label items such as calories, serving size, ingredients, alcohol content, and so forth. These commenters claimed this action would provide essential information to consumers regarding these products.

2. TTB Response

TTB believes that these comments are outside the scope of the current rulemaking, as we did not specifically solicit comments on these issues in Notice No. 4. However, the CSPI, the NCL, and other public interest groups have recently petitioned TTB to require additional labeling of all alcohol beverages. TTB will separately study the petition in order to determine whether to propose such labeling for alcohol beverages. Therefore, TTB is not considering this request for additional labeling of flavored malt beverages as part of this rulemaking.

E. Establishing Another Category of Alcohol Beverages

1. Comments Received

Some commenters suggested that, instead of attempting to classify FMBs as either beer or distilled spirits, TTB should seek an amendment to Federal law to define a new class of alcohol beverages. These commenters suggested that with a new category of alcohol beverages, TTB could better address taxation, labeling, and other issues that apply to FMBs. This suggestion would establish a unique category of alcohol beverages unlike distilled spirits or traditional beer.

2. TTB Response

This comment is beyond the scope of the current rulemaking procedure, as its implementation would require amendments to Federal law.

F. Other Comments

One commenter suggested that TTB require identification and labeling of the source of alcohol in FMBs in order to inform consumers of their composition.

TTB believes that this comment is outside the scope of the proposals contained in Notice No. 4. Accordingly, we are not addressing this subject in the final rule.

XIV. Implementation Dates

TTB received 20 comments expressing opinions about implementation dates, and related tax issues, for adoption of either the 0.5 percent standard or the majority standard for flavored malt beverages. Among these comments, 6 were from brewers, 3 were from Members of Congress, 2 were from State licensing agencies, 3 were from national brewery trade associations, and the rest were from individuals.

A. Effective Date for Compliance With the New Added Alcohol Standard

1. Comments Received

Comments concerning implementation, or a regulatory effective date, varied from a minimum of ''as short a period as is reasonable'' to a maximum of two years after publication of the final rule containing an added alcohol standard for FMBs.

All brewers that commented on this issue expressed concerns regarding the time needed for reformulating products, and for the purchase, installation, and testing of new equipment. Among the reasons presented for establishing a longer effective date were: the need to develop the correct taste profile in a reformulated product; the need to invest and install new equipment to produce reformulated FMBs; the time needed to gear up for mass production of reformulated products; the time required to invest in co-packers equipment; and the need to test new formulations of FMBs. One brewer stated that reformulation of their products would require them to produce as much as 8 times the amount of fermented malt base and that they would require significant time to procure the necessary equipment. Another brewer commented that they would be able to comply with a 0.5% alcohol standard, as proposed, within 3 months time, and requested, at most, a 6-month delayed effective date. Six brewers requested effective dates of 6 months, 6 to 9 months, 1 year (two comments), 18 months, and 2 years.

Three trade associations commented on this issue. One brewery trade association commented that 3 months was an adequate amount of time to comply with the new standard. Another commented that 18 months would be required. The third, a wholesaler association, requested that TTB establish a reasonable amount of time for brewers to comply with the new standard.

One State regulatory authority requested swift action to re-classify FMBs to the 0.5 percent standard, specifying that a TTB delay will force them to initiate a more restrictive regulation for alcohol beverages. Another State believed it would not need new State legislation for the 0.5 percent standard, and urged TTB to adopt this standard in the minimum period needed to assure industry compliance.

2. TTB Response

TTB is sensitive to the time needs and excise tax concerns of the FMB industry during this period of transition. We realize that adoption of any added alcohol standard will impact production methods, ingredients, suppliers, costs, and other facets of the business. Moreover, we recognize that considerable time is needed to develop new products that not only conform to an added alcohol standard, but which taste the same or are similar to existing non-conforming FMBs.

Based on the submitted comments and the considerations noted above, we are prescribing a one-year delayed effective date for the regulatory changes adopted in this final rule document. We believe this will allow ample time to develop new products and to acquire the necessary equipment to place them into production. We believe the three-month and six-month periods requested by two commenters are too short for some industry members to make the necessary transition to the new rules. We also believe that industry members will be able to comply with the new rules in considerably less time than the 2-year period requested by one commenter, especially since we are adopting the less stringent 51/49 standard for FMB products.

In adopting a one-year delayed effective date, we also note that, due to the complex nature of this rulemaking, more than one year has already passed since the publication of the proposed rule. Thus, brewers have already had a substantial period of time to focus on the research and development necessary to bring their products into compliance with a new standard.

Accordingly, we provide a one-year period of time from publication of this final rule in the **Federal Register** for brewers and importers to comply with the 51/49 standard as well as other new regulatory requirements. As of the effective date of this final rule, products that do not comply with the new 51/49 standard may not be produced at a brewery, bottled at a brewery, removed from a brewery with or without the payment of tax, removed from customs custody for consumption, or (in the case of products not destined for exportation) transferred to a second customs bonded warehouse.

B. Effect on Products in the Marketplace

1. Comments Received

Three brewers and two trade associations commented about FMBs that are in the marketplace at the time of the effective date of a new standard. These commenters sought reassurance that these FMBs would not be subject to a floor stocks tax at the higher distilled spirits excise tax rate, and that these products would not be subject to destruction or recall from the market since they might be considered distilled spirits at that time. One brewer requested a six-month delay from the final rule's effective date so that wholesalers could deplete their inventories of FMBs not in conformity with new alcohol standards.

2. TTB Response

As noted above, the effective date for implementation of the alcohol standard impacts only the production and removal from a brewery, or the importation and removal from customs custody of malt beverage or beer products. Thus, TTB will continue to treat as beer or malt beverages those products made according to previously existing standards and removed from the brewery or from customs custody before the effective date. TTB will not assess a distilled spirits tax on them or require their recall or destruction. Wholesalers and retailers holding these products on or after the effective date may continue to market them in the same manner as prior to the effective date, until their supplies in the marketplace are exhausted.

Notwithstanding the above, it is incumbent on wholesalers and retailers who hold these products to ensure compliance with the requirements of the States in which the products are held or introduced for sale. Many States have requested that TTB provide a Federal FMB definition and added alcohol percent standard that can serve as a guide for State classification of alcohol beverages. In adopting a 51/49 standard for malt beverages containing no more than 6% alcohol by volume, and by adding to the regulations a 1.5% standard for malt beverages with an alcohol content in excess of 6% as explained later in this preamble, TTB is furnishing guidelines to the various States concerning the classification of flavored malt beverages. As already noted in this preamble, while most States look to Federal guidance in this area and rely on Federal classification of alcohol beverages, there is certainly no requirement for them to do so. Thus, individual States may take a different view of the classification and taxable status of these products, and may reclassify FMBs as distilled spirits products, perhaps even before the effective date of this final rule.

C. Additional TTB Comment on the Effective Date

We are using a single effective date for the new alcohol percent standards for FMBs. This date will permit affected industry members to transition their product lines according to their own needs. Until the effective date of this final rule, industry members may continue to produce and remove, at the beer tax rate, FMBs that do not meet the new alcohol percent standards.

Producers who cannot comply with the new 51/49 standard as of the effective date of the final rule must stop producing those FMB products at a brewery. As of the effective date of the final rule, products deriving more than 49% of their alcohol content from the distilled spirits components of added flavors may only be produced at distilled spirits plants. Such products would of course be subject to tax at the appropriate distilled spirits excise tax rate.

Until the effective date of the final rule, TTB's Advertising, Labeling and Formulation Division (ALFD) will continue to approve statements of process and certificates of label approval (COLAs) for FMBs that may not comply with the new added alcohol standards. During this interim period, ALFD will qualify these statements of process and COLA approvals with reference to this final rule's effective date. However, whether qualified or not, statements of process for FMBs not in compliance (including those permitting you to make a product not in compliance with the 51/49 standard) will become obsolete as of the effective date of this final rule and will be revoked by operation of the regulation. This means that no individual proceedings are necessary in order to revoke those formulas. Similarly, whether qualified or not, COLAs for these products that do not comply with the 51/49 standard as of the effective date will also be considered revoked by operation of regulation unless the underlying statement of process is superseded by a new formula that is in compliance with the 51/49 standard.

Because this final rule incorporates, in large part, the holdings of ATF Rulings 96–1 and 2002–2, while establishing new standards for added alcohol from flavors and other nonbeverage products, these rulings will become obsolete as of the effective date of the final rule.

XV. Comments on the Proposed Regulatory Text; Regulatory Text Changes

Several commenters suggested changes to the proposed regulatory text amendments contained in Notice No. 4. These comments are not directed to the policy behind the proposed regulatory amendments, but rather to their wording, clarity, or organization. In addition, TTB has independently reviewed the texts of the proposed amendments and has made a number of changes as a result of that review. The comments submitted and the changes made that are not of a minor editorial nature are discussed below.

A. Reference to Malt Beverage Standards, §§ 7.10 and 7.11

1. Comment Received

The FMBC commented that creating a new section to include standards for malt beverages is unnecessary because persons seeking information on this topic would look at the definition of a malt beverage in § 7.10. The FMBC suggested incorporating the standards proposed in § 7.11 into the definition of malt beverage appearing in § 7.10.

2. TTB Response

TTB does not agree with the comment and suggested text change. The statutory definition of a malt beverage is not affected by this final rule; that definition cannot change without legislative action. Standards applying to production or composition of a malt beverage are more technical and may change from time to time. We wish to separate the relatively simple statutory definition from the more technical production requirements that we are adopting in this final rule. Further, we note that § 7.10 would become unnecessarily long and technical if we were to place malt beverage standards in that section. Therefore, we have decided to place the standards applying to production and composition of malt beverages in § 7.11.

We have provided a cross reference in § 7.10 to the standards for malt beverages appearing in § 7.11 in order to alert readers that additional conditions may apply to the production or composition of malt beverages. We also have changed proposed § 7.10 by including a reference to ''processes'' as well as standards for flavors in order to alert the reader to the fact that malt beverages may undergo certain processing specified in § 7.11.

TTB has changed the heading of § 7.11 to read ''Use of ingredients containing alcohol in malt beverages; processing of malt beverages.'' We

believe this title more accurately reflects the provisions of this section, which permit the use of certain processes and authorize the use of certain ingredients containing alcohol in malt beverages.

B. Comments on Alcohol Flavoring Material Reference, §§ 7.11 and 25.15

1. Comments Received

The FMBC commented on the wording in proposed § 7.11, specifically the phrase ''alcohol flavoring materials and other ingredients containing alcohol.'' The FMBC supported this wording, and suggested that this language recognized that brewers may add other ingredients containing alcohol, such as taxpaid distilled spirits and wine, to malt beverages. This commenter suggested that the final rule further clarify this policy by authorizing the use of ''alcohol flavors, taxpaid wine, taxpaid distilled spirits, or any other ingredient containing alcohol'' in both § 7.11 and § 25.15.

2. TTB Response

TTB used the wording ''alcohol flavoring materials and other ingredients containing alcohol'' in proposed § 7.11 to describe the kinds of materials that might contribute alcohol to a finished malt beverage. We do not agree with this commenter's suggestion that this language includes, or should be extended to include, the use of taxpaid distilled spirits or taxpaid wine.

The provision allowing the addition of flavors and other ingredients containing alcohol to malt beverages was specifically designed to permit the addition of alcohol flavors to malt beverages and to allow the addition of certain other materials such as blenders containing alcohol to malt beverages. TTB in Notice No. 4 did not intend to authorize the direct addition of distilled spirits to malt beverages. TTB reaffirms its long-held position that the IRC does not explicitly authorize the direct addition of distilled spirits to malt beverages. Thus, this final rule will not authorize the addition of distilled spirits to malt beverages.

TTB did include a reference to taxpaid wine in proposed § 25.15(b) and in proposed § 25.55(a)(2). However, this final rule does not authorize that use of taxpaid wine.

Like distilled spirits, taxpaid wine is a beverage product. Neither the IRC nor the FAA Act specifically authorizes the use of taxpaid wine in the production of malt beverages. TTB will not allow taxpaid wine to make up to 49% of the alcohol content of a malt beverage. Thus, this final rule does not authorize the use of taxpaid wine in any malt beverage.

Accordingly, in this final rule we have clarified our intent regarding the use of ingredients containing alcohol by using the phrase ''flavors and other nonbeverage ingredients containing alcohol'' in §§ 7.11 and 25.15. Use of this modified language makes it very clear that flavoring materials may contain alcohol and that other nonbeverage ingredients such as blenders may contain alcohol. It does not authorize the use of taxpaid distilled spirits or taxpaid wine in the production of malt beverages.

TTB notes that the FMBC also supported the Notice No. 4 recognition that various processes and treatments may be used on malt beverages to remove color, aroma, bitterness or other characteristics derived from fermentation. This provision remains unchanged in § 7.11.

C. Malt Beverages Above 6.0% Alc/Vol; Status of ATF Ruling 96–1

1. Comments Received

The FMBC commented that ATF Ruling 96–1 limits the contribution of added alcohol in malt beverages over 6.0% alc/vol to not more than 1.5% of the total volume. This commenter stated that Notice No. 4 neither incorporated nor addressed this limitation and requested that TTB clarify the status of the limit in the ruling on alcohol addition for malt beverages over 6.0% alc/vol.

Coors commented that the practical effect of the proposed 0.5% added alcohol limitation is to establish a natural limitation on the [upper] alcohol content of malt beverages. This commenter noted that the TTB alternative 51/49 percent proposal would permit a brewer to produce a 35% alc/vol malt beverage by combining a high alcohol fermented malt beverage of 18% alc/vol with an additional 17% alc/vol through alcohol flavor and blender use. Coors stated that ATF Ruling 96–1 clearly presented TTB's intention that alcohol in malt beverages should be derived from fermentation and not from fortification.

2. TTB Response

Notice No. 4 proposed to limit the addition of alcohol to all malt beverages from flavors and other materials containing alcohol to less than 0.5% alc/vol. This proposal would have included malt beverages with an alcohol content exceeding 6% alcohol by volume. Thus, there was no need to separately address these malt beverages in the proposed regulations.

As stated above, we have decided to adopt the more liberal 51/49 standard instead of the proposed 0.5% standard. However, Coors has accurately pointed out one hazard of extending the 51/49% majority rule to malt beverages of any alcohol strength including those over 6% alc/vol. To do so would facilitate the production of extremely high strength malt beverages at breweries.

Prior to issuing ATF Ruling 96–1, our predecessor agency reviewed FMBs on the market and determined that, based on approved statements of process, the only FMBs containing a significant amount of alcohol derived from flavors were for products that contained 6% or less alcohol by volume in the finished product. Although ATF had approved statements of process under § 25.67 for FMBs containing in excess of 6% alcohol by volume, in no instance had the quantitative amount of alcoholic flavoring materials used in such products contributed more than 1.5% alc/vol to the finished product. Accordingly, to preserve the status quo pending rulemaking on this issue, ATF ruled that FMBs containing in excess of 6% alcohol by volume may derive no more than 1.5% alcohol by volume from added alcoholic flavoring materials.

Based on the rulemaking record, there is no need to liberalize the added alcohol standard for FMBs with an alcohol content in excess of 6%. TTB believes that any such liberalization would raise serious questions as to whether the finished product was appropriately classified as a malt beverage or as a distilled spirits product.

Accordingly, this final rule incorporates the terms of ATF Ruling 96–1 with respect to malt beverages with an alcohol content of more than 6% alc/vol, by restricting the addition of alcohol to malt beverages above 6.0% alc/vol to not more than 1.5% of the volume of the finished product. We have incorporated this policy in the regulatory texts by adding a new paragraph (a)(2) to § 7.11 and by modifying § 25.15(b) to include the same 1.5% added alcohol qualification for malt beverages and beer over 6% alc/vol.

D. Changes to § 7.31

Although there is no substantive change in the proposed amendment to § 7.31, we have reversed the order of existing paragraph (d) and proposed new paragraph (e), so that paragraph (d) contains the new provision for submitting a formula or sample of a malt beverage to TTB in conjunction with the filing of an application for a certificate of label approval. We have also changed the term ''you'' to ''importer'' to clarify

the person required to comply with the regulation.

E. Reference to Standards for Beer, §§ 25.11 and 25.15

1. Comment Received

The FMBC commented that creating a new § 25.15 to include standards for beer production is unnecessary because persons seeking this information would look at the definition of beer in § 25.11. The FMBC therefore suggested incorporating the proposed § 25.15 standards into the existing definition of beer in § 25.11.

2. TTB Response

TTB is not adopting this suggestion for the reasons previously set forth in this comment discussion. We wish to separate the relatively simple statutory definition of beer from the more technical production requirements that we are adopting in this final rule. Further, we note that § 25.11 would become unnecessarily long and technical if we were to include standards for beer in that section. Therefore, we have retained the proposed standards applying to the production and composition of beer in new § 25.15.

We believe that the inclusion of a cross reference at the end of the § 25.11 beer definition to the standards for beer appearing in § 25.15 is sufficient to alert readers that additional conditions may apply to the production and composition of beer.

F. Other § 25.15 Issues

We have changed the title of § 25.15 to read, ''Materials for the production of beer.'' This change better reflects the content since this section specifies materials that may be used in producing beer at a brewery, and does not refer to the tax on beer.

G. Comments on Formula Proposals, §§ 25.55–25.58

We have conformed the language throughout §§ 25.55–25.58 to the use of the phrase ''flavors and other nonbeverage ingredients containing alcohol'' in referring to the materials containing alcohol that may be used in producing beer. We have also removed the term ''taxpaid wine'' that appeared in proposed §§ 25.55(a)(2) and 25.57(a)(3)(ii). As noted earlier in this comment discussion, these formula regulations do not authorize the use of taxpaid wine or taxpaid distilled spirits in the production of beer. We also added exception language regarding hop extract in § 25.55(a)(2) to clarify that the use of hop extract containing alcohol does not require the filing of a formula.

It has been TTB's policy to authorize the use of a formula covering production of a beer base that the brewer does not intend to market, but will use in the eventual production of a product such as an FMB. For example, a brewer might choose to file a formula for a beer base that the brewer has produced and removed character from through a variety of processes. At a later stage, the brewer could produce several distinct fermented products by adding different flavors to this base. We have added a new paragraph (b)(2) to § 25.55 to reflect this practice.

If a brewer adds flavors to a beer base or otherwise treats it to produce a fermented beverage that the brewer intends to market, any approved beer base formula should be referenced in the formula information specified in § 25.57. We have added a new paragraph (d) to § 25.57 to clarify this point.

Although we did not receive comments directed to § 25.58, we have reorganized and revised this section in order to clarify the distinction between a new formula and a superseding formula. We have not changed the substantive requirements in proposed § 25.58.

Paragraph (a) sets forth conditions that trigger the filing of a new formula, and these conditions are the same as those in paragraphs (a)(1) through (a)(6) of proposed § 25.58. The revised introductory text of paragraph (a) merely incorporates the terms of proposed paragraph (c) regarding giving each new formula a new formula number.

Paragraph (b) of § 25.58 combines proposed paragraphs (b) and (d). The introductory text of revised paragraph (b) clarifies when a brewer may file a superseding formula in lieu of filing an entirely new formula. Under this text, a brewer may file a superseding formula when the brewer makes a change to an existing approved formula that is not of a type that would require a holder of a certificate of label approval to file a new application for label approval on TTB Form 5100.31, regardless of whether the formula is for a product covered by a certificate of label approval. Thus, when a brewer replaces one ingredient with a similar ingredient, and this replacement is not of a type that would require a new certificate of label approval for the product, the brewer may file a superseding formula rather than a new formula.

Paragraph (b)(1) specifies that superseding formulas must be approved by TTB before they may be used, and that TTB will cancel the original formula upon approval of the superseding formula. Under § 25.58(b)(2), a superseding formula retains the original formula number but it must be annotated to show it is a superseding formula. If an existing certificate of label approval covers the product, the brewer may continue to use that certificate.

We have changed the section headings in §§ 25.15 and 25.53 through 25.58 by changing the question-style headings to declarative statement headings. We believe the latter approach is more effective than question-style headings in helping the reader to find regulatory information. Additionally, we note that part 25 does not contain other question-style headings at this time.

XVI. Regulatory Analysis and Notices

A. Executive Order 12866

As noted in the comment discussion in this final rule, several commenters suggested that the proposed 0.5% standard would impose significant regulatory burdens and economic costs on the FMB industry. One comment in particular, from the FMBC, suggested that the costs of the proposed 0.5% standard, when extrapolated to the entire FMB industry, would exceed $600 million over the next 4 years. In addition, this commenter suggested that the proposed 0.5% standard would have a negative impact on revenue collections by the Federal government due to reductions in sales of FMBs.

TTB believes that the FMBC comment may have overstated the regulatory burdens and economic costs that would be imposed by the proposed rule. However, as already pointed out in this document, we are persuaded by this and other comments that imposition of a 0.5% standard for all FMBs would impose greater regulatory burdens and economic costs than the 51/49 standard.

In response to these comments, TTB evaluated several options to minimize the regulatory burdens and economic costs imposed by the rule. In particular, we adopted an option that we believe will meet the important regulatory goals of this rulemaking project, while reducing in a meaningful fashion the regulatory burdens and costs imposed by the rule. In other words, we adopted the more lenient alternative advocated by the FMBC and others who opposed the 0.5% rule; thus, the final rule allows products labeled as FMBs to derive up to 49% of their alcohol content from the distilled spirits components of added flavors and other nonbeverage products.

In response to concerns raised by the comments, TTB also adopted a one-year delayed effective date for the final rule,

to allow affected producers adequate time to reformulate their products, if necessary. We believe that this delayed effective date also serves to address the concerns of affected industry members.

Accordingly, for the reasons set forth above, we have determined that the final rule, as modified in response to the comments, is not a significant regulatory action as defined in E.O. 12866. Therefore, a regulatory assessment is not required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

We have determined that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

In Notice No. 4, we stated our belief that 10 or fewer qualified small breweries actually manufacture flavored malt beverages subject to this rule. We specifically solicited comments on the number of small breweries that may be affected by this rule and on the impact of this rule on those breweries. We asked small breweries that believe they would be significantly affected by this rule to let us know and to tell us how the rule would affect them.

In response to Notice No. 4, we received only a few comments from brewers that identified themselves as small brewers that would be affected by the rule. These comments, as well as other comments submitted by FMB producers, suggested that the proposed 0.5% standard would unfairly burden small brewers, and could result in putting these companies out of business. The comments indicated that the small brewers would be able to comply with the 51/49 standard without such significant adverse consequences.

In response to these comments and others, we have modified the regulatory texts contained in this final rule to reduce the potential economic impact of the rule on small businesses that produce FMBs. As indicated earlier in the preamble to this document, we considered several options to reduce the economic impact on small businesses.

For various reasons, most importantly because the pertinent statutes would not authorize such an option, we rejected the option of exempting small businesses from compliance with the requirements of the final rule. However, for a number of reasons explained in detail earlier in the preamble to this document, we have adopted the more liberal 51/49 standard for products labeled as FMBs. We have also adopted a one-year delayed effective date for the provisions of this final rule, to allow adequate time for those FMB producers that wish to reformulate their products or otherwise conform to the requirements of the final rule regulatory texts. Accordingly, we believe that we have responded to the concerns raised by small businesses and have meaningfully reduced the costs and regulatory burdens imposed by the rule.

It should be noted that several small wholesalers and retailers commented that the proposed rule would have an adverse impact on them, because State law might not allow them to sell FMB products that are reclassified as distilled spirits products. We believe that the modifications discussed above address their concerns. Furthermore, the FMB producers that commented on this issue all indicated an intention to reformulate their products within the requirements of the final rule, rather than produce beverages that would be classified as distilled spirits products under Federal law. Finally, we would note that the Regulatory Flexibility Act does not require us to consider indirect effects on businesses that are not directly subject to the requirements of the final rule; instead, the relevant economic impact is ''the impact of compliance with the proposed rule on regulated small entities.'' *Mid-Tex Electric Cooperative, Inc.* v. *FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985). Wholesalers and retailers of FMBs are not directly subject to the requirements of the final rule.

Finally, a comment from the FMBC suggested that the alcohol content labeling requirement would have a significant economic impact on a substantial number of small entities, including many small brewers that produce beers and ales that contain only a small quantity of flavors. The FMBC comment conceded that it did not know how many brewers might be impacted by this requirement but suggested that many small brewers would be affected. The FMBC stated that its members already label their FMB products with alcohol content statements.

TTB did not receive any comments from small brewers who produce traditional flavored beers and ales suggesting that the requirement for an alcohol content statement would impose a significant economic burden. The Brewer's Association of America, a trade association representing more than 1,400 small brewers, supported the proposed rule without mentioning the alcohol content statement requirement. Furthermore, we note that brewers are already required to keep records of alcohol content under the IRC regulations set forth in 27 CFR 25.293. We have no information indicating that the requirement to disclose alcohol content on brand labels for malt beverages deriving alcohol from added flavors or other nonbeverage ingredients would impose a significant economic burden on a substantial number of small entities. Accordingly, the record does not support such a finding.

Pursuant to section 7805(f) of the Internal Revenue Code of 1986, we submitted the notice of proposed rulemaking preceding this final rule to the Chief Counsel for Advocacy of the Small Business Administration (SBA) for comment on its impact on small businesses. We received no comment from the SBA in response to that submission.

C. Paperwork Reduction Act

In Notice No. 4, TTB stated that the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, did not apply to the notice of proposed rulemaking, because we were not proposing any new or revised recordkeeping requirements. After review of the comments on this issue, TTB has determined that the final rule includes a new reporting requirement and a revision of an existing reporting requirement. The new reporting requirement involves the specific detail that must be included in the formulas for certain fermented products produced at a brewery. The revision involves the mandatory alcohol content statement for malt beverages that derive alcohol from added flavors or other ingredients. Because the final rule does not take effect for one year from publication of this document in the **Federal Register**, there is time to air these requirements for public comment prior to the effective date of the rule.

These collections of information have been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507(j) and assigned control numbers 1513–0118 and 1513–0087. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information in this regulation covered by OMB control

number 1513–0118 is found in §§ 25.55–25.58. This collection is necessary to ensure that producers of certain beers provide enough information to TTB to ensure the proper tax classification of the products. The likely respondents are businesses.

• *Estimated total annual reporting and/or recordkeeping burden:* 500 hours.

• *Estimated average annual burden hours per respondent and/or recordkeeper:* 5 hours.

• *Estimated number of respondents and/or recordkeepers:* 100.

• *Estimated annual frequency of responses:* 5.

The collection of information in this regulation covered by OMB control number 1513–0087 is in § 7.22, which imposes a requirement for an alcohol content statement on labels of malt beverages deriving any alcohol from added flavors or other nonbeverage ingredients. This information is required to ensure that consumers are not misled as to the alcohol content of malt beverages that derive alcohol from sources other than fermentation at a brewery. The likely respondents are businesses. This information constitutes one element of the labeling information on alcohol beverages required under authority of the Federal Alcohol Administration Act (FAA Act), and it relates to only one sector of the alcohol beverage industry. The policy of TTB and its predecessor agency has been to treat all labeling requirements under the FAA Act as resulting in one burden hour per respondent. Accordingly, because the producers of malt beverages already know the alcohol content of their products and displaying that content on the label constitutes only a small portion of the existing labeling requirements, the burden estimate associated with this alcohol content labeling requirement is minimal.

Comments concerning each collection of information should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Chief, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220. Any such comments should be submitted not later than March 4, 2005. Comments are invited on:

• Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• The accuracy of the agency's estimate of the information collection burden;

• Ways to enhance the quality, utility, and clarity of the information to be collected;

• Ways to minimize the information collection burden on respondents, including through the use of automated collection techniques or other forms of information technology; and

• Estimates of capital or start up costs and costs of operations, maintenance, and purchase of services to provide information.

XVII. Drafting Information

This principal author of this document is Charles N. Bacon. Other personnel in the Alcohol and Tobacco Tax and Trade Bureau and in the Department of the Treasury participated in the drafting of the document.

List of Subjects

27 CFR Part 7

Advertising, Authority delegations, Beer, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

27 CFR Part 25

Beer, Claims, Electronic fund transfers, Excise taxes, Exports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Surety bonds.

Amendment to the Regulations

■ For the reasons discussed in the preamble, TTB amends 27 CFR parts 7 and 25 as follows:

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

■ 1. The authority citation for 27 CFR part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

■ 2. We amend § 7.10 by revising the definition of ''malt beverage'' to read as follows:

§ 7.10 Meaning of terms.

* * * * *

Malt beverage. A beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption. Standards applying to the use of processing methods and flavors in malt beverage production appear in § 7.11.

* * * * *

■ 3. We amend subpart B by adding a new § 7.11 to read as follows:

§ 7.11 Use of ingredients containing alcohol in malt beverages; processing of malt beverages.

(a) *Use of flavors and other nonbeverage ingredients containing alcohol—*

(1) *General.* Flavors and other nonbeverage ingredients containing alcohol may be used in producing a malt beverage. Except as provided in paragraph (a)(2) of this section, no more than 49% of the overall alcohol content of the finished product may be derived from the addition of flavors and other nonbeverage ingredients containing alcohol. For example, a finished malt beverage that contains 5.0% alcohol by volume must derive a minimum of 2.55% alcohol by volume from the fermentation of barley malt and other materials and may derive not more than 2.45% alcohol by volume from the addition of flavors and other nonbeverage ingredients containing alcohol.

(2) In the case of malt beverages with an alcohol content of more than 6% by volume, no more than 1.5% of the volume of the malt beverage may consist of alcohol derived from added flavors and other nonbeverage ingredients containing alcohol.

(b) *Processing.* Malt beverages may be filtered or otherwise processed in order to remove color, taste, aroma, bitterness, or other characteristics derived from fermentation.

■ 4. We amend § 7.22 by adding a new paragraph (a)(5) to read as follows:

§ 7.22 Mandatory label information.

* * * * *

(a) * * *

(5) Alcohol content in accordance with § 7.71, for malt beverages that contain any alcohol derived from added flavors or other added nonbeverage ingredients (other than hops extract) containing alcohol.

* * * * *

■ 5. We amend § 7.29 by revising the introductory text of paragraph (a) and by adding a new paragraph (a)(7) to read as follows:

§ 7.29 Prohibited practices.

(a) *Statements on labels.* Containers of malt beverages, or any labels on such

containers, or any carton, case, or individual covering of such containers, used for sale at retail, or any written, printed, graphic, or other material accompanying such containers to the consumer, must not contain:

* * * * *

(7) Any statement, design, device, or representation that tends to create a false or misleading impression that the malt beverage contains distilled spirits or is a distilled spirits product. This paragraph does not prohibit the following on malt beverage labels:

(i) A truthful and accurate statement of alcohol content, in conformity with § 7.71;

(ii) The use of a brand name of a distilled spirits product as a malt beverage brand name, provided that the overall label does not present a misleading impression about the identity of the product; or

(iii) The use of a cocktail name as a brand name or fanciful name of a malt beverage, provided that the overall label does not present a misleading impression about the identity of the product.

* * * * *

■ 6. We amend § 7.31 by redesignating paragraph (d) as paragraph (e) and by adding a new paragraph (d) to read as follows:

§ 7.31 Label approval and release.

* * * * *

(d) *Formula and samples.* The appropriate TTB officer may require an importer to submit a formula for a malt beverage, or a sample of any malt beverage or ingredients used in producing a malt beverage, prior to or in conjunction with the filing of a certificate of label approval on TTB Form 5100.31.

* * * * *

■ 7. We amend § 7.54 by revising the introductory text of paragraph (a) and by adding a new paragraph (a)(8) to read as follows:

§ 7.54. Prohibited statements.

(a) *General prohibition.* An advertisement of malt beverages must not contain:

* * * * *

(8) Any statement, design, device, or representation that tends to create a false or misleading impression that the malt beverage contains distilled spirits or is a distilled spirits product. This paragraph does not prohibit the following in advertisements for malt beverages:

(i) A truthful and accurate statement of alcohol content, in conformity with § 7.71;

(ii) The use of a brand name of a distilled spirits product as a malt beverage brand name, provided that the overall advertisement does not present a misleading impression about the identity of the product; or

(iii) The use of a cocktail name as a brand name or fanciful name of a malt beverage, provided that the overall advertisement does not present a misleading impression about the identity of the product.

* * * * *

PART 25—BEER

■ 8. The authority citation for part 25 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5002, 5051–5054, 5056, 5061, 5091, 5111, 5113, 5142, 5143, 5146, 5222, 5401–5403, 5411–5417, 5551, 5552, 5555, 5556, 5671, 5673, 5684, 6011, 6061, 6065, 6091, 6109, 6151, 6301, 6302, 6311, 6313, 6402, 6651, 6656, 6676, 6806, 7011, 7342, 7606, 7805; 31 U.S.C. 9301, 9303–9308.

■ 9. We amend § 25.11 by revising the definition of ''beer'' to read as follows:

§ 25.11 Meaning of terms.

* * * * *

Beer. Beer, ale, porter, stout, and other similar fermented beverages (including saké and similar products) of any name or description containing one-half of one percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from any substitute for malt. Standards for the production of beer appear in § 25.15.

* * * * *

■ 10. We amend subpart B by adding an undesignated center heading and a new § 25.15 to read as follows:

Standards for Beer

§ 25.15 Materials for the production of beer.

(a) Beer must be brewed from malt or from substitutes for malt. Only rice, grain of any kind, bran, glucose, sugar, and molasses are substitutes for malt. In addition, you may also use the following materials as adjuncts in fermenting beer: honey, fruit, fruit juice, fruit concentrate, herbs, spices, and other food materials.

(b) You may use flavors and other nonbeverage ingredients containing alcohol in producing beer. Flavors and other nonbeverage ingredients containing alcohol may contribute no more than 49% of the overall alcohol content of the finished beer. For example, a finished beer that contains 5.0% alcohol by volume must derive a minimum of 2.55% alcohol by volume from the fermentation of ingredients at the brewery and may derive not more than 2.45% alcohol by volume from the addition of flavors and other nonbeverage ingredients containing alcohol. In the case of beer with an alcohol content of more than 6% by volume, no more than 1.5% of the volume of the beer may consist of alcohol derived from added flavors and other nonbeverage ingredients containing alcohol.

■ 11. We amend subpart F by adding two undesignated center headings, and by adding new §§ 25.53 and 25.55 through 25.58, to read as follows:

Samples

§ 25.53 Submissions of samples of fermented products.

The appropriate TTB officer may, at any time, require you to submit samples of:

(a) Cereal beverage, saké, or any fermented product produced at the brewery,

(b) Materials used in the production of cereal beverage, saké, or any fermented product; and

(c) Cereal beverage, saké, or any fermented product, in conjunction with the filing of a formula.

(26 U.S.C. 5415, 5555, 7805(a))

Formulas

§ 25.55 Formulas for fermented products.

(a) *For what fermented products must a formula be filed?* You must file a formula for approval by TTB if you intend to produce:

(1) Any fermented product that will be treated by any processing, filtration, or other method of manufacture that is not generally recognized as a traditional process in the production of a fermented beverage designated as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor.'' For purposes of this paragraph:

(i) Removal of any volume of water from beer, filtration of beer to substantially change the color, flavor, or character, separation of beer into different components, reverse osmosis, concentration of beer, and ion exchange treatments are examples of non-traditional processes for which you must file a formula.

(ii) Pasteurization, filtration prior to bottling, filtration in lieu of pasteurization, centrifuging for clarity, lagering, carbonation, and blending are examples of traditional processes for which you do not need to file a formula.

(iii) If you have questions about whether or not use of a particular process not listed in this section requires the filing of a formula, you may request a determination from TTB in

accordance with paragraph (f) of this section.

(2) Any fermented product to which flavors or other nonbeverage ingredients (other than hop extract) containing alcohol will be added.

(3) Subject to paragraph (f) of this section, any fermented product to which coloring or natural or artificial flavors will be added.

(4) Subject to paragraph (f) of this section, any fermented product to which fruit, fruit juice, fruit concentrate, herbs, spices, honey, maple syrup, or other food materials will be added.

(5) Saké, including flavored saké and sparkling saké.

(b) *Are separate formulas required for different products?*

(1) You must file a separate formula for approval for each different fermented product for which a formula is required.

(2) You may file a formula for a beer base to be used in the production of one or more other fermented products. The beer base must conform to the standards set forth in § 25.15.

(c) *When must I file a formula?*

(1) Except as provided in paragraph (c)(2) of this section, you may not produce a fermented product for which a formula is required until you have filed and received approval of a formula for that product.

(2) You may, for research and development purposes (including consumer taste testing), produce a fermented product without an approved formula, but you may not sell or market this product until you receive approval of the formula for it.

(d) *How long is my formula approval valid?* Your formula approved under this section remains in effect until: you supersede it with a new formula; you voluntarily surrender the formula; TTB cancels or revokes the formula; or the formula is revoked by operation of law or regulation.

(e) *Are my previously approved statements of process valid?* Your statements of process approved before January 3, 2006 are considered approved formulas under this section, provided that any finished product that could be made under the statement of process would be in compliance with the provisions of this part. You do not need to submit a formula for approval if a statement of process that remains valid covers the product.

(f) *Determinations by TTB regarding specific processes and ingredients.*

(1) The appropriate TTB officer may determine whether or not use of a process not listed in paragraph (a)(1) of this section requires you to file a formula for approval. The appropriate TTB officer may also exempt the use of a particular coloring, flavoring, or food material from the formula filing requirement of paragraph (a)(3) or paragraph (a)(4) of this section upon a finding that the coloring, flavoring, or food material in question is generally recognized as a traditional ingredient in the production of a fermented beverage designated as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor.''

(2) You may request a determination from TTB on whether or not the use of a process not listed in paragraph (a)(1) of this section will require the filing of a formula or whether the use of a particular coloring, flavoring or food material may be exempted from the formula filing requirement of paragraph (a)(3) or paragraph (a)(4) of this section. You should mail your request to the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(i) When requesting a determination as to whether a process is subject to the formula filing and approval requirement, the request must include:

(A) A detailed description of the proposed process;

(B) Evidence establishing that the proposed process is generally recognized as a traditional process in the production of a fermented beverage designated as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor''; and

(C) An explanation of the effect of the proposed process on the production of a fermented product.

(ii) When requesting an exemption from the formula filing requirement in paragraph (a)(3) or paragraph (a)(4) of this section regarding coloring, flavoring, or food material ingredients, the request must include the following information:

(A) A description of the proposed ingredient;

(B) Evidence establishing that the proposed ingredient is generally recognized as a traditional ingredient in the production of a fermented beverage designated as ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor''; and

(C) An explanation of the effect of the proposed ingredient in the production of a fermented product.

§ 25.56 Filing of formulas.

(a) *What are the general requirements for filing a formula?* (1) You must file your formula in writing. Your formula must identify each brewery where the formula applies by including each brewery name, address, and registry number.

(2) You must serially number each formula, commencing with ''1'' and continuing in numerical sequence.

(3) You must date and sign each formula.

(4) You must file two copies of each formula with TTB.

(b) *Where do I file a formula?* File your formula with the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(26 U.S.C. 5401, 7805)

§ 25.57 Formula information.

(a) *Ingredient information.* (1) For each formula you must list each separate ingredient and the specific quantity used, or a range of quantities used. You may include optional ingredients in a formula if they do not impact the labeling or identity of the finished product.

(2) For fermented products containing flavorings you must list for each formula: The name of the flavor; the product number or TTB drawback number and approval date of the flavor; the name and location (city and State) of the flavor manufacturer; the alcohol content of the flavor; and the point of production at which the flavor was added (that is, before, during, or after fermentation).

(3) For formulas that include the use of flavors and other nonbeverage ingredients containing alcohol, you must explicitly indicate:

(i) The volume and alcohol content of the beer base;

(ii) The maximum volumes of the flavors and other nonbeverage ingredients containing alcohol to be used;

(iii) The alcoholic strength of the flavors and other nonbeverage ingredients containing alcohol;

(iv) The overall alcohol contribution to the finished product provided by the addition of any flavors or other nonbeverage ingredients containing alcohol. You are not required to list the alcohol contribution of individual flavors and other nonbeverage ingredients containing alcohol. You may state the total alcohol contribution from these ingredients to the finished product; and

(v) The final volume and alcohol content of the finished product.

(b) *Process information.* For each formula you must describe in detail each process used to produce a fermented beverage.

(c) *Alcohol content.* For each formula you must state the alcohol content of the fermented product after fermentation

and the alcohol content of the finished product.

(d) *Beer base formulas.* You must refer in your formula to any approved formula number that covers the production of any beer base used in producing the formula product. If the beer base was produced by another brewery of the same ownership, you must also provide the name and address or name and registry number of that brewery.

(e) *Additional information.* The appropriate TTB officer may at any time require you to file additional information concerning a fermented product, ingredients, or processes, in order to determine whether a formula should be approved or disapproved or whether the approval of a formula should be continued.

(26 U.S.C. 5415, 5555, 7805(a))

§ 25.58 New and superseding formulas.

(a) *New formulas.* Except as otherwise provided in paragraph (b) of this section, you must file a new formula (with a new formula number) for approval by TTB if you—

(1) Create an entirely new fermented product that requires a formula;

(2) Add new ingredients to an existing formulation;

(3) Delete ingredients from an existing formulation;

(4) Change the quantity of an ingredient used from the quantity or range of usage in an approved formula;

(5) Change an approved processing, filtration, or other special method of manufacture that requires the filing of a formula; or

(6) Change the contribution of alcohol from flavors or ingredients that contain alcohol.

(b) *Superseding formulas.* You may file a superseding formula, instead of a new formula, if you have made any change listed in paragraphs (a)(2) through (a)(6) of this section and that change is not of a type that would require a holder of a certificate of label approval to file a new application for label approval on TTB Form 5100.31.

(1) A superseding formula replaces an existing formula, and you should file one only if you do not intend to use the existing formula any more. A superseding formula must be filed with TTB for approval. When TTB approves a superseding formula, TTB will cancel your previous formula.

(2) You may use the same formula number for a superseding formula that you used for the formula the superseding formula replaces, but you must annotate the formula number to indicate it is a superseding formula number. (For example, ''Formula 2, superseding.'')

(c) When you file a new or superseding formula with TTB, you must follow the procedures and other requirements of §§ 25.56 and 25.57.

§ 25.62 [Amended]

■ 12. We amend § 25.62 by removing and reserving paragraph (a)(7).

§ 25.67 [Removed and Reserved]

■ 13. We amend Subpart G by removing and reserving § 25.67.

§ 25.76 [Removed and Reserved]

■ 14. We amend Subpart G by removing and reserving § 25.76.

Signed: August 6, 2004.

Arthur J. Libertucci,

Administrator.

Approved: December 22, 2004.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

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