

Rules and Regulations

Federal Register

Vol. 70, No. 11

Tuesday, January 18, 2005

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 2004N-0214]

Public Information Regulations; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the *Federal Register* of September 2, 2004, a direct final rule to incorporate exemptions one, two, and three of the Freedom of Information Act (FOIA) into FDA's public information regulations. The purpose was to implement more comprehensively the exemptions contained in FOIA. The comment period closed November 16, 2004. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published at 69 FR 53615 (September 2, 2004), is withdrawn as of January 13, 2005.

FOR FURTHER INFORMATION CONTACT: Betty B. Dorsey, Division of Freedom of Information (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6567.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 2, 2004 (69 FR 53615), is withdrawn.

Dated: January 11, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-955 Filed 1-13-05; 9:55 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4 and 24

[T.D. TTB-23; Ref. Notice No. 13]

RIN 1513-AC21

Production of Dried Fruit and Honey Wines (2001R-136P)

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

ACTION: Treasury decision; final rule.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) makes two amendments to its regulations in response to two petitions submitted by producers of raisin and honey wines. One amendment allows the production of dried fruit wines with an alcohol by volume content of more than 14 percent. The other amendment lowers the minimum starting Brix of 22 degrees to 13 degrees in the production of honey wines. In addition, TTB corrects a technical error in the wine labeling regulations by raising the maximum limit on alcohol content derived from fermentation from 13 to 14 percent for ameliorated agricultural wines.

EFFECTIVE DATE: March 21, 2005.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry of the Alcohol and Tobacco Tax and Trade Bureau, Regulations and Procedures Division, at P.O. Box 18152, Roanoke, VA 24014; or telephone (540) 344-9333.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 5387 of the Internal Revenue Code of 1986 (IRC), 26 U.S.C. 5387, provides that wines made from agricultural products other than the juice of fruit must be made "in accordance with good commercial practice" as may be prescribed by the Secretary of the Treasury by regulation. Under this statutory provision, wines made according to those regulations are classed as "'standard agricultural wines.'" However, § 5387 precludes the following production processes:

- The addition of wine spirits to agricultural wines;
- The addition of coloring or flavoring materials to agricultural wines,

with the exception of the addition of hops to honey wine; or

- The blending of wines from different agricultural commodities.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the administration of the IRC provisions that relate to alcohol beverages, including wine. Part 24 of the TTB regulations (27 CFR part 24) addresses the IRC provisions pertaining to wine and contains, in subpart I, Production of Agricultural Wine, regulations that implement the provisions of IRC § 5387.

Requirements

Subpart I concerns the production of agricultural wines. Sections 24.202 and 24.203 specifically address dried fruit wine and honey wine, respectively, and § 24.204 addresses requirements for all agricultural wines other than dried fruit and honey wines. These sections prohibit the production of any agricultural wine with an alcohol content of more than 14 percent by volume following complete fermentation or complete fermentation and sweetening. The IRC does not specify this limitation, which has been in the regulations since 1954. Rather, the limitation derives from the law's "good commercial practice" standard.

Sections 24.202, 24.203, and 24.204 also contain limits on degrees Brix prior to fermentation for agricultural wines. Brix is the quantity of dissolved solids in a wine expressed as grams of sucrose in 100 grams of solution at 60 degrees Fahrenheit, that is, the percent of sugar by weight stated in degrees. The regulations permit the addition of water during the production of agricultural wines, to facilitate fermentation, as long as the density of the fermenting mixture is not reduced below 22 degrees Brix. The 22 degree limit, like that on alcohol content discussed above, was placed in the wine regulations in 1954 and is based on "good commercial practice" standards and not on specific statutory language.

Petitions

Dried Fruit Wine Petition

Bruno and George Wines, Inc., of Beaumont, Texas, petitioned TTB to amend § 24.202 to allow for the production of a standard dried fruit wine that contains more than 14 percent alcohol by volume. Because of the current prohibition in § 24.202 against

dried fruit wines with a higher alcohol content, we now classify such wines as Other Than Standard Wine (OTSW) under 27 CFR 24.210.

Shawn Bruno, president of Bruno and George Wines, Inc., wishes to produce and market a raisin wine made according to his grandfather's traditional Sicilian recipe. The resulting wine would have an alcohol content greater than 14 percent alcohol by volume, and Mr. Bruno argues that his wine can be classified as a dessert wine. Upon lifting this prohibition, Mr. Bruno's wine can be classified as a dessert raisin wine because § 4.21(f)(3) of the TTB regulations (27 CFR 4.21(f)(3)) allows designation of agricultural wines as agricultural dessert wines if they have an alcohol content greater than 14 percent but less than 24 percent by volume. This provision currently only applies to imported products by default because domestic producers are limited to the 14 percent maximum alcohol content.

Honey Wine Petition

Redstone Meadery of Boulder, Colorado, petitioned TTB to amend § 24.203 to allow for the production of a standard honey wine with a minimum starting Brix of less than 22 degrees. As indicated above, § 24.203 permits the addition of water in the production of honey wine to facilitate fermentation, as long as the density of the honey and water mixture is not reduced below 22 degrees Brix. We currently classify honey wines with a lower starting Brix as OTSW.

David Myers of Redstone Meadery states that he wants to make a lower alcohol honey wine that requires a starting Brix below 22 degrees. Mr. Myers argues that, because such a wine would still have honey as its primary fermentable ingredient, we should classify it as honey wine. He suggests that we create a new category for low-alcohol honey wines if the minimum starting Brix cannot be lowered. He proposes the names "light honey wine" or "honey wine varietal" for this new category, which would encompass honey wines with a starting Brix of between 22 degrees and 13 degrees, or roughly 7 percent alcohol by volume in the finished product.

Analysis

Both the language of IRC § 5387 and its implementing regulations in 27 CFR 24.202, 24.203, and 24.204 date from the Internal Revenue Code of 1954. The legislative history relating to § 5387 includes the following passage:

These wines are not specifically referred to in existing law. This addition to the law

enables the setting up by regulations of standards of agricultural wines after experience has shown to what extent provisions of law relating to natural wines should be considered applicable. Uniform limitations cannot be prescribed for all agricultural wines. Limitations consistent with good commercial practices in respect to the production of rice wines could not be prescribed for other wines, such as honey wine, rhubarb wine, etc. (H.R. Rep. 1337, 83rd Cong., 2nd Sess. (1954), reprinted 1954 U.S. Code Cong. & Admin. News 3, 4518.)

This explanation shows that the law recognizes that agricultural wines are unique, with production standards that may vary significantly from one type of wine to another. While standards for natural wine (wines made from sound, ripe grapes or other sound, ripe fruit) may influence agricultural wine standards, the two can vary significantly.

In 1954, the Internal Revenue Service established regulations based on standards of good commercial practice at that time. Because such standards change over time as a result of technical developments and consumer preferences, it is prudent to reassess these regulations in light of current industry practice and consumer understanding of these products.

TTB research initiated as a result of these proposals failed to locate the rationale for the maximum alcohol content limit of 14 percent for agricultural wines. The initial implementing regulations in 1954 do not explain why the limitation of 14 percent alcohol content was determined to be a good commercial practice for agricultural wines. (See 19 FR 7642, November 27, 1954, and 19 FR 9633, December 31, 1954.) While the IRC places similar limits on sweetened grape and sweetened fruit and berry wines (see 26 U.S.C. 5383(a) and 5384(a)), we decided that it may be unreasonable to apply standards for fruit and berry wines to all agricultural wines, since agricultural products typically have different requirements for fermentation.

Also, as noted by one of the petitioners, § 4.21(f)(3) permits a dessert wine classification for agricultural wines that are 14 to 24 percent alcohol by volume. Currently, producers of imported agricultural wines can legally call their products "dessert agricultural wine," and some dessert raisin wines, in fact, are imported into the United States. On the other hand, because domestic raisin wine producers must comply with the production provisions in part 24, they cannot take advantage of § 4.21(f)(3) and label their wines as dessert wines. We expect that changing § 24.202 will put domestic dried fruit wines on an equal footing with

imported products. In addition, customer preference drives the importation of these dried fruit dessert wines, which is evidence that the higher alcohol content represents a good commercial practice.

We also were unable to document a reason for the 22 degrees Brix limitation, but we believe it derives from the limitations placed on grape and fruit natural wines. IRC § 5382(b)(1) (26 U.S.C. 5382(b)(1)) states, in this regard, that the juice or must of grape and fruit wines may not be reduced with water to less than 22 degrees. It may be inappropriate to apply this same standard to all agricultural wines, since source products such as honey, raisins, and dandelions often contain far less natural water than do grapes and other fruits. In these cases, vintners must add water in order to achieve fermentation.

Our research into the production of honey wines identified references to a category of low-alcohol honey wine called "hydromel." The fact that a recognized category already exists for a lower alcohol honey wine indicates that such a wine is consistent with good commercial practice.

Notice of Proposed Rulemaking

TTB published Notice No. 13 regarding these two petition proposals in the July 2, 2003, **Federal Register** (68 FR 39500). We received three comments, all of which supported the proposed amendments to the honey wine regulations. Two of the commenters produce honey wine; the third produces apple wine. They stated that the proposed amendments were consistent with producer practices and would allow them to make better products. One of the honey wine producers suggested additional changes to further liberalize the honey wine regulations. These changes were beyond the scope of the present rulemaking. We will, however, consider future petitions that propose additional amendments to the honey wine regulations.

Conclusion

Based on the above analysis, we amend § 24.202 to remove the 14 percent alcohol by volume limitation on wine produced from dried fruit. In addition, based on the above analysis and the submitted comments, we amend § 24.203 to lower the minimum Brix from 22 degrees to 13 degrees for honey wine. We also amend the latter section to make it clear that vintners may add sugar to sweeten honey wine only after fermentation. This restriction ensures that the alcohol in honey wine derives from honey and not from added sugar.

During the comment period, we also received an informal verbal comment from a wine industry member who felt that the proposed regulatory language for § 24.203 was confusing. We agree and have changed the structure of this paragraph. We have not, however, altered the meaning.

We do not adopt the suggestion of Mr. Myers to create a separate category for low-alcohol honey wines. No separate category exists for low-alcohol grape or fruit wines. Therefore, we see no need to have one for agricultural wines.

Also, the terms proposed by Mr. Myers, "light honey wine" and "honey wine varietal," have other connotations that could cause consumer confusion when they are used in labeling wines. Section 4.21(a)(2) of the TTB regulations currently allows use of the term "light" on labels of grape wines that are less than 14 percent alcohol by volume. This authorization encompasses wines that are not usually considered low-alcohol. Creating a different meaning for "light" honey wines could confuse consumers.

In addition, we feel that the consumer associates the word "varietal" with grape varieties, not with agricultural products. In Notice No. 13, we stated that we would reconsider the creation of a separate category if we received sufficient comments that favor such a change over the lowering of the minimum Brix. We received no comments addressing this issue.

Technical Correction

While reviewing the regulations relating to agricultural wines, we noted a technical error in § 4.21(f)(1)(i) of the TTB regulations, which states that ameliorated agricultural wines may not have an alcohol content of more than 13 percent by volume that is derived from fermentation. This 13 percent limit is inconsistent with the IRC's treatment of other types of ameliorated wines. While the IRC does not contain a limit on alcohol content for ameliorated agricultural wines, it gives a 14 percent limit for ameliorated fruit and berry wines. Until corrected by T.D. ATF-458, §§ 4.21(d)(1)(i) and (e)(1)(i), the standards of identity for citrus and fruit wines respectively, also contained an incorrect limit of 13 percent. In order to establish consistency for all classes of wine, we amend § 4.21(f)(1)(i) to raise the alcohol content limit on ameliorated agricultural wines to 14 percent. Note that § 4.21(f)(1)(i) addresses only ameliorated agricultural wines and does not prohibit the production of nonameliorated agricultural wines that are greater than 14 percent alcohol by volume.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we certify that implementation of this regulation will not have a significant economic impact on a substantial number of small business entities. We expect no negative impact on small entities and are not enacting new reporting, recordkeeping, or other administrative requirements. Accordingly, a regulatory flexibility analysis is not required.

Executive Order 12866

This rule is not a significant regulatory action, as defined in Executive Order 12866. Therefore, it requires no regulatory analysis.

Drafting Information

The principal author of this document is Jennifer Berry, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau.

List of Subjects

27 CFR Part 4

Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

27 CFR Part 24

Administrative practice and procedure, Claims, Electronic funds transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Vinegar, Warehouses, Wine.

Amendments to the Regulations

■ For the reasons discussed in the preamble, we amend 27 CFR parts 4 and 24 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

■ 1. The authority citation for 27 CFR part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

§ 4.21 [Amended]

■ 2. Amend § 4.21 by removing the phrase "13 percent" where it appears in the proviso in paragraph (f)(1)(i) and adding in its place the phrase "14 percent".

PART 24—WINE

■ 3. The authority citation for part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5081, 5111'5113, 5121, 5122, 5142, 5143, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364'5373, 5381'5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7011, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 4. Amend § 24.202 by revising the last sentence to read as follows:

§ 24.202 Dried fruit.

* * * After complete fermentation or complete fermentation and sweetening, the finished product may not have a total solids content that exceeds 35 degrees Brix. (26 U.S.C. 5387)

■ 5. Revise § 24.203 to read as follows:

§ 24.203 Honey wine.

(a) Subject to paragraph (b) of this section, a winemaker, in the production of wine from honey, may add the following:

(1) Water to facilitate fermentation, provided the density of the honey and water mixture is not reduced below 13 degrees Brix;

(2) Hops in quantities not to exceed one pound for each 1,000 pounds of honey; and

(3) Pure, dry sugar or honey for sweetening. Sugar may be added only after fermentation is completed.

(b) After complete fermentation or complete fermentation and sweetening, the wine may not have an alcohol content of more than 14 percent by volume or a total solids content that exceeds 35 degrees Brix. (26 U.S.C. 5387)

Signed: November 18, 2004.

Arthur J. Libertucci,
Administrator.

Approved: November 24, 2004.

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

[FR Doc. 05-911 Filed 1-14-05; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[TTB T.D.-22; Re: Notice No. 12]

RIN 1513-AA63

Establishment of the McMinnville Viticultural Area (2002R-217P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.