

Health Service Act (42 U.S.C. 216, 241, 262, 263, 263a-263n).

2. Section 812.18 is amended by revising paragraph (b) to read as follows:

**§ 812.18 Import and export requirements.**

\* \* \* \* \*

(b) *Exports.* A person exporting an investigational device subject to this part shall comply with section 801(e)(1) of the act, and shall obtain FDA's prior approval, as required by section 801(e)(2) of the act. However, if the investigational device to be exported is the subject of an investigational device exemption application (IDE) approved by FDA:

(1) No prior approval shall be necessary provided that the investigational device to be exported will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices that are the subjects of FDA-approved IDE's. (For devices that have received a "CE" mark from the European Union, the valid granting of a CE mark for a device that is the subject of an FDA-approved IDE shall constitute approval of the device for importation into any country in the European Economic Area.) A list of countries that have approved the importation of investigational devices that are the subjects of IDE's approved by FDA is available from the Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(2) If FDA withdraws approval of the IDE or the sponsor terminates any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects, exportation of the investigational device may continue only with FDA approval in accordance with section 801(e)(2) of the act.

Dated: November 13, 1995.

William B. Schultz,

*Deputy Commissioner for Policy.*

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**DEPARTMENT OF THE TREASURY**

**27 CFR Parts 5, 19, 24, 25, 70, and 250**

[Notice No. 816]

RIN 1512-AB40

**Registration of Formulas and Statements of Process for Certain Domestically Produced Wines, Distilled Spirits and Beer (95R-019P)**

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) is proposing to amend the regulations to require the registration, rather than approval, of formulas and statements of process for certain domestically produced wines, distilled spirits, and beer. ATF believes that the proposed regulations will provide greater flexibility to the industry by enabling proprietors to commence production in a more expeditious manner.

The proposed amendments are part of the Administration's Reinventing Government effort to reduce burden and streamline requirements.

**DATES:** Written comments must be received on or before January 26, 1996.

**ADDRESSES:** Send written comments to: Chief, Wine, Beer and Spirits Regulations Branch; Bureau of Alcohol, Tobacco and Firearms; P.O. Box 50221; Washington, DC 20091-0221; ATTN: Notice No. 816.

**FOR FURTHER INFORMATION CONTACT:** James P. Ficaretta, Wine, Beer and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202-927-8230).

**SUPPLEMENTARY INFORMATION:**

**Background**

Under the current regulations, approved formulas or statements of process are required for certain domestically produced distilled spirits, wines, and beer. Pursuant to regulations in 27 CFR Part 5, an approved formula on ATF Form 5110.38 (Formula For Distilled Spirits Under The Federal Alcohol Administration Act) is required to blend, mix, purify, refine, compound, or treat distilled spirits in a manner which results in a change of character, composition, class or type of the spirits. The formula requirement applies to: (1) Proprietors of distilled spirits plants qualified as processors under 27 CFR Part 19; (2) Persons in Puerto Rico who manufacture distilled spirits products

for shipment to the United States in accordance with 27 CFR Part 250; and (3) Persons who ship Virgin Islands distilled spirits products into the United States in accordance with 27 CFR Part 250.

As it relates to wine, the regulations in 27 CFR Part 24 provide that a proprietor must, before commencing production, obtain approval of the formula and process by which special natural wine, agricultural wine, and certain other than standard wines (e.g., Spanish type blending sherry) are to be made. An approved formula is also required under certain conditions in the production of an effervescent (sparkling) wine. Wine formulas are filed on ATF Form 5120.29, Formula And Process For Wine.

With regard to beer, the regulations in 27 CFR Part 25 require that a brewer file a statement of process for any fermented beverage which the proprietor intends to produce and market under a name other than "beer," "ale," "porter," "stout," "lager," or "malt liquor." The statement of process, which is contained in the Brewer's Notice, ATF Form 5130.10, includes the name or designation of the product, the kinds and quantities of materials to be used, the method of manufacture, and the approximate alcohol content of the finished product.

ATF reviews approximately 1,700 formulas and statements of process annually. The Bureau examines the formulas and statements of process to ensure that, among other things, the ingredients used are not only approved by the Food and Drug Administration (FDA), but are used within prescribed limitations established by the FDA. The average turnaround time for processing a formula or statement of process is approximately 3 weeks.

The majority of formulas and statements of process that ATF examines are approved without any substantive changes. The Bureau attributes this, in part, to its continued efforts at providing guidance and information to members of the alcoholic beverage industry. Through the publication of industry circulars and other publications, such as the "Compliance Matters" bulletin, ATF is able to apprise the industry of policies or procedures which might affect them. With regard to formulas for wine and distilled spirits, specifically, the Bureau recommends that proprietors review Industry Circular 89-3. This circular clarifies and provides information and guidelines for the completion and submission of formulas. This circular can also be utilized by brewers in the

preparation of statements of process for flavored malt beverage products.

#### *Proposed Registration of Formulas and Statements of Process*

ATF is proposing to amend the regulations to provide for the registration, rather than approval, of formulas and statements of process. ATF believes that a registration system will provide greater flexibility to the industry by enabling proprietors to commence production in a more expeditious manner. As indicated, ATF's current average turnaround time for processing a formula or statement of process is 3 weeks. Under a registration system, the turnaround time would be less than 1 week. The proposed amendments are part of the Administration's Reinventing Government effort to reduce burden and streamline requirements.

Registration merely indicates that a formula or statement of process is on file with ATF. For formulas and statements of process registered on or after the effective date of the final rule, registration does not mean that ATF has determined that the formula or statement of process complies with the laws and regulations enforced by ATF.

If the proposed regulations are adopted, the forms which are currently used by proprietors for filing distilled spirits and wine formulas (ATF F 5110.38 and ATF F 5120.29, respectively) will be revised accordingly. No additional information will be required on the revised forms. With regard to distilled spirits and wine, the procedures for filing the revised forms will be the same as currently required. For beer products, the statement of process will no longer be included as part of the Brewer's Notice, Form 5130.10. Rather, brewers will prepare the statement of process on letterhead stationery, in triplicate. The statement will be filed with the Chief, Product Compliance Branch.

Once received, ATF will register the formula or statement of process and include the date of registration. The registered formula or statement of process will then be forwarded to the proprietor. Production may commence upon the receipt by the proprietor of a registered formula or statement of process.

With the exception of special natural wines, ATF will register all formulas for distilled spirits and wine as well as statements of process for beer. In the case of special natural wine, section 5386 of the Internal Revenue Code of 1986, 26 U.S.C. 5386, requires that such wine be made pursuant to an approved formula. Therefore, ATF will continue

to approve formulas for special natural wine filed on ATF Form 5120.29.

Each applicant submitting a formula or statement of process for registration should ensure that such formula or statement of process is properly completed. In addition to following the guidelines presented in Industry Circular 89-3, the instructions on the reverse side of the forms should be followed carefully. ATF will continue to provide guidance to proprietors, as needed, through the publication of its "Compliance Matters" bulletin and through other methods.

Previously approved formulas and statements of process will not have to be submitted to ATF for registration. These will continue to be valid and, except for special natural wines, will automatically be deemed and included as registered formulas and statements of process for all purposes. When a change is made in the registered formula or statement of process (including those previously approved), the new formula or statement of process must be registered. When a change is made in an approved special natural wine formula, the new formula must be approved.

#### *Cancellation of Registered Formulas and Statements of Process*

The proposed regulations also set forth the procedures for the cancellation of registered formulas and statements of process (including those previously approved). These procedures will appear in 27 CFR Part 70, Procedure and Administration. The establishment of these procedures in the regulations will ensure that all industry members are aware of this practice and will afford due process of a notice and opportunity to present their position before their registered formula or statement of process is cancelled. The proposed cancellation procedures do not apply to approved formulas for special natural wines. ATF is considering whether these procedures should apply to such approved formulas and is interested in comments on this question.

#### *Executive Order 12866*

It has been determined that this proposed rule is not a significant regulatory action as defined in E.O. 12866. Therefore, a regulatory assessment is not required.

#### *Regulatory Flexibility Act*

It is hereby certified that this proposed regulation will not have a significant economic impact on a substantial number of small entities. The proposed rule is liberalizing in nature in that domestic proprietors will be able to commence production in a

more timely manner for those wines, distilled spirits, and beers which require a registered formula or statement of process. Accordingly, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, this proposed regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

#### *Paperwork Reduction Act*

The collections of information contained in this notice of proposed rulemaking have been previously reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)) under the following control numbers: 1512-0045, 1512-0058, 1512-0059, 1512-0192, 1512-0198, 1512-0203, 1512-0204, 1512-0205, 1512-0206, 1512-0207, 1512-0216, 1512-0250, 1512-0298, 1512-0352, 1512-0461, 1512-0462, 1512-0503. These control numbers were in effect on October 1, 1995, the effective date of the Paperwork Reduction Act of 1995. Comments on the collections of information should be sent to the Office of Management and Budget, Attention: Desk officer for the Department of the Treasury, Bureau of Alcohol, Tobacco and Firearms, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Chief, Document Services Branch, Room 3450, Bureau of Alcohol, Tobacco, and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226.

#### *Public Participation*

ATF requests comments on the proposed regulations from all interested persons. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director within the 60-day comment period. The

Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing is necessary.

#### Disclosure

Copies of this notice and the written comments will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC.

#### Drafting Information:

The author of this document is James P. Ficaretta, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms.

#### List of Subjects

##### Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, and Packaging and containers.

##### Part 19 q02

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations, Claims, Chemicals, Customs duties and inspection, Electronic funds transfers, Excise taxes, Exports, Gasohol, Imports, Labeling, Liquors, Packaging and containers, Reporting requirements, Research, Security measures, Spices and flavorings, Surety bonds, Transportation, U.S. possessions, Warehouses, and Wine.

##### Part 24

Administrative practice and procedure, Authority delegations, 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, Taxpaid wine bottling house, Transportation, Vinegar, Warehouses, and Wine.

##### Part 25

Administrative practice and procedure, Authority delegations, Beer, Claims, Electronic funds transfers, Excise taxes, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Research, Surety bonds, and Transportation.

##### Part 70

Administrative practice and procedure, Alcohol and alcoholic beverages, Appeals, Authority delegations, Cancellations, Claims, Government employees, Informal conferences, Law enforcement, and Law enforcement officers.

#### Part 250

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Beer, Claims, Customs duties and inspection, Drugs, Electronic funds transfers, Excise taxes, Foods, Liquors, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Spices and flavorings, Surety bonds, Transportation, Virgin Islands, Warehouses, and Wine.

#### Authority and Issuance

27 CFR Parts 5, 19, 24, 25, 70, and 250 are amended as follows:

### PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Paragraph 1. The authority citation for 27 CFR Part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805; 27 U.S.C. 205.

Par. 2. Section 5.11 is amended by adding a definition for “registered formula” to read as follows:

#### § 5.11 Meaning of terms.

\* \* \* \* \*

*Registered formula.* A distilled spirits formula which has been filed with the Director and bears the signature of the Director or the Director's delegate.

\* \* \* \* \*

Par. 3. Section 5.26 is revised to read as follows:

#### § 5.26 Formula requirements.

(a) *General.* A registered formula is required to blend, mix, purify, refine, compound, or treat spirits in a manner which results in a change of character, composition, class or type of the spirits. Form 5110.38 (formerly 27-B Supplemental) shall be filed with the Director in accordance with the instructions on the form and shall designate all ingredients and, if required, the process used. Any approved formula on Form 27-B Supplemental and any approved or registered formula on Form 5110.38 shall remain in effect until canceled, superseded, or voluntarily surrendered. Any existing qualifying statements as to the rate of tax or the limited use of drawback flavors appearing on a Form 27-B Supplemental are obsolete.

(b) *Registration of formulas approved before (effective date of final rule).* Any formula on Form 27-B Supplemental or Form 5110.38 that was approved before (effective date of final rule) is included as a registered formula, as required by paragraph (a) of this section, without any resubmission by the holder of the

approved formula or notification by ATF.

(c) *Change in formula.* Any change in a registered formula shall require the filing of a new Form 5110.38. After a change in a formula has been registered, the original formula shall be surrendered to the Director.

(d) *Cancellation of registered formula.* The procedures for the cancellation of a registered formula are prescribed in 27 CFR Part 70, Subpart E.

Par. 4. Section 5.28 is revised to read as follows:

#### § 5.28 Adoption of predecessor's formulas.

The adoption by a successor of registered Forms 5110.38 shall be in the form of an application filed with the Director. The application shall clearly show that the predecessor has authorized the use of its previously approved or registered formulas by the successor. The application shall list the formulas for adoption by:

- (a) Formula number,
- (b) Name of product, and
- (c) Date of registration (or original date of approved formula, if any).

### PART 19—DISTILLED SPIRITS PLANTS

Par. 5. The authority citation for 27 CFR Part 19 continues to read as follows:

Authority: 19 U.S.C. 81c, 1311; 26 U.S.C. 5001, 5002, 5004–5006, 5008, 5010, 5041, 5061, 5062, 5066, 5081, 5101, 5111–5113, 5142, 5143, 5146, 5171–5173, 5175, 5176, 5178–5181, 5201–5204, 5206, 5207, 5211–5223, 5231, 5232, 5235, 5236, 5241–5243, 5271, 5273, 5301, 5311–5313, 5362, 5370, 5373, 5501–5505, 5551–5555, 5559, 5561, 5562, 5601, 5612, 5682, 6001, 6065, 6109, 6302, 6311, 6676, 6806, 7011, 7510, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 6. Section 19.11 is amended by adding a definition for “registered formula” to read as follows:

#### § 19.11 Meaning of terms.

\* \* \* \* \*

*Registered formula.* A distilled spirits formula which has been filed with the Director and bears the signature of the Director or the Director's delegate.

\* \* \* \* \*

Par. 7. Section 19.187(a) is revised to read as follows:

#### § 19.187 Adoption of formulas.

(a) *Forms 5110.38.* The adoption by a successor of registered Forms 5110.38 shall be in the form of an application, filed with the Director. The application shall list the formulas for adoption by formula number, name of product, and date of registration (or original date of

the approved formula, if any). The application shall clearly show that the predecessor has authorized the use of its previously registered formulas by the successor.

\* \* \* \* \*

Par. 8. Section 19.324(b), under the undesignated center heading "FORMULA", is revised to read as follows:

Formula

**§ 19.324 Statement of production procedure or Form 5110.38.**

\* \* \* \* \*

(b) As provided in 27 CFR 5.27, a registered formula on Form 5110.38 is required for the redistillation of spirits in the production account. Any formula on Form 5110.38 that was approved before (effective date of final rule) is included as a registered formula, as required by this paragraph, without any resubmission by the holder of the approved formula or notification by ATF. The procedures for the cancellation of a registered formula are prescribed in 27 CFR Part 70, Subpart E.

\* \* \* \* \*

Par. 9. Section 19.331 is revised to read as follows:

**§ 19.331 General.**

Distillers or processors may redistill spirits, denatured spirits, articles, and spirits residues. Certain products may only be redistilled pursuant to a registered formula on Form 5110.38, as specified in 27 CFR 5.27. Any formula on Form 5110.38 that was approved before (effective date of final rule) is included as a registered formula, as required by this paragraph, without any resubmission by the holder of the approved formula or notification by ATF. The procedures for the cancellation of a registered formula are prescribed in 27 CFR Part 70, Subpart E.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1365, as amended (26 U.S.C. 5223))

Par. 10. Section 19.378, under the undesignated center heading "FORMULAS", is revised to read as follows:

Formulas

**§ 19.378 Formula requirements.**

A registered formula on ATF Form 5110.38 must be secured for spirits for domestic use or export as provided in 27 CFR 5.26-5.27 before processors may blend, mix, purify, refine, compound or treat spirits in any manner which results in a change of character, composition, class or type of the spirits including redistillation as provided in § 19.331, and the production of gin or vodka by

other than original and continuous distillation. Any formula on ATF Form 5110.38 that was approved before (effective date of final rule) is included as a registered formula, as required by this paragraph, without any resubmission by the holder of the approved formula or notification by ATF. The procedures for the cancellation of a registered formula are prescribed in 27 CFR part 70, Subpart E. (Sec. 201, Pub. L. 85-859, 72 Stat. 1356, as amended, 1395, as amended (26 U.S.C. 5201, 5555))

Par. 11. Section 19.596(b)(6) is amended by removing the words "an approved" and adding the words "a registered" in their place.

Par. 12. Section 19.723(c)(2) is amended by removing the word "approved" and adding in its place the word "registered" in the first sentence.

Par. 13. Section 19.778(b) is amended by removing the word "approved" and adding in its place the word "registered".

**PART 24—WINE**

Par. 14. The authority citation for 27 CFR 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, 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.

Par. 15. Section 24.10 is amended by adding the words "or registered" after the word "approved" in the definition for "formula wine" and by adding a definition for "registered formula" to read as follows:

**§ 24.10 Meaning of terms.**

\* \* \* \* \*

*Registered formula.* A wine formula which has been filed with the Director and bears the signature of the Director or the Director's delegate.

\* \* \* \* \*

Par. 16. Sections 24.80, 24.81, and 24.82, under the designated heading "FORMULAS", are revised and new section 24.83 is added to read as follows:

Formulas

**§ 24.80 General.**

The proprietor shall, before production, register the formula and process by which agricultural wine and other than standard wine (except distilling material or vinegar stock) are to be made. Any formula for an

agricultural wine and other than standard wine that was approved before (effective date of final rule) is included as a registered formula, as required by this section, without any resubmission by the holder of the approved formula or notification by ATF. For special natural wine, the proprietor shall, before production, obtain approval of the formula and process by which such wine is to be made. The formula shall be prepared and filed with the Director on ATF F 5120.29, Formula and Process for Wine, in accordance with the instructions on the form. A nonbeverage wine formula shall show the intended use of the finished wine or wine product. Any formula registered or approved under this section shall remain in effect until revoked, cancelled, superseded, or voluntarily surrendered. Except for research, development, and testing, no special natural wine, agricultural wine or, if required to be covered by a registered formula, other than standard wine may be produced prior to approval or registration by the Director of a formula covering each ingredient and process (if the process requires approval or registration) used in the production of the product.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1380, as amended, 1381, as amended, 1386, as amended, 1395, as amended (26 U.S.C. 5361, 5367, 5386, 5387, 5555))

(Approved by the Office of Management and Budget under control number 1512-0059)

**§ 24.81 Filing of formulas.**

The proprietor shall designate on each formula filed all ingredients and, if required, describe each process used to produce the wine. The addition or elimination of ingredients, changes in quantities used, and changes in the process of production or any other change in an approved or registered formula shall require the filing of a new ATF F 5120.29. After a change in formula is approved or registered, the original formula shall be surrendered to the Director. The proprietor shall serially number each formula, commencing with "1" and continuing thereafter in numerical sequence. Nonbeverage wine formulas shall be prefixed with the symbol "NB." The Director or the regional director (compliance) may at any time require the proprietor to file a statement of process in addition to that required by the ATF F 5120.29 or any other data to determine whether the formula should be approved, registered, revoked, or cancelled.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1381, as amended, 1395, as amended (26 U.S.C. 5367, 5555))

(Approved by the Office of Management and Budget under control number 1512-0059)

**§ 24.82 Samples.**

The Director or the regional director (compliance) may, at any time, require the proprietor to submit samples of any wine or wine product made in accordance with an approved or registered formula or of any materials used in production.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1380, as amended (26 U.S.C. 5351, 5361, 5362))

(Approved by the Office of Management and Budget under control number 1512-0059)

**§ 24.83 Cancellation of registered formulas.**

The procedures for the cancellation of a registered formula are prescribed in 27 CFR part 70, subpart E.

Par. 17. Section 24.127 is revised to read as follows:

**§ 24.127 Adoption of formulas.**

The adoption of approved or registered formulas by a successor proprietor shall be in the form of an application, filed with the Director. The application shall list the formulas for adoption by formula number, name of product, and date of approval or registration (or original date of the approved formula for an agricultural wine or other than standard wine, if any). The application shall clearly show that the outgoing proprietor has authorized the successor proprietor's use of the approved or registered formulas.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

(Approved by the Office of Management and Budget under control number 1512-0058)

Par. 18. Section 24.192 is amended by removing the word "approval" in the third sentence and by adding in its place the word "registration".

Par. 19. Section 24.201 is revised to read as follows:

**§ 24.201 Formula required.**

Before producing any agricultural wine, the proprietor shall register with the Director the formula and process by which it is to be made pursuant to the provisions of § 24.80. Any change in a formula shall be registered in advance as provided by § 24.81. The procedures for the cancellation of a registered formula are prescribed in 27 CFR part 70, subpart E.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1386, as amended (26 U.S.C. 5387))

(Approved by the Office of Management and Budget under control number 1512-0059)

Par. 20. Section 24.211 is revised to read as follows:

**§ 24.211 Formula required.**

A proprietor who desires to produce other than standard wine shall first register the formula by which it is to be made, except that no formula is required for distilling material or vinegar stock. The formula shall be filed with the Director as provided by § 24.80. Any change in the formula shall be registered in advance as provided by § 24.81. The procedures for the cancellation of a registered formula are prescribed in 27 CFR part 70, subpart E.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1387, as amended (26 U.S.C. 5388))

(Approved by the Office of Management and Budget under control number 1512-0059)

Par. 21. Section 24.214 is amended by removing the words "an approved" in the fourth sentence and by adding in its place the words "a registered".

Par. 22. Section 24.303(b) is amended by adding the words "or registered" after the word "approved".

**PART 25—BEER**

Par. 23. The authority citation for 27 CFR 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.

Par. 24. Section 25.11 is amended by adding definitions for "Chief, Product Compliance Branch" and "registered statement of process" to read as follows:

**§ 25.11 Meaning of terms.**

\* \* \* \* \*

*Chief, Product Compliance Branch.*

The ATF official responsible for registering statements of process under this part.

\* \* \* \* \*

*Registered statement of process.* A statement of process under § 25.67 which has been filed with ATF and bears the signature of the Chief, Product Compliance Branch or his or her delegate.

\* \* \* \* \*

Par. 25. Section 25.62 is amended by removing paragraph (a)(7) and by redesignating paragraphs (a)(8) through (a)(12) as paragraphs (a)(7) through (a)(11).

Par. 26. Section 25.67 is amended by revising paragraphs (a) and (c), and by adding new paragraph (d) to read as follows:

**§ 25.67 Statement of process.**

(a) A statement of process shall be prepared on letterhead stationery, in triplicate, and filed and registered with the Chief, Product Compliance Branch for any fermented beverage which the brewer intends to produce and market under a name other than "beer," "ale," "porter," "stout," "lager," or "malt liquor." Each statement of process shall include a serial number and shall identify each of the brewer's breweries for which it is filed. The brewer may not commence production of such beverages until the statement of process has been registered. Any statement of process that was approved before (effective date of final rule) is included as a registered statement of process, as required by this paragraph, without any resubmission by the holder of the approved statement of process or notification by ATF.

\* \* \* \* \*

(c) The base product for any fermented beverage (other than sake or cereal beverage) requiring a statement of process shall have the characteristics of beer as defined in § 25.11.

(d) The procedures for the cancellation of a registered statement of process are prescribed in 27 CFR part 70, Subpart E.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1333, as amended, 1388, as amended (26 U.S.C. 5052, 5401))

Par. 27. Section 25.71(b)(2) is revised to read as follows:

**Changes After Original Qualification**

**§ 25.71 Amended or superseding notices.**

\* \* \* \* \*

(b) \* \* \*

(2) If the information required by § 25.62(a)(4), (5), (6), (8), and (9) is on file as part of an approved Form 5130.10 and is current, the brewer may incorporate by reference those documents as part of any superseding notice.

\* \* \* \* \*

Par. 28. Section 25.76 is revised to read as follows:

**§ 25.76 Change in statement of process.**

When there is a change in the information in a statement of process required by § 25.67 for any fermented beverage produced and marketed under a name other than "beer," "ale," "porter," "stout," "lager," or "malt liquor," the brewer shall file and register an amended statement of process with the Chief, Product Compliance Branch prior to using such changed statement.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1388, as amended (26 U.S.C. 5401))

## PART 70—PROCEDURE AND ADMINISTRATION

Par. 29. The authority citation for 27 CFR Part 70 continues to read as follows:

Authority: 5 U.S.C. 301, 552; 26 U.S.C. 4181, 4182, 5146, 5203, 5207, 5275, 5367, 5415, 5504, 5555, 5684(a), 5741, 5761(b), 6020, 6021, 6064, 6102, 6155, 6159, 6201, 6203, 6204, 6301, 6303, 6311, 6313, 6314, 6321, 6323, 6325, 6326, 6331–6343, 6401–6404, 6407, 6416, 6423, 6501–6503, 6511, 6513, 6514, 6532, 6601, 6602, 6611, 6621, 6622, 6651, 6653, 6656, 6657, 6658, 6665, 6671, 6672, 6701, 6723, 6801, 6862, 6863, 6901, 7011, 7101, 7102, 7121, 7122, 7207, 7209, 7214, 7304, 7401, 7403, 7406, 7423, 7424, 7425, 7426, 7429, 7430, 7432, 7502, 7503, 7505, 7506, 7513, 7601–7606, 7608–7610, 7622, 7623, 7653, 7805.

Par. 30. Section 70.11 is amended by adding definitions for “Chief, Alcohol and Tobacco Programs Division”, “Chief, Product Compliance Branch”, “registered formula”, and “registered statement of process” to read as follows:

### § 70.11 Meaning of terms.

\* \* \* \* \*

*Chief, Alcohol and Tobacco Programs Division.* The Bureau official responsible for deciding appeals of cancellations of registered formulas and registered statements of process under this part.

*Chief, Product Compliance Branch.* The Bureau official responsible for issuing cancellations of registered formulas and registered statements of process under this part.

\* \* \* \* \*

*Registered formula.* A distilled spirits or wine formula which has been filed with the Bureau and bears the signature of the Director or the Director’s delegate.

*Registered statement of process.* A statement of process under 27 CFR 25.67 which has been filed with the Bureau and bears the signature of the Chief, Product Compliance Branch or his or her delegate.

\* \* \* \* \*

Par. 31. Sections 70.421 through 70.428, under the new undesignated center heading “CANCELLATION OF REGISTERED FORMULAS OR STATEMENTS OF PROCESS FOR DISTILLED SPIRITS, WINES AND BEER”, are added to Subpart E to read as follows:

Cancellation of Registered Formulas or Statements of Process for Distilled Spirits, Wines and Beer

### § 70.421 Cancellation of registration.

(a) *Cancellation of registered formulas or statements of process.* Formulas registered on ATF Form 5110.38 or ATF

Form 5120.29 and registered statements of process, may be cancelled by the Chief, Product Compliance Branch, upon a finding that the formula or statement of process is not in compliance with the applicable laws or regulations.

(b) *Notice of proposed cancellation.* Except as provided in section 70.422(a), when the Chief, Product Compliance Branch, determines that a formula or statement of process which has been registered is not in compliance with the laws or regulations, he or she shall issue to the holder of the formula or statement of process a notice of proposed cancellation which shall set forth the basis for the proposed cancellation. The notice of proposed cancellation will advise the holder of the formula or statement of process that he or she has 45 days from the date of the notice in which to present written arguments or evidence as to why the cancellation should not occur. If the holder of the formula or statement of process does not respond to the notice of proposed cancellation within 45 days of such notice, the holder will be deemed to concur with the finding of non-compliance, and the formula or statement of process will be cancelled. In either case, the right of appeal afforded in paragraph (d) of this section applies.

(c) *Decision after notice of proposed cancellation.* After considering any written arguments or evidence presented by the holder of the registered formula or statement of process, the Chief, Product Compliance Branch, shall issue a decision. If the decision is to cancel the registered formula or statement of process, a letter shall be issued explaining the basis for the cancellation and the specific laws or regulations relied upon in determining that the registered formula or statement of process was not in conformance with law or regulations. If the decision is to withdraw the proposed cancellation, a letter to that effect shall be issued.

(d) *Appeal of cancellation.* A holder of a registered formula or statement of process who wishes to appeal the decision of the Chief, Product Compliance Branch, may file a written appeal with the Chief, Alcohol and Tobacco Programs Division. The written appeal should set forth in detail the reasons he or she believes the decision of the Chief, Product Compliance Branch, was in error. Such appeal must be filed with the Chief, Alcohol and Tobacco Programs Division, within 45 days after the date of the decision of the Chief, Product Compliance Branch.

(e) *Final decision after appeal.* After considering any written arguments or

evidence presented by the holder of the registered formula or statement of process the Chief, Alcohol and Tobacco Programs Division, shall issue a written decision to the holder of the registered formula or statement of process. If the decision is to cancel the registered formula or statement of process, a letter shall be issued explaining the basis for the cancellation and the specific laws or regulations relied upon in determining that the registered formula or statement of process was not in conformance with law or regulations. If the decision is to withdraw the proposed cancellation, a letter to that effect shall be sent to the holder of the registered formula or statement of process. The decision of the Chief, Alcohol and Tobacco Programs Division, shall be the final decision of the Bureau.

### § 70.422 Cancellation of registration by operation of law or regulation.

(a) *Cancellation by operation of law or regulation.* The Bureau will not individually notify all holders of registered formulas or statements of process that such registrations have been canceled in situations where such cancellation occurs by operation of law or regulation. Where changes in requirements are made as a result of amendments or revisions to the law or regulations, it is the responsibility of the holder of the registered formula or statement of process to surrender voluntarily all registered formulas or statements of process which are no longer in compliance and to submit new formulas and statements of process that are in compliance with the new requirements; *Provided*, that in certain circumstances, the Bureau may announce that the submission of new formulas or statements of process for registration is not necessary in order to implement a new requirement in the law or regulations. In such circumstances, it is the responsibility of the holder of the registered formula or statement of process to ensure that formulas and statements of process are in compliance with the requirements of the new regulations or law, notwithstanding the fact that registration of new formulas or statements of process was not required.

(b) *Notice of cancellation.* If the Bureau determines that a holder of a registered formula or statement of process is using such registered formula or statement of process when it is no longer in compliance due to amendments or revisions in the law or regulations, the Chief, Product Compliance Branch, will notify the holder of the registered formula or statement of process in writing that the

subject formula or statement of process has been canceled by operation of law or regulations, with a brief description of the grounds for such cancellation.

(c) *Appeal of notice of cancellation.* Within 45 days after the date of a notice of cancellation by operation of law or regulations, the holder of a registered formula or statement of process may file a written appeal with the Chief, Alcohol and Tobacco Programs Division. The appeal should set forth the reasons why the holder of the registered formula or statement of process believes that the regulation or law at issue does not require the cancellation of the registered formula or statement of process.

(d) *Decision after appeal.* After considering all written arguments and evidence submitted by the holder of the registered formula or statement of process, the Chief, Alcohol and Tobacco Programs Division, shall issue a decision regarding the cancellation by operation of law or regulation of the registered formula or statement of process. If the decision is that the law or regulation at issue requires the cancellation of the registered formula or statement of process, a letter shall be issued explaining the basis for the cancellation and citing the specific laws or regulations which required the cancellation of the registered formula or statement of process. If the decision is that the law or regulation at issue does not require the cancellation of such registered formula or statement of process, a letter to that effect shall be sent to the holder of the registered formula or statement of process. The decision of the Chief, Alcohol and Tobacco Programs Division, shall be the final decision of the Bureau.

**§ 70.423 Informal conferences.**

(a) *General.* As part of a timely filed written appeal of a notice of proposed cancellation, notice of cancellation by operation of law or regulations, or a decision of the Chief, Product Compliance Branch, to cancel a registered formula or statement of process, a holder of a registered formula or statement of process may file a written request for an informal conference with the Chief, Alcohol and Tobacco Programs Division. The decision whether to hold an informal conference is at the sole discretion of the Chief, Alcohol and Tobacco Programs Division.

(b) *Informal conference procedures.* If the Chief, Alcohol and Tobacco Programs Division determines that the holding of an informal conference would be beneficial, he or she shall inform the holder of the registered formula or statement of process and a

date shall be agreed upon. The informal conference is for purposes of discussion only and no transcript shall be made. If the holder of the registered formula or statement of process wishes to rely upon arguments, facts, or evidence presented at the informal conference, he or she has 10 days after the date of the conference to incorporate such arguments, facts, or evidence in a written submission to the Chief, Alcohol and Tobacco Programs Division.

**§ 70.424 Effective dates of cancellations.**

With the exception of cancellations occurring pursuant to section 70.422(a), the Bureau shall allow at least 45 days between the issuance of a decision to cancel a registered formula or statement of process and the actual cancellation of the registered formula or statement of process. The deciding official may, at his or her discretion, allow the holder of the registered formula or statement of process a longer period of time in which to use the registered formula or statement of process. The decision to allow such a "use-up" period and the length of the "use-up" period allowed are matters committed entirely to the discretion of the deciding official, based on the circumstances of the case.

**§ 70.425 Effect of cancellations.**

(a) *General.* On the effective date of a final decision which has been issued by the Chief, Product Compliance Branch, or the Chief, Alcohol and Tobacco Programs Division, to cancel a registered formula or statement of process, the holder of the registered formula or statement of process shall be asked to surrender the original of such registered formula or statement of process to the Bureau for manual cancellation. Whether or not the original registered formula or statement of process has been manually cancelled, the formula or statement of process shall be null and void after the effective date of the cancellation of the registered formula or statement of process. It shall be a violation of this section for any holder of a registered formula or statement of process to present a registered formula or statement of process to an official of the United States Government as a valid registered formula or statement of process if the holder of the registered formula or statement of process has been previously notified that such registered formula or statement of process has been cancelled by the Bureau or the formula or statement of process was cancelled by operation of law or regulation.

(b) *Use of registered formula or statement of process during period of appeal.* If a holder of a registered

formula or statement of process files a timely appeal after receipt of a notice of cancellation from the Chief, Product Compliance Branch pursuant to section 70.421(c), he or she may continue to use the registered formula or statement of process at issue until the effective date of a final decision issued by the Chief, Alcohol and Tobacco Programs Division. However, the effective date of a notice of cancellation by operation of law or regulations, issued pursuant to section 70.422(b), is not stayed during the pendency of an appeal.

**§ 70.426 Service on holder of registered formula or statement of process.**

Notices of proposed cancellation and notices of cancellation shall be served on a holder of a registered formula or statement of process by first class mail or by personal delivery. When service is by mail, a signed duplicate original copy of the document shall be mailed to the holder of the registered formula or statement of process at the address stated on the registered formula or statement of process or at the last known address. If authorized by the holder of the registered formula or statement of process, the signed duplicate original copy of the document may be mailed to a designated representative. Where service is by personal delivery, a signed duplicate original copy of the document shall be delivered to the holder of the registered formula or statement of process or to a designated representative or, in the case of a corporation, partnership, or association, by delivering it to an officer, manager, or general agent thereof or to its attorney of record.

**§ 70.427 Representation before the Bureau.**

A holder of a registered formula or statement of process may be represented by an attorney, certified public accountant, or other person recognized to practice before the Bureau as provided in 31 CFR Part 8 (Practice Before the Bureau of Alcohol, Tobacco and Firearms) if he or she has otherwise complied with the applicable requirements of 26 CFR 601.521 through 601.527 (conference and practice requirements for alcohol, tobacco, and firearms activities).

**§ 70.428 Computation of time.**

(a) *Computation.* In computing any period of time prescribed or allowed by sections 70.421 through 70.425, the day of the act, event or default after which the designated period of time is to run is not to be included. The last day of the period to be computed is to be included, unless it is a Saturday, Sunday, or legal

holiday, in which event the period runs until the next day which is neither a Saturday, Sunday, or legal holiday. Papers or documents which are required or permitted to be filed under the aforementioned sections of regulations must be received for filing at the appropriate office within the time limits, if any, for such filing.

(b) *Extensions.* For good cause shown, the Chief, Product Compliance Branch, or the Chief, Alcohol and Tobacco Programs Division, may grant extensions as to any time limits prescribed in sections 70.421 through 70.425.

**PART 250—LIQUORS AND ARTICLES FROM PUERTO RICO AND THE VIRGIN ISLANDS**

Par. 32. The authority citation for 27 CFR Part 250 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5061, 5081, 5111, 5112, 5114, 5121, 5122, 5124, 5131–5134, 5141, 5146, 5207, 5232, 5271, 5276, 5301, 5314, 5555, 6001, 6301, 6302, 6804, 7101, 7102, 7651, 7652, 7805; 27 U.S.C. 203, 205; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 33. Section 250.50 is amended by revising paragraph (b) and by adding new paragraph (c) to read as follows:

**§ 250.50 Formula for liquors.**

\* \* \* \* \*

(b) *Wine.* Persons in Puerto Rico who ship wine to the United States shall comply with the formula requirements of 27 CFR Part 24. If any wine contains liquors made outside of Puerto Rico, the country of origin for each such liquor shall be stated on the formula. All formulas required by this paragraph shall be submitted on ATF Form 5120.29, in accordance with § 250.54.

(c) *Cancellation of registered formulas.* The procedures for the cancellation of a registered distilled spirits or wine formula are prescribed in 27 CFR Part 70, Subpart E.

\* \* \* \* \*

(Approved by the Office of Management and Budget under control number 1512–0204)

Par. 34. Section 250.51(b)(2) is revised to read as follows:

**§ 250.51 Formulas for articles, eligible articles and products manufactured with denatured spirits.**

\* \* \* \* \*

(b) \* \* \*

(2) Products made with specially denatured spirits shall be made in accordance with a general-use formula approved as provided in Part 20 of this chapter, or an approved formula on Form 5150.19, or previously approved

on ATF Form 1479–A or registered on 27–B Supplemental.

\* \* \* \* \*

Par. 35. Sections 250.53 and 250.54 are amended by adding the words “or registered” after the word “approved” wherever it appears.

Par. 36. Section 250.55 is revised to read as follows:

**§ 250.55 Previously approved formulas.**

(a) Any formula on Form 27–B Supplemental that was approved before (effective date of final rule) is included as a registered formula as required by 27 CFR 5.26(a) and shall remain in effect until cancelled or voluntarily surrendered. Except as provided in paragraph (b) of this section, any person holding such a formula is not required to submit a new formula.

(b) Any change in a registered formula shall require the filing of a new Form 5110.38. After a change in a formula has been registered, the original formula shall be surrendered to the Director.

(c) If a registered formula on Form 27–B Supplemental indicates that carbon dioxide will be added to, or retained in, still wine, the notice requirement of § 250.52 shall not apply.

Par. 37. Section 250.173(b)(4) is amended by adding the words “or registered” after the word “approved”.

Par. 38. Section 250.197 is amended by removing the word “approved” and adding in its place the word “registered”, and by adding a second sentence to read as follows:

**§ 250.197 Furnishing formula to consignee.**

\* \* \* Any formulas that were approved before (effective date of final rule) are included as registered formulas, without any resubmission by the holder of the approved formula or notification by ATF.

\* \* \* \* \*

Par. 39. Sections 250.205(a)(4) (i) and (ii) are amended by adding the words “or registered” after the word “approved”.

Par. 40. Section 250.220 is amended by revising paragraph (b) and by adding new paragraph (c) to read as follows:

**§ 250.220 Formulas for liquors.**

\* \* \* \* \*

(b) *Wine.* Persons in the Virgin Islands who ship wine to the United States shall comply with the formula requirements of Part 24 of this chapter. If any wine contains liquors made outside of the Virgin Islands, the country of origin for each such liquor shall be stated on the formula. All formulas required by this paragraph shall be submitted on ATF

Form 5120.29, in accordance with § 250.224.

(c) *Cancellation of registered formulas.* The procedures for the cancellation of a registered distilled spirits or wine formula are prescribed in 27 CFR Part 70, Subpart E.

Par. 41. Section 250.221(b)(2) is revised to read as follows:

**§ 250.221 Formulas for articles, eligible articles and products manufactured with denatured spirits.**

\* \* \* \* \*

(b) \* \* \*

(2) Products made with specially denatured spirits shall be made in accordance with a general-use formula approved as provided in Part 20 of this chapter, or an approved formula on Form 5150.19, or previously approved on ATF Form 1479–A or registered on 27–B Supplemental.

\* \* \* \* \*

Par. 42. Sections 250.223 and 250.224 are amended by adding the words “or registered” after the word “approved” wherever it appears.

Par. 43. Section 250.225 is revised to read as follows:

**§ 250.225 Previously approved formulas.**

(a) Any formula on Form 27–B Supplemental that was approved before (effective date of final rule) is included as a registered formula as required by 27 CFR 5.26(a) and shall remain in effect until cancelled or voluntarily surrendered. Except as provided in paragraph (b) of this section, any person holding such a formula is not required to submit a new formula.

(b) Any change in a registered formula shall require the filing of a new Form 5110.38. After a change in a formula has been registered, the original formula shall be surrendered to the Director.

(c) If a registered formula on Form 27–B Supplemental indicates that carbon dioxide will be added to, or retained in, still wine, the notice requirement of § 250.222 shall not apply.

Par. 44. Section 250.309(b)(4) is amended by adding the words “or registered” after the word “approved”.

Signed: October 17, 1995.

John W. Magaw,  
Director.

Approved: October 24, 1995.

Dennis M. O’Connell,  
Acting Deputy Assistant Secretary  
(Regulatory, Tariff and Trade Enforcement).

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