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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 24

[Docket No. TTB–2016–0010; Notice No. 164]

RIN: 1513–AB61

Wine Treating Materials and Related Regulations

AGENCY: Alcohol and Tobacco Tax and Trade Bureau.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is proposing to amend its regulations pertaining to the production of wine and in particular in regard to the permissible treatments that may be applied to wine and to juice from which wine is made. These proposed amendments are in response to requests from wine industry members to authorize certain wine treating materials and processes not currently authorized by TTB regulations. TTB invites comments on the proposed regulatory changes described in this document, as well as on other wine treatment issues for which regulatory amendments are not proposed in this document.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Please send your comments on this document to one of the following addresses:

- <https://www.regulations.gov> (via the online comment form for this document as posted within Docket No. TTB–2016–0010 at Regulations.gov, the Federal e-rulemaking portal);
- U.S. Mail: Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Box 12, Washington, DC 20005; or
- Hand delivery/courier in lieu of mail: Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 400, Washington, DC 20005.

See the Public Participation section of this document for specific instructions and requirements for submitting comments, and for information on how to request a public hearing or view or obtain copies of the petition and supporting materials.

FOR FURTHER INFORMATION CONTACT: Kara Fontaine, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 103.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Chapter 51 of the Internal Revenue Code of 1986, as amended (IRC), 26 U.S.C. chapter 51, contains provisions concerning the taxation and production of distilled spirits, wines, and beer. The Alcohol and Tobacco Tax and Trade Bureau (TTB) has been delegated authority to promulgate regulations pertaining to wine under Chapter 51 of the IRC. The statutory provisions of the IRC related

to the distilled spirits and wine regulations that TTB promulgates include, but are not limited to, the following:

- Section 5002(a)(4) of the IRC (26 U.S.C. 5002(a)(4)), which defines the term “distiller,” in pertinent part, as including any person who “(A) produces distilled spirits from any source or substance” or “(C) by any process separates alcoholic spirits from any fermented substance * * *.”
- Section 5171(a) of the IRC (26 U.S.C. 5171(a)), which requires that operations “as a distiller” only be conducted on the bonded premises of a distilled spirits plant by a person who is qualified under subchapter B of chapter 51 of the IRC.
- Section 5373 of the IRC (26 U.S.C. 5373), which authorizes the promulgation of regulations regarding the type of wine spirits that may be used in wine production.
- Section 5381 of the IRC (26 U.S.C. 5381), which provides that natural wine is the product of the juice or must of sound, ripe grapes or other sound, ripe fruit, made with such cellar treatment as may be authorized under section 5382.
- Section 5382(a) of the IRC (26 U.S.C. 5382(a)), which provides that proper cellar treatment of natural wine constitutes those practices and procedures in the United States, of using various methods and materials to correct or stabilize the wine, or the fruit juice from which it is made, so as to produce a finished product acceptable in good commercial practice as prescribed by regulation. Section 5382(c) also authorizes the promulgation of regulations

setting forth limitations on the preparation and use of methods and materials for clarifying, stabilizing, preserving, fermenting, and correcting wine and juice.

- Section 5387(a) of the IRC (26 U.S.C. 5387(a)), which authorizes the production of agricultural wine, classed as “standard agricultural wine,” from agricultural products other than the juice of fruit. Such agricultural wine must be made in accordance with good commercial practice as prescribed by regulation and may be cellar treated in accordance with sections 5382(a) and (c) of the IRC. Also, section 5387(b) prohibits the addition of wine spirits, coloring material or herbs, or other flavoring material (except hops in the case of honey wine) to agricultural wine, as well as the blending together of wines from different agricultural commodities.

The regulations promulgated under the IRC regarding the production of wine are set forth in part 24 of title 27 of the Code of Federal Regulations (27 CFR part 24) and include, but are not limited to, the following provisions:

- 27 CFR 24.10, which contains the definitions of certain terms used in 27 CFR part 24.
- 27 CFR 24.225, which sets forth rules under which proprietors of a bonded wine premises may withdraw and receive spirits without payment of tax from the bonded premises of a distilled spirits plant and add the spirits to natural wine on bonded wine premises.
- 27 CFR 24.246, which includes a table that lists the materials authorized for the treatment of wine and juice.

- 27 CFR 24.247, which includes a table that lists materials authorized for the treatment of distilling material.
- 27 CFR 24.248, which includes a table that lists processes authorized for the treatment of wine, juice, and distilling materials.

TTB administers chapter 51 of the IRC and its implementing regulations pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01, dated December 10, 2013 (superseding Treasury Order 120-01 dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws.

In addition, TTB consults with the U.S. Food and Drug Administration (FDA) on whether alcohol beverages are adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including whether a substance added to an alcohol beverage is an unapproved food additive. Alcohol beverages are considered “food” under the FD&C Act. A substance added to food is a food additive unless it is otherwise excluded from the definition of a food additive under the FD&C Act. For example, the use of a substance in food that is generally recognized as safe by qualified experts (GRAS) is excluded from the definition of a food additive under the FD&C Act. The use of a food additive in food must be authorized by FDA either through a food additive regulation or an effective food contact notification (FCN). FDA has listed certain GRAS uses in its regulations. In addition, FDA has a voluntary notification procedure by which any

person may notify FDA of a conclusion that a use of a substance is GRAS. FDA evaluates whether the notice provides a sufficient basis for a GRAS conclusion (which results in a “no questions” response) or whether FDA believes there is an insufficient basis for a GRAS conclusion (which results in an “insufficient basis” response). For the purpose of this rulemaking, we use the term “consistent with the food additive requirements under the FD&C Act” to refer to: (1) Authorized food additive uses; (2) uses that are GRAS under FDA’s regulations, that are the subject of a “no questions” letter from FDA in response to a GRAS notice, or that are subject to an opinion letter from FDA stating that the use is GRAS or otherwise permissible; or (3) uses that are otherwise excluded from regulation as a food additive.

Based on TTB's experience in administering the statutory and regulatory provisions mentioned above, TTB is proposing in this document a number of amendments to the TTB regulations and inviting comments from the public on these proposed regulatory changes. In addition, TTB is outlining in this document a number of other issues that are not the subject of proposed regulatory changes. TTB invites comments from the public on those issues to assist TTB in determining whether any of those issues warrant specific regulatory changes.

Terms Used in this Document

TTB is providing the following definitions to assist in the comprehension of this final rule. The definitions of agricultural wine, amelioration, brix, natural wine, standard wine, and wine spirits come from § 24.10, the definition of essences is

derived from 27 CFR 24.85, and the definition of special natural wine is derived from 27 CFR 24.10 and 24.195. The definitions of “natural wine” and “standard wine” are consistent with statutory provisions at sections 5381 and 5392, respectively. The definitions of “agricultural wine,” “amelioration,” and “special natural wine” reflect language used in statutory provisions at sections 5387, 5383, and 5386, respectively. The definition of “brix” is derived, in part, from statutory provisions at sections 5382 and 5393. Definitions of industry member and yeast nutrients also are provided, although these terms are not specifically defined in statutory provisions or elsewhere in the regulations.

- Agricultural wine: Wine made from suitable agricultural products other than the juice of grapes, berries, or other fruits.
- Amelioration: The addition to juice or natural wine before, during, or after fermentation, of either water or pure dry sugar, or a combination of water and sugar to adjust the acid level.
- Brix: The quantity of dissolved solids expressed as grams of sucrose in 100 grams of solution at 68 degrees F (20 degrees C.) (Percent by weight of sugar). (The definition of "Brix" in § 24.10 incorrectly refers to 60 degrees F rather than 68, which is the equivalent of 20 degrees C; TTB is proposing to correct this typographical error in this document.)
- Essences: Preparations of natural constituents extracted from fruit, herbs, berries, etc.
- Industry member: For the purposes of this document, a proprietor of a bonded wine premises.

- Natural wine: The product of the juice or must of sound, ripe grapes or other sound, ripe fruit (including berries) made with any cellar treatment authorized by 27 CFR part 24, subparts F and L, and containing not more than 21 percent by weight (21 degrees Brix dealcoholized wine) of total solids.
- Special natural wine: A product produced from a base of natural wine (including heavy bodied blending wine) to which natural flavorings are added, and made pursuant to an approved formula in accordance with 27 CFR part 24, subpart H. In subpart H, § 24.195 additionally explains that, among other things, natural flavorings are added in quantities or proportions such that the resulting product derives character and flavor distinctive from the base wine and distinguishable from other natural wine.
- Standard wine: Natural wine, specially sweetened natural wine, special natural wine, and standard agricultural wine, produced in accordance with 27 CFR part 24, subparts F, H, and I.
- Wine spirits: Brandy or wine spirits authorized under 26 U.S.C. 5373 for use in wine production.
- Yeast nutrients: For the purposes of this document, vitamins and minerals that aid in the fermentation of juice to wine by acting as food for yeast.

TTB Administrative Approvals of Wine and Juice treatments

Industry members who wish to experiment with, or commercially use, a treating material or process not specifically authorized in 27 CFR part 24 must file an application with TTB requesting authorization to use the new material or process. TTB may approve such requests as experiments under 27 CFR 24.249

or allow for the continual use of the new material or process under 27 CFR 24.250.

Standards regarding approval of the experimental use of a new treating material or process are set forth in § 24.249. The provisions covering applications for commercial use of a new material or process are contained in § 24.250. Consistent with §§ 24.246 and 24.248, TTB may approve the use of wine treating materials and processes that are determined to be acceptable in good commercial practice. In general, good commercial practice includes addressing the reasonable technological or practical need to enhance the keeping, stability, or other qualities of the wine, and achieving the winemaker's desired effect without creating an erroneous impression about the character and composition of the wine.

If TTB believes that it would be appropriate to approve the request, whether as an experiment under § 24.249 or for continued commercial use under § 24.250, it will send a letter to the industry member authorizing use of the material or process and setting forth the conditions for that use. Also, when TTB approves the continued commercial use of a wine treatment material or process under § 24.250, it will provide public notice of such approval on its Web site at https://www.ttb.gov/wine/wine_treating_materials.shtml. The listing of administrative approvals on the TTB Web site affords all industry members the opportunity to use an administratively approved wine treating material or process pending future rulemaking.

TTB conducts rulemaking to consider adding to or amending the materials and processes authorized in the regulations for treating wine, juice, and distilling material listed in §§ 24.246 through 24.248 for several reasons. First, when TTB administratively approves wine treatments for continued commercial use under § 24.250, TTB makes an initial determination that such material or process is consistent with “good commercial practice.” Administrative approval provides a more expeditious process than rulemaking for industry members to obtain approval to use new materials and processes. On the other hand, the rulemaking process allows industry members and the public an opportunity to comment on, and specifically to confirm or refute, TTB’s initial determination that the use of a material or process is consistent with good commercial practice. TTB believes that input from industry members, the users and potential users of these treatments commercially, should be obtained before making a final determination concerning the acceptability of the treatment in good commercial practice.

Similarly, TTB might not approve a request for administrative approval of a wine treatment because the Bureau is reluctant to approve the use of that particular wine treatment without input from industry members and the public concerning the treatment’s acceptability in good commercial practice. After obtaining information and comments through rulemaking, TTB may determine that the wine treatment is consistent with good commercial practice and approve the use of such treatment. As discussed below, through this document, TTB is

seeking comments on the approval of the use of several proposed treatments that have not been administratively approved by the Bureau.

In addition, administrative approval of a wine treatment under § 24.250 does not guarantee acceptance in foreign markets of any wine so treated, and conducting rulemaking and adding wine treating materials and processes to §§ 24.246 through 24.248 results in acceptance of the treated wines in certain foreign jurisdictions. For example, under Article 4.2 of the 2006 Agreement between the United States of America and the European Community on Trade in Wine (Wine Agreement), the United States and the European Union agreed not to restrict “on the basis of either wine-making practices or product specifications, the importation, marketing or sale of wine originating in the territory of the other Party that is produced using wine-making practices that are authorized under laws, regulations and requirements of the other Party listed in Annex I and published or communicated to it by that other Party.” Article 5.1 of the Wine Agreement also contains provisions to authorize new or modified wine-making practices if a party to the Wine Agreement provides public notice and specific notice to the other Party, and provides a reasonable opportunity for comment and to have those comments considered. For new wine treatments administratively approved in the United States, TTB provides such public notice and opportunity to comment through the regulatory rulemaking process.

TTB’s most recent amendment of §§ 24.246 through 24.248 to reflect treating material and process approvals was published as Treasury Decision (T.D.) TTB–61 in the **Federal Register** (72 FR 51707) on September 11, 2007.

Since that time, TTB has received and approved a number of applications for experimental or commercial uses. These include the 15 wine and juice treating materials and the combined use of two existing wine treatment processes, discussed below, on which TTB believes it has accumulated enough analytical data or other information to propose adding them to the list of approved materials and processes in the TTB regulations at §§ 24.246 and 24.248.

TTB is soliciting comments from all interested persons on TTB's position that, based on the information set forth below, the use of each of these materials or processes is consistent with good commercial practice.

Yeast Nutrients

Seven of the administrative approvals mentioned above authorize the use of additional yeast nutrients in the treatment of wine. TTB and its predecessor agencies have recognized the need to supply yeast with appropriate nutrients to facilitate healthy fermentation and to prevent "stuck fermentation" (fermentation that has halted before completion due to, among other things, high sugar levels or nutrient deficiencies). The following yeast nutrients are currently listed in § 24.246 as authorized wine and juice treating materials:

- Ammonium phosphate;
- Calcium pantothenate (for apple wine);
- Soy flour (defatted);
- Thiamine hydrochloride;
- Yeast, autolyzed; and
- Yeast, cell wall/membrane of autolyzed yeast.

In 2007, TTB received a petition from Gusmer Enterprises Inc. (Gusmer) to amend § 24.246 to allow the use of 19 vitamins and minerals as yeast nutrients in the production of wine. Gusmer provided the names, descriptions, functional roles for yeast metabolism, conditions of use, and suggested maximum amounts for the proposed vitamins and minerals. The petitioner also provided documentation on the regulatory status of the uses of 15 of the 19 proposed vitamins and minerals. Four materials identified by the petitioner, selenium, boron, molybdenum, and chromium, are not included in this proposal because no information was provided to demonstrate that their uses would be consistent with the food additive requirements under the FD&C Act.

Of the remaining 15 vitamins and minerals proposed as yeast nutrients for the production of wine by the petitioner, seven have been administratively approved by TTB for continued commercial use as yeast nutrients under § 24.250 in response to industry member requests which were received by TTB subsequent to TTB's receipt of the Gusmer petition. TTB is proposing, in this document, to amend the regulations to add six of these vitamins and minerals to the list of approved treating materials and expand the approved use of a seventh that already appears on the list. Specifically, TTB is proposing to add biotin, folic acid, inositol, magnesium sulfate, niacin, and pyridoxine hydrochloride to the list of authorized wine and juice treating materials in § 24.246, and to expand the current permitted use of calcium pantothenate in that section, as described later in this document.

For each of these seven yeast nutrients TTB is proposing to limit the amount of usage to the amounts provided in the Gusmer petition. While many of these yeast nutrients are vitamins that are authorized for use in food, in the recent past FDA has advised TTB that the fortification of “alcoholic beverages” with nutrients is not consistent with FDA's fortification policy in 21 CFR 104.20 or the Dietary Guidelines for Americans. In addition, FDA has informed TTB that FDA regulations for certain vitamins (e.g., folic acid and inositol) would not authorize their use in alcohol beverages as nutrients. Nonetheless, FDA has stated to TTB that these vitamins could be used for the purpose of providing nutrients to the yeast, and not to fortify the wine, where the levels of the vitamin remaining in the wine would be of a de minimis level. For these reasons, TTB believes it is important to place limitations on the use of these substances that permit their use as nutrients for yeast growth but not as food additives for human consumption.

For reasons discussed below in the section titled “Other Issues for Public Comment and Possible Regulatory Action,” TTB is not proposing in this document to add the eight vitamins and minerals that TTB has not approved administratively under § 24.250 to the list of authorized wine and juice treating materials in § 24.246. However, TTB is seeking comments on whether these eight additional vitamins and minerals should be approved as authorized wine treating materials.

Proposed Regulatory Amendments

Wine Treating Materials

General Comment on Yeast Nutrients

The six new yeast nutrients that TTB is proposing for the first time, based on the Gusmer petition described above, and the six yeast nutrients already authorized for use by regulation, as listed in § 24.246 (including calcium pantothenate), have been grouped together in the proposed § 24.246 table below under the heading “Yeast nutrients.” This format is similar to the one that currently exists for “Enzymatic activity.” TTB is also broadening the use of those yeast nutrients that are currently listed in § 24.246 to allow for their use in all juice and wine.

Blends and Other Combinations of Approved Treating Materials

TTB notes that, while the table in § 24.246 includes some references to approved materials used in combination (see, for example, the entry for potassium carbonate), there is no general statement to the effect that one or more approved materials may be used as a blend or otherwise in combination with another. TTB believes that such combined uses should be permitted, provided that the use of each material conforms to the conditions specified for that material (that is, the reason or purpose for its use and the references and limitations that apply to its use). TTB is proposing, in this document, to amend § 24.246 accordingly. This revision appears in proposed § 24.246(b), with the current § 24.246(b) moved to the proposed § 24.246(c).

Specific Wine Treating Materials

Acacia (gum arabic): TTB is proposing to authorize a maximum use rate of 8 pounds of acacia per 1,000 gallons (1.92 grams per Liter (g/L)) of wine in the list of authorized wine and juice treating materials in § 24.246. Acacia is currently listed in § 24.246 as an authorized treating material to clarify and stabilize wine, subject to a limitation that its use shall not exceed 2 pounds per 1,000 gallons (0.24 g/L) of wine. TTB has administratively approved several requests from industry members to use acacia to treat wine at levels exceeding the current maximum. The current limitation in § 24.246 was based on earlier evaluations of treated wine and was adopted through a public rulemaking procedure on September 24, 1984 (T.D. ATF-182, 49 FR 37522). Acacia also has a long record of use at the level prescribed in the regulation.

While the increased amounts specified in those requests ranged as high as 25 pounds of acacia per 1,000 gallons of wine, 16 pounds per 1,000 gallons was the highest level that TTB approved. In those reviews and approvals, TTB referenced FDA's regulation (21 CFR 184.1330) for the use of acacia at a rate greater than the amount listed in § 24.246, and TTB reviewed and considered relevant submitted data required under § 24.250(b). TTB notes that some of the requests to use higher amounts of acacia also requested approval for an additional purpose, that is, to improve "mouthfeel"; however, TTB's authority under 26 U.S.C. 5382 to authorize wine treating materials only extends to correcting or stabilizing the wine or the fruit juice from which it is made. As reflected in its implementing regulations in § 24.246, TTB policy is to allow for

wine treating materials that filter, clarify, or purify wine or juice as materials that correct or stabilize wine. Accordingly, TTB did not approve the use of acacia for the purpose of improving the “mouthfeel” of wine.

TTB’s administrative approvals authorized the use of acacia in the treatment of wine at a level of 16 pounds per 1,000 gallons of wine, which is equivalent to a maximum usage level of 2 percent. Subsequent to those administrative approvals, TTB learned that although the FDA regulation cited for acacia gum in § 24.246 (§ 184.1330) is the correct citation, the beverage category listed in the table of FDA’s regulation does not cover TTB’s intended use in wine. This is because the FDA regulation further cites the food category definition in 21 CFR 170.3(n)(3), which does not cover use in wine. Accordingly, the correct category from the table in § 184.1330 is “all other food categories.” This category has a limit of one percent acacia gum (rather than 2 percent); the functional effects for this category match TTB’s uses as clarifying and stabilizing wine. TTB is correcting this mistake in this rulemaking by proposing to increase the maximum use rate of acacia gum in wine to 8 pounds per 1,000 gallons of wine. TTB’s earlier administrative approvals authorizing the use of acacia at levels greater than 8 pounds per 1,000 gallons of wine are revoked.

Bakers yeast mannoprotein: TTB is proposing to add bakers yeast mannoprotein, at a use rate of 50–400 milligram per liter (mg/L) of wine, to the list of approved wine and juice treating materials contained in § 24.246.

TTB administratively approved the use of bakers yeast mannoprotein to stabilize wine from the precipitation of potassium bitartrate crystals, in response

to a number of requests from industry members. In response to GRAS Notice No. GRN 000284, the FDA stated that it had no questions regarding the notifier's conclusion that bakers yeast mannoprotein is GRAS for use as a stabilizing agent in wines at levels ranging from 50–400 milligrams per liter (mg/L), to prevent tartaric acid precipitation. In its administrative approval, TTB restricted the use of bakers yeast mannoprotein to 50–400 mg/L.

Beta-glucanase having an enzyme activity derived from *Trichoderma harzianum*: TTB is proposing to add beta-glucanase, at a use rate of 30 parts per million (ppm) of wine, to the list of approved wine and juice treating materials contained in § 24.246. TTB administratively approved the use of beta-glucanase having an enzyme activity derived from *Trichoderma harzianum*. Several industry members requested approval to treat wine with an enzymatic blend consisting of pectinase and beta-glucanase having an enzyme activity derived from *Trichoderma harzianum*. Pectinase is an approved wine treating material listed with carbohydrase in § 24.246. While beta-glucanase is also approved as a wine treating material listed with cellulose in § 24.246, that approval is limited to beta-glucanase having an enzyme activity derived from *Trichoderma longibrachiatum*. In response to GRAS Notice No. GRN 000149, FDA stated that it had no questions concerning the notifier's conclusion that the beta-glucanase enzyme preparation derived from *Trichoderma harzianum* is GRAS at the minimum levels necessary to achieve the desired effect, typically ranging from 1 to 3 grams per hectoliter of wine (10 – 30 ppm). In its administrative approval posted on https://www.ttb.gov/wine/wine_treating_materials.shtml in 2010, TTB

inadvertently stated that the amount of beta-glucanase derived from Trichoderma harzianum used must not exceed 300 ppm. TTB is correcting this mistake in this rulemaking by aligning the proposed use rate with the rate stated in GRAS Notice No. GRN 000149. Accordingly, TTB is proposing to amend the table in § 24.246 by adding to the entry on “Enzymatic activity: Cellulase (beta-glucanase)” a second source, Trichoderma harzianum, stating that its use must not exceed 30 ppm, and by referencing GRAS Notice No. GRN 000149. TTB is soliciting comments on this proposed addition, the limitation of 30 ppm, and also on whether beta-glucanase enzymatic activity derived from Trichoderma longibrachiatum is still relevant for wine treatments.

Biotin: TTB is proposing the addition of biotin to the list of authorized wine and juice treating materials in § 24.246 as a yeast nutrient at a use rate not to exceed 25 parts per billion (ppb). TTB administratively approved an industry member’s request to use biotin as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion that biotin can be used for the purpose of providing nutrients to yeast, and not to fortify the wine, where the levels of biotin remaining in the wine would be of a de minimis level. The Gusmer petition proposed a maximum use rate for biotin of 25 ppb.

Calcium pantothenate (vitamin B5): TTB is proposing to amend § 24.246 to expand the current authorized use of calcium pantothenate from use as a yeast nutrient in just apple wine to use as a yeast nutrient in all wine. TTB administratively approved an industry member’s request to use calcium pantothenate as a yeast nutrient in the production of wine. FDA has stated to

TTB in an informal opinion that calcium pantothenate can be used for the purpose of providing nutrients to yeast, and not to fortify the wine, where the levels of calcium pantothenate remaining in the wine would be of a de minimis level. TTB's administrative approval restricted its use to that which is consistent with good commercial practice. TTB is proposing to apply the same use limit as is provided for the use of calcium pantothenate in apple wine, that is, a use rate of 0.1 pound of calcium pantothenate per 25,000 gallons (1.5 ppm), and to allow for the use of calcium pantothenate for all juice and wine by removing the current apple wine limitation specified in § 24.246.

Chitosan: TTB is proposing to add chitosan from Aspergillus niger, at a use rate not to exceed 10 grams per 100 liters of wine, to the list of approved wine and juice treating materials contained in § 24.246. TTB administratively approved several industry member requests to use chitosan from Aspergillus niger to remove spoilage organisms, such as *Brettanomyces*, from wine. In its response to GRAS Notice No. GRN 000397, FDA stated that it had no questions regarding the notifier's conclusion that chitosan from Aspergillus niger is GRAS for use as a secondary direct food ingredient in alcoholic beverage production at levels between 10 and 500 grams per hectoliter (100 liters). In its administrative approvals, TTB restricted the use of chitosan from Aspergillus niger to an amount not to exceed 10 grams per 100 liters of wine.

Folic acid: TTB is proposing to add folic acid to the list of authorized wine and juice treating materials in § 24.246 for use as a yeast nutrient at a use rate not to exceed 100 ppb. TTB administratively approved an industry member's

request to use folic acid as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion, that folic acid can be used for the purpose of providing nutrients to the yeast, and not to fortify the wine, where the levels of folic acid remaining in the wine would be of a de minimis level. In TTB's administrative approval, TTB limited the use of folic acid to that which is consistent with good commercial practice and did not provide a specific use limit. The Gusmer petition proposed a maximum use rate of 100 ppb for folic acid when used as a yeast nutrient in the production of wine. Such a use rate will ensure that any folic acid remaining in the wine would be of a de minimis level.

Inositol (myo-inositol): TTB is proposing to add inositol to the list of authorized wine and juice treating materials in § 24.246 to be used as a yeast nutrient at a use rate not to exceed 2 ppm. TTB administratively approved an industry member's request to use inositol as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion that inositol could be used for the purpose of providing nutrients to the yeast, and not to fortify the wine, where the levels of inositol remaining in the wine would be of a de minimis level. In TTB's administrative approval, TTB restricted the use of inositol to that which is consistent with good commercial practice and did not provide a specific use limit. The Gusmer petition proposed a maximum use rate of 2 ppm for inositol when used as a yeast nutrient in the production of wine. The maximum use rate of 2 ppm will ensure that any inositol remaining in the wine would be of a de minimis level.

L(+) tartaric acid: TTB administratively approved several industry member requests to use L(+) tartaric acid, prepared using an enzyme from immobilized Rhodococcus ruber cells, to correct natural acid deficiencies and to reduce pH when ameliorating material is used in the production of grape wine. Tartaric acid is currently listed in § 24.246 as a material authorized for the treatment of wine and juice for these same purposes; however, the current reference in § 24.246 is to the FDA regulation at 21 CFR 184.1099, which specifies that tartaric acid with the L configuration is obtained as a byproduct of wine manufacturing.

In response to GRAS Notice No. GRN 000187 for L(+) tartaric acid (alternative method) prepared using an enzyme from immobilized Rhodococcus ruber cells, FDA stated that it had no questions regarding the notifiers' conclusion that the substance is GRAS for use as an alternative source of L (+) tartaric acid in food at levels not to exceed current good manufacturing practices for use as a firming agent, a flavor enhancer, a flavoring agent, a humectant, and a pH control agent, as described in 21 CFR 184.1099. The FDA also noted that the material is chemically identical to the tartaric acid affirmed as GRAS in 21 CFR 184.1099.

Based on the FDA response to the GRAS notice and TTB's analysis of wine treated with L(+) tartaric acid, TTB is proposing to amend the entry for "tartaric acid" in the table at the end of § 24.246 to indicate that "tartaric acid" may be manufactured by either the method specified in 21 CFR 184.1099 or the method specified in GRAS Notice No. GRN 000187, and to add the citation to the FDA GRAS notice in the "Specific limitation" column.

Magnesium sulfate: TTB is proposing to add magnesium sulfate to the list of authorized wine and juice treating materials in § 24.246 to be used as a yeast nutrient at a use rate not to exceed 15 ppm. TTB administratively approved an industry member's request to use magnesium sulfate as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion that magnesium sulfate can be used for the purpose of providing nutrients to yeast, and not to fortify the wine, where the levels of magnesium sulfate remaining in the wine would be of a de minimis level. In TTB's administrative approval, TTB restricted the use of magnesium sulfate as a yeast nutrient to that which is consistent with good commercial practice and did not provide a specific use limit. The Gusmer petition proposed a maximum use rate of 15 ppm for magnesium sulfate when used as a yeast nutrient in the production of wine.

Niacin (vitamin B3): TTB is proposing to add niacin to the list of authorized wine and juice treating materials in § 24.246 to be used as a yeast nutrient at a use rate not to exceed 1 ppm. TTB administratively approved an industry member's request to use niacin as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion that niacin can be used for the purpose of providing nutrients to yeast, and not to fortify the wine, where the levels of niacin remaining in the wine would be of a de minimis level. In TTB's administrative approval, TTB restricted the use of niacin as a yeast nutrient to that which is consistent with good commercial practice and did not provide a specific use limit. The Gusmer petition proposed a maximum use rate of 1 ppm for niacin when used as a yeast nutrient in the production of wine.

Polyvinyl-pyrrolidone (PVP)/polyvinylimadazole (PVI) polymer: In 2005, TTB began administratively approving industry member requests to use a polyvinyl-pyrrolidone (PVP) and polyvinylimadazole (PVI) copolymer (PVP/PVI) as a wine treating material to be used for clarifying and stabilizing alcohol beverages. PVP had once been listed as an authorized wine treating material in ATF regulations at 27 CFR 240.1051, Materials Authorized for Treatment of Wine. Specifically, it was authorized as a clarifying agent for wine. After a 1990 recodification of 27 CFR part 240, ATF rescinded its approval of PVP as a wine treating material because it was no longer in use by wine producers. See T.D. ATF-299 (55 FR 24974). However, in the past several years TTB has received a number of requests to use the PVP/PVI copolymer as an authorized wine treating material. The PVP/PVI copolymer binds heavy metal ions and sulfides present in juice and wine, after which the bound materials and the PVI/PVP can be removed from the liquid during filtration.

On July 5, 2003, FDA allowed BASF Corporation's Food Contact Substance (FCS) Notification for their PVP/PVI copolymer to become effective (FCN No. 320). Under section 409(h)(2)(C) of the FD&C Act (21 U.S.C. 348 (h)(2)(C)) a food contact notification (FCN) is only effective for the manufacturer or supplier identified in the notification. Persons who market a FCS based on an effective notification must be able to demonstrate that the notification is effective for their food contact substance. All persons who purchase a food contact substance manufactured or supplied by a manufacturer or supplier identified in an effective notification may rely on that notification to legally market or use the

food contact substance for the use that is the subject of the notification, consistent with any limitations in that notification. According to FDA FCN No. 320, the blend “is intended to be added directly to alcoholic beverages during the maturation process . . . is to be completely removed by filtration . . . and is limited to single use applications.” The amount must not exceed 80 grams per 100 liters of wine.

Based on FDA FCN No. 320, TTB’s experience with the use of sulfide and metal reducing matrix sheets (which contain PVI and are approved wine treating processes listed in § 24.248), and TTB’s analysis of wine treated with the PVP/PVI copolymer, TTB is proposing to amend the table at the end of § 24.246 by adding the PVP/PVI copolymer as described by FDA FCN No. 320 for use at a level not to exceed 80 grams per 100 liters of wine to remove heavy metal ions and sulfides from wine.

Potato protein isolates: TTB is proposing to add potato protein isolates, at a use rate of 500 ppm or 50 grams per 100 liters (50 g/hL) of wine, as a fining agent, to the list of approved wine and juice treating materials contained in § 24.246. TTB administratively approved an industry member’s request to use potato protein isolates as a fining agent for wine. In response to GRAS Notice No. GRN 000447, FDA stated that it had no questions regarding the notifier’s conclusion that potato protein isolates are GRAS for various technical effects in a variety of foods that include alcoholic beverages at levels ranging from 0.01 to 15 percent. In its administrative approval, TTB restricted the use of potato protein

isolates to an amount not to exceed 500 ppm or 50 g/hL of wine for the purpose of fining wine. The proposed limitation is consistent with that of other countries.

Pyridoxine hydrochloride (vitamin B6): TTB is proposing to add pyridoxine hydrochloride to the list of authorized wine and juice treating materials in § 24.246 to be used as a yeast nutrient at a use rate not to exceed 150 ppb. TTB administratively approved an industry member's request to use pyridoxine hydrochloride as a yeast nutrient in the production of wine. FDA has stated to TTB in an informal opinion that pyridoxine hydrochloride can be used for the purpose of providing nutrients to yeast, and not to fortify the wine, where the levels of pyridoxine hydrochloride remaining in the wine would be of a de minimis level. In its administrative approval, TTB restricted the use of pyridoxine hydrochloride as a yeast nutrient to that which is consistent with good commercial practice and did not provide a specific use limit. The Gusmer petition proposed a maximum use rate of 150 ppb for pyridoxine hydrochloride when used as a yeast nutrient in the production of wine.

Sodium carboxymethyl cellulose: TTB is proposing to add sodium carboxymethyl cellulose to the list of authorized wine and juice treating materials in § 24.246, to be used to stabilize wine from tartrate precipitation at a level not to exceed 0.8 percent of the wine. TTB administratively approved several industry member requests to use sodium carboxymethyl cellulose to stabilize wine by preventing tartrate precipitation. FDA regulations at 21 CFR 182.1745 state that sodium carboxymethyl cellulose is GRAS when used in accordance with good manufacturing practice. In TTB's administrative approval, TTB restricted the use

of sodium carboxymethyl cellulose to stabilize wine by preventing tartrate precipitation to an amount not to exceed 0.8 percent of the wine.

Processes for the Treatment of Wine, Juice, and Distilling Material

TTB is proposing to amend the regulations in § 24.248, which set forth certain processes that TTB has approved as being consistent with good commercial practice for use by proprietors in the production, cellar treatment, or finishing of wine, juice, and distilling materials, within the limitations of that section. Please note that industry members are responsible for ensuring that any component used in an approved process, including materials in contact with wine or juice, is used in a way that is consistent with any applicable FDA regulations, including FDA food contact regulations.

Cross Flow Filtration

TTB is proposing to expand the authorized uses of nanofiltration and ultrafiltration in § 24.248 to include dealcoholization (reduction of the alcohol content). Currently, nanofiltration is authorized to reduce the level of volatile acidity in wine when used with ion exchange. Ultrafiltration is authorized for use to remove proteinaceous material from wine; to reduce harsh tannic material from white wine produced from white skinned grapes; to remove pink color from blanc de noir wine; and to separate red wine into high color and low color wine fractions for blending purposes. Ultrafiltration has also been administratively approved to separate red juice into low color and high color fractions. (The administrative approval for ultrafiltration is discussed later in this document.)

Both nanofiltration and ultrafiltration are capable of reducing alcohol content in wine, and this proposed liberalization will provide industry members with more tools to reduce the alcohol content of wine. However, as required with those processes for dealcoholization currently authorized in § 24.248 (reverse osmosis, osmotic transport, and spinning cone column), ultrafiltration and nanofiltration, when used to reduce the alcohol content of wine, must take place on distilled spirits plant premises. TTB also is proposing to place nanofiltration, ultrafiltration, and reverse osmosis under the umbrella term “cross flow filtration.” In cross flow filtration, the wine is passed across the filter membrane (tangentially) at positive pressure relative to the permeate side. A proportion of the wine which is smaller than the membrane pore size passes through the membrane as permeate or filtrate; everything else is retained on the feed side of the membrane as retentate. TTB is adding this definition of “cross flow filtration” as a footnote to the table at the end of § 24.248.

Reverse Osmosis in Combination with Osmotic Transport

TTB administratively approved several requests to use reverse osmosis in combination with osmotic transport to reduce the ethyl alcohol content in wine. Reverse osmosis and osmotic transport are both separately listed in § 24.248 as approved wine treatment processes to reduce the ethyl alcohol content of wine. Under this combined process, the wine to be treated is separated by reverse osmosis into two portions called permeate and concentrate streams. The alcohol rich permeate is then degassed, warmed, and pumped along one side of a completely hydrophobic microporous osmotic transport membrane, which is used

to separate out the alcohol. The dealcoholized permeate is then recombined with the wine from which it was extracted, thus lowering the alcohol content of the wine.

TTB is proposing to amend the table at the end of § 24.248 by revising the listings for reverse osmosis and osmotic transport to state that each process can be used in combination with the other to reduce the ethyl alcohol content of wine. These processes, whether used separately or in combination, must take place on distilled spirits plant premises.

Ultrafiltration

In two separate requests, an industry member requested to use ultrafiltration to separate red grape juice into high and low color fractions for blending purposes, and to separate white grape juice that had darkened due to oxidation during storage into high and low color fractions for blending purposes. As described above, ultrafiltration is authorized for use under § 24.248 to remove proteinaceous material from wine; to reduce harsh tannic material from white wine produced from white skinned grapes; to remove pink color from blanc de noir wine; and to separate red wine into low color and high color wine fractions for blending purposes. Since ultrafiltration is currently authorized under § 24.248 to separate red wine into low color and high color fractions for blending, TTB administratively approved use of ultrafiltration to separate red grape juice into low and high color fractions and is proposing to amend the table at the end of § 24.248 accordingly. TTB did not administratively approve the use of ultrafiltration to separate high and low colored fractions of discolored white grape

juice, but as discussed under the heading “Other Issues for Public Comment and Possible Regulatory Action” in this document, invites comments on whether this practice constitutes good commercial practice.

Use of Wood to Treat Natural Wine

Section 24.246 currently authorizes the use of uncharred and untreated oak chips or particles to smooth wine. TTB’s predecessor agency had a longstanding policy allowing the use of "toasted" wood as a wine treating material, and TTB has issued several private letter rulings allowing this use. In addition, wooden storage tanks used for the addition of spirits to wine may be used for the baking of wine under § 24.225.

TTB is proposing a new 27 CFR 24.185 to clarify TTB’s policy on the treatment of wine with wood contact. Section 24.185(a) would clarify that natural wine may be treated by contact with any wood that is consistent with the food additive requirements under the FD&C Act and that wood may be toasted, but not charred. Toasted wood refers to wood that has been heated but has not undergone combustion (that is, hasn’t been burned or blackened). TTB is authorizing the use of toasted wood in this proposal. Section 24.185(b) would state TTB’s position on the use of wood essences and extracts in the production of wine.

TTB is also proposing to remove the last sentence from § 24.225 (“Wooden storage tanks used for the addition of spirits may be used for the baking of wine”) and include it in the new § 24.185, and to remove the reference to oak chips from § 24.246 and include it in new § 24.185, in an effort to maintain

in one location all regulatory provisions pertaining to the treatment of wine with wood.

Wine Spirits/Revision of § 24.225

TTB is proposing to amend § 24.225 by removing the last sentence as described above, by revising the section heading, and by dividing the text into paragraph (a), covering withdrawal of spirits, paragraph (b), covering production and use of wine spirits, and paragraph (c), covering spirits other than wine spirits, and by otherwise revising the text, in order to accomplish the following:

- To incorporate the terms of section 5373(a) of the IRC related to standards for the production of wine spirits, including that portion of section 5373(a) that reads, “where, in the production of natural wine or special natural wine, sugar has been used, the wine or the residuum thereof may not be used if the unfermented sugars therein have been refermented.” The proposed text clarifies and simplifies this statutory language without changing the meaning or intent, which TTB believes is to prevent the production of wine spirits by refermenting wine to develop alcohol from sugar added to the wine after fermentation.

- To allow the use of lower-proof spirits in wine production in certain circumstances. Section 5373(a) of the IRC sets a general standard of 140 degrees of proof or above for wine spirits used in wine production but also provides for two exceptions to this rule: (1) distillation may be at less than 140 degrees of proof if regulations so provide; and (2) commercial brandy aged in wood for not less than 2 years, and barreled at not less than 100 degrees of

proof, is deemed to be wine spirits for purposes of section 5373(a). TTB believes that allowing the byproducts of alcohol reduction to be used as wine spirits if they are 100 degrees of proof or more is consistent with the intent of the statute. TTB notes that these alcohol reduction treatments, which are listed in § 24.248, must be performed at a qualified distilled spirits plant because they result in a spirits byproduct. Thus, when the wine subjected to alcohol reduction is natural wine or special natural wine (and is subject to the other conditions of section 5373(a) and § 24.225), the alcohol-containing byproduct would still constitute wine spirits even though the spirits may not have been distilled at or above 140 degrees of proof. Accordingly, TTB is proposing, in revised § 24.225, to allow spirits derived from authorized alcohol reduction treatments to be used as wine spirits if the spirits were distilled at 100 degrees of proof or more and if the spirits conform to the other terms of section 5373(a) as reflected in the revised regulatory text.

- To clarify the status of wine spirits derived from special natural wine.

This source of spirits was codified in section 5373(a) of the IRC, which also authorized the Secretary of the Treasury to impose conditions on the use of special natural wine to make wine spirits. TTB is proposing to specify in the revised text that wine spirits derived from special natural wine may only be used in the production of special natural wine when such wine spirits contain a distinctive flavor from the ingredients used in the originating special natural wine.

Within the proposed new paragraph (b) text, subparagraphs (1) through (3) primarily reflect the terms of section 5373(a) of the IRC that TTB believes

should be reflected in the regulatory text as discussed above, and subparagraph (4) primarily reflects the existing § 24.225 text.

Accidental Water Additions

TTB is proposing to add a new 27 CFR 24.251, to provide for the correction of standard wine when the wine becomes other than standard wine due to accidental water additions in excess of the authorized levels provided for in 27 CFR part 24, subparts F and L. Accidental water additions can occur during production of wine at various stages, for example during filtration when water is accidentally left in a tank that is later filled with wine. TTB has received requests from industry members who wish to be allowed to take corrective action regarding these water additions. To correct wine that has been diluted with water is referred to within TTB as “to salvage.”

The most common way to salvage wine is to remove the water accidentally added to the wine through the use of reverse osmosis, in combination with distillation. The reverse osmosis creates a colorless and flavorless permeate, essentially consisting of alcohol and water. The permeate is distilled to create a high ethanol fraction and a low ethanol fraction. The high ethanol fraction is returned to the wine and the low ethanol fraction is discarded. Through the use of reverse osmosis and distillation, the industry member removes the accidentally added water and raises the alcohol by volume of the wine back to its level before the accidental water addition, without affecting the vinous character of the wine.

TTB has approved the use of reverse osmosis and distillation to remove water from wine under TTB's authority in § 24.249. In those reviews, TTB considered how the accidental water addition occurred, the ratio of water to wine, and whether or not the requesting industry member has submitted similar requests in the past. TTB applied the following conditions to those approvals.

The industry member must:

- Return the wine to its original condition;
- Transfer the wine to and from the distilled spirits plant for treatment in bond;
- Not remove more water than was accidentally added;
- Not alter the vinous character of the wine; and
- Keep the usual and customary records of the processing.

TTB believes that proprietors should have the authority to remove small amounts of accidentally added water from wine using reverse osmosis and distillation without first seeking TTB approval. Proposed § 24.251 sets forth authority and standards to allow for removal of accidental additions of water of not more than 10 percent of the original volume of the wine without the need to first seek TTB approval. Proposed § 24.251 also allows the appropriate TTB officer to approve other removals of accidentally added water upon application by a proprietor and sets forth the requirements for submitting an application to TTB. It also specifies that, in evaluating any request under this section, the appropriate TTB officer may consider as a factor whether the proprietor has demonstrated good commercial practices, taking into account the proprietor's prior history of

accidental dilutions of water to wine and of compliance with other regulations in part 24.

TTB has also received requests to allow wine to be salvaged by blending the accidentally diluted wine with standard wine to reduce the level of unauthorized water addition to less than 1 percent of the volume of the blended wine. The requesters have asserted that, since § 24.246 provides that when a wine or juice treating material is used and water is added to facilitate the solution or dispersal of the material, the volume of water added may not exceed 1 percent of the juice or wine, reduction of the accidentally added water to less than 1 percent by blending wines meets the intent of the regulations. TTB has not approved these requests because the accidental addition of water renders the wine an “other than standard” wine, and such wine cannot be blended with standard wine. Also, TTB’s authority to approve experimental or new wine treatments under §§ 24.249 and 24.250 does not extend to blending of wine, which is not a wine treatment or process. Additionally, wine diluted with water in excess of that permitted in part 24 renders the wine “other than standard” (see 27 CFR 24.218). Section 24.218 provides that other than standard wine must be segregated from standard wine, and accordingly the blending of standard and other than standard wine generally is not permitted under TTB’s regulations.

While TTB has not previously approved these requests, TTB notes that current § 24.246 permits the addition to wine of a limited amount of water with a wine treating material without affecting the classification of the wine as a standard wine. Accordingly, TTB believes that the regulations should be

changed to recognize that the accidental addition of water to a standard wine that represents 1 percent or less of the total volume of the wine does not render the wine other than standard. TTB also believes that blending wine should be permitted to reduce the accidentally added water to 1 percent or less of the total volume of the blended wine, and the resultant blended wine should be considered standard wine. Accordingly, TTB has incorporated these two provisions into a new section, proposed § 24.186, with a reference to a new § 24.251, regarding accidental additions of water to wine.

Other Proposed Regulatory Amendments

In addition to the changes discussed above, this document includes the following proposed regulatory amendments:

Definitions

As a consequence of the proposed changes to § 24.225(a), discussed above, TTB is proposing to revise the definition of “wine spirits” in § 24.10 to include a reference to that regulatory provision.

Wood Essences

TTB is proposing to amend § 24.85, which concerns essences, by adding the term “wood” as an additional example of a source material for essences used in the production of formula wine. (The TTB regulations at 27 CFR 24.10 define formula wine as special natural wine, agricultural wine, and other than standard wine (except for distilling material and vinegar stock) produced on bonded wine premises under an approved formula.) TTB believes that it is appropriate to add wood to this provision to reflect a longstanding policy that an extract of wood

made using any solvent but wine should be treated as an essence or flavoring material.

List of Authorized Wine and Juice Treating Materials

TTB is proposing to amend the heading in paragraph (a) of § 24.246 to read “Wine and juice” rather than just “Wine.” This is a clarifying change. TTB is also proposing numerous technical and clarifying changes to the table in § 24.246. A significant portion of these technical changes involves revising the measurement references specified for the limitation on use of the authorized wine treating materials by making the notation of units of measurement consistent throughout the chart, supplying closing parentheses where they were absent, and removing decimal points followed only by zeroes. In addition, where units are only in U.S. Common (English) units or SI (International Standard, or metric) units, TTB is adding the other unit of measure for reference purposes, where appropriate. Since the majority of the units are expressed in U.S. Common units first and then in SI units, TTB is proposing to continue with that convention. TTB is including a footnote reference after each use of ppm and ppb in the chart to indicate parts per million and parts per billion, respectively. TTB is also including a definition of the word “stabilize” at the end of the chart and footnoting every appearance of the word “stabilize” with a “1” in the table. TTB is also adding a third column to the table in § 24.246 titled “FDA reference”. This new column contains references to relevant FDA regulations in title 21 of the CFR, FDA GRAS notifications, and FDA advisory opinions. These references have been moved to this new column wherever such a reference appears in the

table. The “FDA reference” column provides a limit or reference where there is no “Specific limit” listed for a wine treating material.

FDA recently provided TTB with a new advisory opinion dated September 8, 2016, updating their acceptance of TTB’s approval for certain materials as wine and juice treating materials. This new advisory opinion was necessary because in some cases, TTB’s current listing of FDA’s acceptance of the material as a wine treating material was not entirely accurate because those references were not specific to the use of wine. In other cases, references to old advisory opinions were subsequently revoked by FDA rulemaking. TTB is replacing the current FDA references in § 24.246 with an updated reference to an advisory opinion in which FDA stated “We have evaluated the list of substances * * * along with their proposed limitations for use in wine and juice treatment and conclude that they are safe under the conditions of their intended use. We would not question a conclusion that these uses of substances added to wine would be generally recognized as safe (GRAS).” Accordingly, TTB is updating the FDA reference for: acetaldehyde, activated carbon, albumen (egg white), casein, potassium salt of casein, gelatin, potassium bi-tartrate, silica gel (colloidal silicon dioxide), and tannin.

FDA also provided TTB with an advisory opinion dated August 29, 2016, regarding the use of current and proposed yeast nutrients. With regard to current yeast nutrients, FDA indicated that the use of yeast nutrients as a treatment for wine is not listed in its regulations or GRAS notices. FDA did, however, state: “We have evaluated the list of yeast nutrients * * * along with their proposed

limitations for use prior to and during juice fermentations for wine production, taking into consideration: (1) their likely consumption by yeasts and bacteria [is] likely to be largely consumed during fermentations and (2) their likely presence in finished wine products at levels that would not exceed those in unprocessed grape juice. We conclude that [the] increase in human dietary exposure to the substances resulting from their addition to wine juice is de minimis with respect to human nutrition, [and that] they are safe under the conditions of their intended use. Such levels would be far below any level that would result in a safety concern for any of these substances. Thus, we would not consider this very low level exposure to be significant and we would not question a conclusion that these uses of substances added to wine as yeast nutrients would be GRAS.” Accordingly, TTB is updating the FDA reference for calcium panthothenate, soy flour, thiamine, yeast autolyzed, and yeast cell wall/membranes of autolyzed yeast.

Due to the large number of proposed changes to § 24.246, this document presents those changes as a revision of the entire section. Finally, TTB is proposing to make the following other changes to the current entries in the table:

- Activated carbon: One of the entries in the “Materials and use” column currently refers to removing color in wine and/or juice from which the wine was produced. TTB is proposing to refer instead to removing color from wine and/or juice, for clarity.

- Albumen: In the “Specific limitation” column, TTB is adding the words “of brine” in the second sentence after the word “Usage” and removing the words “of solution.”
- Ammonium phosphate (*mono-* and *di* basic): TTB is revising the name of the material to include “diammonium phosphate” and including it on the list of yeast nutrients in the table in § 24.246. (TTB is also making a conforming change revising the name of the material in § 24.247.)
- Calcium carbonate: TTB is adding the abbreviation “CaCO₃” and, in the “Materials and use” column, TTB is replacing the word “and” with the word “or” in the first use entry and replacing the word “A” with the words “As a” in the second use entry.
- Casein, potassium salt of casein: In the “Specific limitation” column, TTB is referring only to the citation “27 CFR 24.243” and removing references to FDA’s GRAS opinions.
- Citric acid: In the “Materials and use” column, TTB is adding the words “certain juice or” after the word “in” in the first use entry. The limitations on what types of juice or wine may be treated with citric acid may be found in the regulations cited in the “Specific limitation” column.
- Copper sulfate: In the “Specific limitation” column, TTB is removing the word “added” after the word “sulfate” and adding the words “added to wine” after the first parenthetical.
- Dimethyl dicarbonate: For purposes of clarity, TTB is adding the abbreviation “(DMDC)” after the material name “Dimethyl dicarbonate” and

removing the phrases “dealcoholized wine,” and “low alcohol wine,” from the entry to reduce redundancy.

- Ferrocyanide: TTB believes that ferrocyanide compounds are no longer available on the United States market and no longer being used by the U.S. wine industry. Accordingly, TTB is removing “ferrocyanide” from the list of authorized wine treating materials.
- Milk products: With the publication of T.D. ATF–350 (58 FR 52222) in the **Federal Register** on October 7, 1993, ATF approved the use of milk products as a fining agent in white grape wine or sherry. With the publication of T.D. TTB–17 (69 FR 67639) in the **Federal Register** on November 19, 2004, TTB extended this approval to all wines. The listing in § 24.246 for the use of milk products, revised in 2004, reads, “Fining agent for grape wine or sherry.” TTB believes this phrase may cause confusion because under the standards of identity in § 4.21(a) sherry is a grape wine. Accordingly, TTB is amending the first listed use in the “Materials and use” column for this entry to read: “Fining agent for grape wine.”
- Oxygen and compressed air: In the “Materials and use” column, TTB is replacing the words “May be used in juice and wine” with the words “Various uses in juice and wine.”
- Polyvinyl-polypry-rolidone (PVPP): In the “Materials and use” column, TTB is making a technical change by removing the phrase “black wine.” In the “Specific limitation” column, TTB is replacing the two asterisk footnote references with a reference to footnote “3” after the abbreviation “AOAC.”

- Sorbic acid and potassium salt of sorbic acid: In the “Materials and use” column, TTB is adding the words “potassium sorbate” in parentheses before the colon.
- Sulfur dioxide: Sulfur dioxide was added to the list of approved materials with the issuance of T.D. Internal Revenue Service (IRS)–6475 (25 FR 6184) in 1960. At that time, the stated use of sulfur dioxide was to sterilize and preserve wine. The list of authorized treating materials in 1960 was codified in 26 CFR 240.1051 and was titled “Materials authorized for treatment of wine.”

Through the publication of T.D. ATF–182 (49 FR 37510) in 1984, ATF retitled the list of authorized wine treating materials as “Materials authorized for treatment of wine and juice.” In T.D. ATF–182, the comment discussion refers to the use of sulfur dioxide in wine as “necessary, common to, and historically documented in winemaking,” and it is further referred to in the use of juice for purposes of winemaking twice on page 37513, under the subheading Antimicrobial Agents. Sulfur dioxide is GRAS in the FDA regulations at 21 CFR 182.3862 as a chemical preservative. Section 182.3862 states that sulfur dioxide cannot be applied to fruit that is intended to be served or sold raw to consumers. Juice to be used in the production of wine is not fruit to be served or sold raw to consumers; thus, the use of sulfur dioxide in juice that will be used in the production of wine is GRAS. Further, 27 CFR 24.176 authorizes the use of sterilizing agents in juice. Accordingly, TTB is correcting the entry for sulfur dioxide to include its use in juice.

- Thiamine hydrochloride: As noted above, the yeast nutrient Thiamine hydrochloride will be re-organized and grouped under the heading, “Yeast nutrients” with the other yeast nutrients.
- Shall vs. must: Finally, to promote the use of plain language, TTB is also proposing to change "shall" to "must" wherever the former appears in the affected regulations.

TTB is proposing to amend § 24.250(a)(4) to require that an industry member must provide documentary evidence from the FDA showing that the proposed material is consistent with the food additive requirements under the FD&C Act for its intended purpose in the amounts proposed for the particular treatment contemplated. This differs from the original text in that it is not requiring documentary evidence that the FDA has “approved” the use of the proposed material. This editorial change is consistent with similar changes in §§ 24.246 and 24.248.

Other Issues for Public Comment and Possible Regulatory Action

In addition to the comments TTB is soliciting on the proposed regulatory changes contained in this document, as discussed above, TTB is inviting public comments on a number of other regulatory issues to assist TTB in determining whether it would be appropriate to incorporate additional changes to part 24 in a final rule. Most of these issues were raised in petitions for rulemaking or arose in connection with wine treatment approval requests under §§ 24.249 or 24.250, and in each case, TTB determined that more information would be required before a decision could be taken on whether, and if so how, appropriate

regulatory changes should be proposed. The issues in question, and the specific points on which TTB is requesting public comments, are outlined below.

TTB requests comments and, where appropriate, evidence supporting the position that the particular wine treatment is consistent with good commercial practice. If applicable, use rates should be recommended, and the rationale as to why those use rates are recommended should be stated in any comments.

Alcoholic Oak Extract

In 2008, Oak Tannin Technologies submitted a petition to amend the regulations to allow “alcoholic oak extracts for use in natural wines as a stabilizing, enriching and integrating agent.” The petitioner stated that use of such extracts in wine is approved by the South African Wine and Spirit Board. However, TTB understands that South Africa passed legislation that actually prohibits the use of such extracts in natural wines. In addition, TTB and its predecessor agencies’ longstanding policy has been to treat such materials as essences or extracts, which, under § 24.85, may be used only in the production of formula wines except agricultural wine.

As noted earlier in this document, TTB approves the use of wine treating materials for, among other things, the stabilization, clarification, and filtration of natural wine based on the materials’ acceptance in good commercial practice. In order to assist TTB in determining whether it would be appropriate to propose a specific regulatory change in response to this petition, TTB is inviting comments regarding the use of an alcoholic oak extract in the production of natural wines, in particular, as a material for use as a wine stabilizer, but also for any other

purpose that is consistent with good commercial practice. TTB also advises that a manufacturer of alcoholic oak extract must contact FDA and go through the FDA pre-market review processes.

Lactic Acid

In 2007, Hyman, Philips, & McNamara, P.C. petitioned TTB to amend 27 CFR 24.182 and 24.246 to allow use of lactic acid in juice, must, and wine prior to fermentation. Lactic acid is most commonly found in dairy products and is a common component in both plant and animal metabolic processes. Under § 24.246, lactic acid is currently authorized for use in grape wine to correct natural acid deficiencies. In the table in § 24.246, the entry in the “Reference or limitation” column for lactic acid simply provides a citation to 27 CFR 24.182 and 24.192. Section 24.192 then refers back to the limitations on the use of acid, among other things, prescribed in § 24.182. The regulations in § 24.182 state that acids of the kinds occurring in grapes or other fruit (including berries) may be added within the limitations of § 24.246 to juice or wine in order to correct natural deficiencies. Section 24.182 also states that, after fermentation is completed, citric acid, fumaric acid, malic acid, lactic acid, or tartaric acid, or a combination of two or more of these acids, may be added to correct natural deficiencies. The petitioner noted that lactic acid is currently allowed by § 24.246 for treatment of wine after fermentation and provided evidence that lactic acid may be added before fermentation in certain other countries. Further, the petitioner noted that lactic acid is less expensive and more reliably available than tartaric acid.

TTB is not proposing any changes to the regulations concerning the use of lactic acid in this document; however, TTB invites comments regarding whether or not the use of lactic acid prior to fermentation is good commercial practice in the production of natural wine. Comments should address whether or not lactic acid should be authorized for use prior to the fermentation of natural wine and provide detailed evidence supporting the stated position.

Reverse Osmosis to Enhance the Phenol Flavor and Characteristics of Wine and to Reduce the Water Content of Standard Wine

Section 24.248 currently provides for the use of reverse osmosis to reduce the ethyl alcohol content of wine and to remove off flavors in wine. However, in 2014, Constellation Wines U.S. Inc. submitted a petition to TTB requesting an expansion of the authorized uses of reverse osmosis in § 24.248 to include (1) improving the phenol and flavor character of wine, and (2) reducing the water content in standard wine. The petition included the following arguments in support of this change:

- Reverse osmosis can effectively eliminate the weak and watery character of the retentate (which, as a product of the reverse osmosis process, is considered to be standard wine but with reduced levels of alcohol and water), resulting in a wine with improved phenol and flavor characteristics.

- The present situation puts U.S. winemakers at a competitive disadvantage in the global marketplace in two ways. First, the petitioner asserts that many foreign countries permit the use of reverse osmosis as an acceptable winemaking practice to concentrate phenols and flavors in wine and in grape must. Exported U.S. wines, which cannot be produced in this way under the

current regulations, would not reflect these characteristics in those foreign markets. Second, under the terms of section 5382 of the IRC, most imported wines that were subjected to such a process would be allowed to compete in the U.S. market against domestic wines to which that process may not be applied.

- Reverse osmosis benefits grape growers, winemakers, and consumers. The expanded use of reverse osmosis would allow grape growers to sell more grapes, particularly those of marginal quality, to winemakers who could produce better quality standard wine with such grapes. Winemakers would be able to produce better quality wine at lower costs, and consumers would be able to purchase better quality wine at lower prices.

- The expanded use of reverse osmosis would provide winemakers with better ability to regulate the alcohol content of wines.

TTB notes that the byproduct of reverse osmosis (the retentate) is only considered to be standard wine if the wine that was processed with reverse osmosis was standard wine. TTB understands that the European Union (EU) only authorizes the use of reverse osmosis to remove water from wine in cold and wet regions and that wine produced with the use of reverse osmosis in the EU must be labeled as “table wine.” TTB’s counterparts in Australia indicate that while authorized, reverse osmosis is not a process officially recognized in the Australia New Zealand Food Standards Code, and is not used frequently. TTB understands that South Africa authorizes the use of reverse osmosis on juice but not wine.

TTB has not received other requests from industry members to use reverse osmosis to improve the phenol and flavor character of wine. However, TTB did receive a request to use reverse osmosis to improve the “sensory quality” of finished wines and to evaluate the potential sensory benefit of water content reduction compared to the resultant loss of volume.

TTB has received and approved industry member requests to use reverse osmosis in combination with distillation to reduce the water content of wine only for the purpose of salvage, discussed above, rather than as a winemaking process to improve the character of the wine. In salvage, the removal of water returns the wine to its previous condition and, as a condition of approval, TTB strictly limited the amount of water to be removed to no more than the amount that had been accidentally added to the wine.

TTB believes that it should provide the public the opportunity to comment before it makes a decision on whether the removal of water from wine to improve the characteristics of the wine would be acceptable in good commercial practice. To assist TTB in deciding whether to adopt any specific regulatory change in this regard, TTB is inviting comments on whether the use of reverse osmosis to reduce the water content of wine, improve the phenol and flavor character of wine, or to improve the sensory quality of the wine would be acceptable in good commercial practice.

If you believe that the use of reverse osmosis for these purposes is consistent with good commercial practice, your comments should explain your position in detail, as well as provide guidelines/standards concerning how much

water (maximum percentage) may be removed. If you believe that the use of reverse osmosis for these purposes is not consistent with good commercial practice, your comments should explain your position in detail.

Ultrafiltration

As previously discussed, an industry member requested to use ultrafiltration to separate white grape juice that had darkened due to oxidation during storage into high and low color fractions for blending purposes. The low color fraction would be blended with white wine, and the high color fraction would be blended with red wine. Ultrafiltration is authorized for use under § 24.248 to separate red wine into low color and high color wine fractions for blending purposes; but the regulations do not provide for the use of ultrafiltration to separate white wine.

TTB believes it should provide the public with the opportunity to comment before it makes a decision on whether the use of ultrafiltration to separate discolored wine for blending as described above would be acceptable in good commercial practice. If you wish to submit a comment on this matter, your comment should explain in detail your position as to why the use of ultrafiltration in this manner is or is not acceptable in good commercial practice.

Yeast Nutrients (Gusmer Petition)

The following list of vitamins and minerals were proposed in the Gusmer petition as yeast nutrients in the production of wine but have not been administratively approved by TTB pursuant to § 24.250: Cobalamin (vitamin B12), iodine (potassium iodide), iron, manganese sulfate, nickel, potassium

chloride, riboflavin (Vitamin B2), and zinc sulfate. With the exception of riboflavin, TTB has not received requests under §§ 24.249 or 24.250 to use these vitamins and minerals as yeast nutrients in the production of wine. TTB did not administratively approve the use of riboflavin as a yeast nutrient because the evidence submitted with the request was not sufficient to conclude that the use of riboflavin as a yeast nutrient is consistent with good commercial practice.

Gusmer provided information on the FDA regulatory status, functional roles, and use rates for the following vitamins and minerals as yeast nutrients. TTB is interested in receiving comments supporting or rejecting the argument that the use of these vitamins and minerals as yeast nutrients in the production of wine is consistent with good commercial practice. Unless otherwise noted, the information that follows was supplied by Gusmer.

- Cobalamin (vitamin B12): Cobalamin is used to promote growth of yeast, and Gusmer proposed that cobalamin be used at a rate not to exceed 15 ppb.
- Iodine (potassium iodide): Iodine is required for yeast growth and fermentation, and Gusmer proposed that iodine be used at a rate not to exceed 10 ppb.
- Iron: Iron is a catalyst for oxidation reactions, and Gusmer proposed that iron be used at a rate not to exceed 2 ppm.
- Manganese sulfate: Manganese sulfate is a pale pink, odorless powder that is freely soluble in water and insoluble in alcohol. Gusmer proposed that manganese sulfate be used at a rate not to exceed 100 ppb.

- Nickel: Nickel is a catalyst for hydrogenation, and Gusmer proposed that nickel be used at a rate not to exceed 5 ppm.
- Potassium chloride: Potassium chloride is a salt that disassociates into ions that are necessary for phosphate uptake by yeast. Gusmer proposed that potassium chloride be used at a rate not to exceed 100 ppm.
- Riboflavin (vitamin B2): Riboflavin is used as a coenzyme in oxidation/reduction reactions, and Gusmer proposed riboflavin be used at a rate not to exceed 600 ppb.
- Zinc sulfate: Zinc sulfate increases alcohol tolerance, and Gusmer proposed zinc sulfate be used at a rate not to exceed 1.5 ppm.

Public Participation

Comments Sought

TTB requests comments from the public and all interested parties. TTB is particularly interested in comments that address the question of whether a particular material, process, or practice addressed in this document is consistent with good commercial practice. Please support your comment with specific information about the material, process, or practice in question.

After TTB analyzes any comments received in response to the regulatory amendments TTB has proposed in this document, we plan to issue a final rule. If TTB receives comments and evidence that persuade it that the use of a particular wine treating material or process is not consistent with good commercial practice, TTB will not include it in the final rule. As a result, and as stated in previously issued administrative approvals, if TTB has determined that

the use of a wine or juice treating material or process is not consistent with good commercial practice, previous approvals of that wine or juice treating material or process will be rescinded by operation of law on the effective date of the final rule.

Additionally, if TTB has determined that the authorized amount of a wine or juice treating material should be decreased because its current authorized amount is not consistent with good commercial practice, previous approvals authorizing the higher amount of that wine or juice treating material will be rescinded on the effective date of the final rule. Wines produced using treatments pursuant to an administrative approval that has been rescinded based upon this rulemaking may nevertheless be labeled as if the materials or processes were authorized, provided such treatments were used prior to the date of rescission.

Submitting Comments

You may submit comments on the proposals described in this document by using one of the following three methods:

- Federal e-Rulemaking Portal: You may send comments via the online comment form linked to this document in Docket No. TTB–2016–0010 on “Regulations.gov,” the Federal e-rulemaking portal, at <https://www.regulations.gov>. Direct links to the comment form and docket are available under Notice No. 164 on the TTB Web site at <https://www.ttb.gov/wine/wine-rulemaking.shtml>. Supplemental files may be

attached to comments submitted via Regulations.gov. For information on how to use Regulations.gov, click on the site's Help tab.

- U.S. Mail: You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Box 12, Washington, DC 20005.

- Hand Delivery/Courier: You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 400, Washington, DC 20005.

Please submit your comments by the closing date shown above in this document. Your comments must reference Notice No. 164 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name, as well as your name and position title. If you comment via Regulations.gov, please enter the entity's name in the "Organization" blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or that is inappropriate for public disclosure.

Public Disclosure

On the Federal e-rulemaking portal, Regulations.gov, TTB will post, and the public may view, copies of this document, selected supporting materials, and any electronic or mailed comments TTB receives about this proposal. A direct link to the Regulations.gov docket containing this document and the posted comments on it is available on the TTB Web site at

<https://www.ttb.gov/wine/wine-rulemaking.shtml> under Notice No. 164. You may also reach the docket containing this document and the posted comments received on it through the Regulations.gov search page at

<https://www.regulations.gov>.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including e-mail addresses. TTB may omit voluminous attachments or material that TTB considers unsuitable for posting.

You and other members of the public may view copies of this document, all supporting materials, and any electronic or mailed comments TTB receives

about these proposals by appointment at the TTB Information Resource Center, 1310 G Street, NW, Washington, DC 20005. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact TTB's information specialist at the above address or by telephone at 202-453-2270 to schedule an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), TTB certifies that these proposed regulations, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule provides for the voluntary use of additional wine and juice treating materials and processes in the production of wine. This authorization does not impose any required change to current winemaking practices, nor does it impose additional compliance burden on small businesses. TTB authorizes new wine treating materials and processes by evaluating proprietors' requests to experiment with such materials and processes, such requests being made via letterhead application to TTB. This rule, if adopted, would allow for certain treatments, under limited circumstances, without the submission of a letterhead application to TTB. TTB estimates that the proposed regulation will reduce the number of respondents by approximately 10 applicants per year, thus slightly reducing the overall burden of the information collection.

In addition, TTB currently requires wineries to maintain usual and customary business records. Included in these records are those records that evidence the details and results of experiments approved by TTB under

§ 24.249. This recordkeeping requirement remains unchanged by this proposal as wineries subject to this part still will be required to maintain those usual and customary records. This proposal has a neutral effect on the current recordkeeping requirements.

Because this proposed rule will not have a significant economic impact on a substantial number of small entities no regulatory flexibility analysis is required. Pursuant to 26 U.S.C. 7805(f), TTB will submit the proposed regulations to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the proposed regulations on small businesses.

Paperwork Reduction Act

Two collections of information approved by the Office of Management and Budget (OMB) would be affected by the adoption of the proposed regulatory changes described in this document. These collections of information, approved in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), are assigned control numbers 1513–0057, titled, “Letterhead Applications and Notices Relating to Wine (TTB REC 5120/2),” and 1513–0115, titled “Usual and Customary Business Records Relating to Wine (TTB REC 5120/1).” 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.

OMB Control Number 1513–0057

TTB authorizes new wine treating materials and processes by evaluating proprietors’ requests to experiment with such materials and processes under

§ 24.249. Section 24.249 states, in part, that such requests must be made in the form of an application filed with TTB. Under this authorization, TTB has approved proprietors' requests to take corrective action when water has been accidentally added to wine in amounts exceeding those authorized for the production of standard wine under 27 CFR part 24. In this notice, TTB is proposing to add a new § 24.251 to provide for the correction of accidentally diluted wine under certain circumstances without the submission of a letterhead application to TTB. TTB estimates that the proposed regulation will reduce the number of respondents by approximately 10 applicants per year and, therefore, will slightly reduce the information collection's overall burden.

TTB estimates that, as a result of the proposed amendments, the new annual burden for control number 1513–0057 will be as follows:

- Estimated total annual reporting and/or recordkeeping burden: 820 hours.
- Estimated average annual burden hours per respondent: 0.5 hours (30 minutes).
- Estimated number of respondents: 1,640.
- Estimated annual frequency of respondents: 1.

Comments on this collection of information should be sent to OMB to Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503; or email to OIRA_submission@omb.eop.gov. A copy also should be sent to the Alcohol and Tobacco Tax and Trade Bureau by any of the methods

previously described. Comments on the information collection should be submitted not later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

OMB Control Number 1513-0115

Under TTB's authority in 26 U.S.C. 5367, 5369, 5370, and 5555, TTB requires wineries to maintain usual and customary business records. Included in these records are those evidencing the details and results of experiments approved by TTB under § 24.249. The proposed regulations contained in this document provide for a recordkeeping requirement in new § 24.251 when wine is corrected for accidental water dilutions. The recordkeeping requirement in this proposed section is already accounted for under OMB Control Number 1513-0115 because such requests currently are treated as experiments under § 24.249. Therefore, TTB does not believe that there is a change in the burden for this recordkeeping requirement, even for those wineries that are exempted from submitting a letterhead request under § 24.251 because still they will be required to maintain the currently required usual and customary business records.

Comments on this collection of information should be sent to OMB to Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503; or email to OIRA_submission@omb.eop.gov. A copy also should be sent to the Alcohol and Tobacco Tax and Trade Bureau by any of the methods previously described. Comments on the information collection should be

submitted not later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Executive Order 12866

Certain TTB regulations issued under the IRC, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required.

Drafting Information

Kara Fontaine of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau drafted this document.

List of Subjects in 27 CFR Part 24

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

Amendments to the Regulations

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR part 24 as follows.

PART 24—WINE

1. 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, 5121, 5122–5124, 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, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

2. Section 24.10 is amended by:

a. Removing the number "60" in the definition of "Brix" and adding, in its place, the number "68"; and

b. Revising the definition of "Wine spirits" to read as follows:

§ 24.10 Meaning of terms.

* * * * *

Wine spirits. Brandy or wine spirits authorized under 26 U.S.C. 5373 and § 24.225 of this part for use in wine production.

[§ 24.85 AMENDED]

3. In § 24.85, the first sentence is amended by adding the word "wood," after the word "berries."

4. Section 24.185 is added to read as follows:

§ 24.185 Use of wood to treat natural wine.

(a) Treatment by contact. Natural wine may be treated by contact with any wood that is consistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act for food contact (see 21 CFR part 7). The wood may be in the form of barrels, staves, chips, particles, or storage tanks that were used for the addition of wine spirits if the tanks are used for the baking of wine. The wood may be toasted (that is, heated to low, medium, or high temperature without undergoing combustion), but not charred, and the wood must not be otherwise treated.

(b) Use of wood essences and extracts. A proprietor may make or purchase for blending purposes wine that has been heavily treated with wood;

however, wood preparations made with an alcohol solution stronger than 24 percent alcohol by volume are essences and must be used in accordance with § 24.85. If any solvent other than alcohol or water is used to make a wood extract, the resulting extract must be consistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act for that purpose and may be used only in “other wine” in accordance with § 24.218. This paragraph applies to liquid extracts and essences and to the extracts and essences in powder form or dissolved in water after the solvent has been evaporated.

(c) Use of wooden storage tanks. Wooden storage tanks used for the addition of spirits may be used for the baking of wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383–1384, 1386, as amended (26 U.S.C. 5382, 5386))

5. Section 24.186 is added to read as follows:

§ 24.186 Accidental additions of water.

(a) Accidental additions of water totaling 1 percent or less of the volume of standard wine. When in the production, storage, treatment, or finishing of standard wine water is accidentally added to a standard wine in an amount that does not exceed 1 percent of the total volume of the wine, such wine shall remain standard wine and the proprietor need not take any action to correct the wine.

(b) Correction of accidental additions of water. When in the production, storage, treatment, or finishing of standard wine water is accidentally added to a

standard wine in an amount that exceeds 1 percent of the volume of the wine, such wine may be corrected by either:

(1) Blending the diluted wine with a quantity of wine of the same kind so that the amount of water accidentally added does not exceed 1 percent of the total volume of the blended wine; or

(2) Removal of the accidentally added water from the wine in accordance with § 24.251.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383–1384, as amended (26 U.S.C. 5382))

6. Section 24.225 is revised to read as follows:

§ 24.225 Production and use of spirits.

(a) Withdrawal of spirits. The proprietor of a bonded wine premises may withdraw and receive wine spirits without payment of tax from the bonded premises of a distilled spirits plant for use as provided in this section.

(b) Production and use of wine spirits.

(1) In general. The only products considered to be wine spirits authorized for use in wine production under this section are brandy or wine spirits produced in a distilled spirits plant (with or without the use of water to facilitate extraction and distillation) exclusively from:

(i) Fresh or dried fruit, or their residues;

(ii) Natural wine or wine residues from fresh or dried fruit, including spirits byproducts of authorized wine treatments to reduce alcohol; or

(iii) Special natural wine. If wine spirits produced from special natural wine contain any flavor characteristics of the special natural wine, those wine spirits may be used only in the production of a special natural wine.

(2) Distillation proof requirements. The proof of wine spirits at distillation must not be reduced by the addition of water. In addition, a product is not considered to be wine spirits if it is distilled at less than 140 degrees of proof except in the following cases:

(i) Commercial brandy aged in wood for a period of not less than 2 years, and barreled at not less than 100 degrees of proof, shall be deemed wine spirits for purposes of this section; and

(ii) Spirits byproducts of alcohol reduction processing authorized under § 24.248 that are produced at a distilled spirits plant and distilled, if necessary, at not less than 100 degrees of proof shall be deemed wine spirits for purposes of this section.

(3) Addition of sugar after fermentation. When, in the production of natural wine or special natural wine, sugar has been added after fermentation, the wine may not be refermented to develop alcohol from such added sugar and then used in the production of wine spirits.

(4) Addition of wine spirits to natural wine.

(i) Wine spirits produced in the United States may be added to natural wine on bonded wine premises if both the wine and the spirits are produced from the same kind of fruit.

(ii) In the case of natural still wine, wine spirits may be added in any State only to wine produced by fermentation on bonded wine premises located within the same State.

(iii) If wine has been ameliorated, wine spirits may be added (whether or not wine spirits were previously added) only if the wine contains not more than 14 percent of alcohol by volume derived from fermentation.

(c) Spirits other than wine spirits. Spirits other than wine spirits may be received, stored, and used on bonded wine premises only for the production of nonbeverage wine and nonbeverage wine products.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381–1384, as amended, and sec. 455, Pub. L. 98–369, (26 U.S.C. 5214, 5362, 5373, 5382, 5383, 5386))

7. Section 24.246 is revised to read as follows:

§ 24.246 Materials authorized for the treatment of wine and juice.

(a) Wine and juice. Materials used in the process of filtering, clarifying, or purifying wine may remove cloudiness, precipitation, and undesirable odors and flavors, but the addition of any substance foreign to wine that changes the character of the wine, or the abstraction of ingredients so as to change the character of the wine, if not consistent with good commercial practice, is not permitted on bonded wine premises. The materials listed in this section are approved as being consistent with good commercial practice in the production, cellar treatment, or finishing of wine and, where applicable, in the treatment of juice, within the “Specific TTB limitation” of this section and subject to the following conditions:

(1) If the FDA informs TTB that a specified use or limitation of any material listed in this section is inconsistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act, the appropriate TTB officer may cancel or amend the approval for use of the material in the treatment of wine and juice in the production, cellar treatment, or finishing of wine; and

(2) Where water is added to facilitate the solution or dispersal of a material, the volume of water added, whether the material is used singly or in combination with other water-based treating materials, may not total more than 1 percent of the volume of the treated wine or juice, or of both the wine and the juice, from which the wine is produced.

(b) Use in combination or in multiple lots. Subject to the conditions specified in paragraph (a) of this section, a proprietor may use the materials listed in this section in combination, provided that each material is used for its specified use and in accordance with any limitation specified for that use. If a proprietor uses several lots that contain the same material, it is the proprietor's responsibility to ensure that the cumulative amount of the material does not exceed the limitation specified in this section for that material.

(c) Formula wine. In addition to the materials listed in this section, other materials may be used in formula wine if approved for such use.

MATERIALS AUTHORIZED FOR TREATMENT OF WINE AND JUICE

Materials and use	Specific TTB limitation (if applicable)	FDA reference
Acacia (gum arabic): To clarify and stabilize ¹ wine.	The amount used must not exceed 8 pounds per 1000 gallons (1.92 g/L) of wine.	21 CFR 184.1330.
Acetaldehyde: For color stabilization of juice prior to concentration.	The amount used must not exceed 300 ppm ² , and the finished concentrate must have no detectable level of the material.	FDA advisory opinion dated September 8, 2016.
<p>Activated carbon:</p> <p>To assist precipitation during fermentation.</p> <p>To clarify and purify wine.</p> <p>To remove color from wine and/or juice from which wine is produced.</p>	<p>27 CFR 24.176.</p> <p>The amount used to clarify and purify wine must be included in the total amount of activated carbon used to remove excessive color in wine. 27 CFR 24.241 and 24.242.</p> <p>The amount used to treat the wine, including the juice from which the wine was produced, must not exceed 25 pounds per 1000 gallons (3 g/L). If the amount necessary exceeds this limit, a notice is required pursuant to 27 CFR 24.242.</p>	<p>FDA advisory opinion dated September 8, 2016.</p> <p>FDA advisory opinion dated January 26, 1979.</p> <p>FDA advisory opinion dated January 26, 1979.</p>

Albumen (egg white): Fining agent for wine.	May be prepared in a light brine 1 ounce (28.35 grams) potassium chloride, 2 pounds (907.2 grams) egg white, 1 gallon (3.785 L) of water. Usage of brine not to exceed 1.5 gallons per 1,000 gallons (1.5 milliliters per liter) of wine.	FDA advisory opinion dated September 8, 2016.
Alumino-silicates (hydrated) e.g., Bentonite (Wyoming clay) and Kaolin: To clarify and stabilize ¹ wine or juice.	None.	21 CFR 182.2727, 182.2729, 184.1155 and 186.1256. FDA advisory opinion dated July 26, 1985.
Ascorbic acid <i>iso</i> -ascorbic acid (erythorbic acid): To prevent oxidation of color and flavor components of juice or wine.	May be added to grapes, other fruit (including berries), and other primary wine making materials, or to the juice of such materials, or to the wine, within limitations which do not alter the class or type of the wine.	21 CFR 182.3013 and 182.3041.
Bakers Yeast Mannoprotein: To stabilize ¹ wine from the precipitation of potassium bitartrate crystals.	The amount used must not exceed 3.3 pounds per 1000 gallons (400 mg/L) of wine.	GRAS Notice No. GRN 284.
Calcium carbonate (CaCO ₃) (with or without calcium salts of tartaric and malic acids): To reduce the excess natural acids in high acid wine, or in juice prior to or during fermentation.	The natural or fixed acids must not be reduced below 40 pounds per 1000 gallons (5 g/L).	21 CFR 184.1069, 184.1099, and 184.1191.

As a fining agent for cold stabilization.	The amount used must not exceed 30 pounds per 1000 gallons (3.59 g/L) of wine.	
Calcium sulfate (gypsum): To lower pH in sherry wine.	The sulfate content of the finished wine must not exceed 1.67 pounds per 1000 gallons (0.2 g/L), expressed as potassium sulfate. 27 CFR 24.214.	21 CFR 184.1230.
Carbon dioxide (including food grade dry ice): To stabilize ¹ and preserve wine.	See 27 CFR 24.245.	21 CFR 184.1240.
Casein, potassium salt of casein: To clarify wine.	See 27 CFR 24.243.	FDA advisory opinion dated September 8, 2016.
Chitosan from <i>Aspergillus niger</i> . To remove spoilage organisms such as <i>Brettanomyces</i> from wine.	The amount used must not exceed 0.8 pounds per 1000 gallons (10 g/hL) of wine.	GRAS Notice No. GRN 000397.
Citric acid: To correct natural acid deficiencies in certain juice or wine. To stabilize ¹ wine other than citrus wine.	See 27 CFR 24.182 and 24.192. The amount of citric acid must not exceed 5.8 pounds per 1000 gallons (0.7 g/L). 27 CFR 24.244.	21 CFR 184.1033. 21 CFR 184.1033.
Copper sulfate: To remove hydrogen sulfide and/or mercaptans from wine.	The quantity of copper sulfate (calculated as copper) added to wine must not exceed 6 ppm ² . The residual level of copper in the finished wine must not exceed 0.5 ppm ² .	21 CFR 184.1261.

<p>Defoaming agents (polyoxyethylene 40 monostearate, silicon dioxide, dimethylpolysiloxane, sorbitan monostearate, glyceryl mono-oleate and glyceryl dioleate): To control foaming, fermentation adjunct.</p>	<p>Defoaming agents which are 100 percent active may be used in amounts not exceeding 0.15 pounds per 1000 gallons (18 mg/L) of wine. Defoaming agents which are 30 percent active may be used in amounts not exceeding 0.5 pounds per 1000 gallons (60 mg/L) of wine. Silicon dioxide must be completely removed by filtration. The amount of silicon remaining in the wine must not exceed 10 ppm².</p>	<p>21 CFR 173.340 and 184.1505.</p>
<p>Dimethyl dicarbonate (DMDC): To sterilize and stabilize¹ wine.</p>	<p>DMDC may be added to wine in a cumulative amount not to exceed 200 ppm².</p>	<p>Must meet the conditions prescribed by FDA in 21 CFR 172.133.</p>
<p>Enzymatic activity: Various enzymes and uses, as shown below:</p>	<p>The enzyme preparation used must be prepared from nontoxic and nonpathogenic microorganisms in accordance with good manufacturing practice and be consistent with FDA's regulations.</p>	

Carbohydrase (<i>alpha</i> -Amylase): To convert starches to fermentable carbohydrates.	The amylase enzyme activity must be derived from:	FDA advisory opinion of August 18, 1983.
	<i>Aspergillus niger</i> , <i>Aspergillus oryzae</i> , <i>Bacillus subtilis</i> , or barley malt; or	
	from <i>Rhizopus oryzae</i> : or	21 CFR 173.130.
	from <i>Bacillus licheniformis</i> .	21 CFR 184.1027.
Carbohydrase (<i>beta</i> -Amylase): To convert starches to fermentable carbohydrates.	The amylase enzyme must be derived from barley malt.	FDA advisory opinion dated August 18, 1983.
Carbohydrase (Glucoamylase, Amylogluco-sidase): To convert starches to fermentable carbohydrates.	The amylase enzyme activity must be derived from <i>Aspergillus niger</i> , <i>Aspergillus oryzae</i> , or	FDA advisory opinion dated August 18, 1983.
	from <i>Rhizopus oryzae</i> ,	21 CFR 173.130.
	or from <i>Rhizopus niveus</i> .	21 CFR 173.110.
Carbohydrase (pectinase, cellulase, hemicellulase): To facilitate separation of juice from the fruit.	The enzyme activity must be derived from <i>Aspergillus aculeatus</i> .	FDA advisory opinion dated December 19, 1996.
Catalase: To clarify and stabilize ¹ wine.	The enzyme activity must be derived from <i>Aspergillus niger</i> or bovine liver.	FDA advisory opinion dated August 18, 1983.
Cellulase: To clarify and stabilize ¹ wine and facilitate separation of the juice from the fruit.	The enzyme activity must be derived from <i>Aspergillus niger</i> .	FDA advisory opinion dated August 18, 1983.

Cellulase (beta-glucanase): To clarify and filter wine.	The enzyme activity must be derived from <i>Trichoderma longibrachiatum</i> or <i>Trichoderma harzianum</i> . The amount used must not exceed 30 ppm ² .	For beta-gucanase derived from <i>Trichoderma longibrachiatum</i> , 21 CFR 184.1250. For beta-glucanase derived from <i>Trichoderma harzianum</i> , GRAS Notice No. GRN 149.
Glucose oxidase: To clarify and stabilize ¹ wine.	The enzyme activity must be derived from <i>Aspergillus niger</i> .	FDA advisory opinion of August 18, 1983.
Lysozyme: To stabilize ¹ wines from malolactic acid bacterial degradation.	The amount used must not exceed 500 ppm ² .	FDA advisory opinion dated December 15, 1993.
Pectinase: To clarify and stabilize ¹ wine and to facilitate separation of juice from the fruit.	The enzyme activity used must be derived from <i>Aspergillus niger</i> .	FDA advisory opinion dated August 18, 1983.
Protease (general): To reduce or to remove heat labile proteins.	The enzyme activity must be derived from: <i>Aspergillus niger</i> or <i>Bacillus subtilis</i> or from; <i>Bacillus licheniformis</i> .	FDA advisory opinion dated August 18, 1983 21 CFR 184.1027
Protease (Bromelin): To reduce or remove heat labile proteins.	The enzyme activity must be derived from <i>Ananus comosus</i> or <i>Ananus bracteatus</i> (L)	FDA advisory opinion dated August 18, 1983.
Protease (Ficin): To reduce or remove heat labile proteins.	The enzyme activity must be derived from <i>Ficus spp.</i>	FDA advisory opinion dated August 18, 1983.

<p>Protease (Papain): To reduce or remove heat labile proteins.</p> <p>Protease (Pepsin): To reduce or remove heat labile proteins.</p> <p>Protease (Trypsin): To reduce or remove heat labile proteins.</p> <p>Urease: To reduce levels of naturally occurring urea in wine to help prevent the formation of ethyl carbamate.</p>	<p>The enzyme activity must be derived from <i>Carica papaya (L)</i></p> <p>The enzyme activity must be derived from porcine or bovine stomachs</p> <p>The enzyme activity must be derived from porcine or bovine pancreas</p> <p>The enzyme activity must be derived from <i>Lactobacillus fermentum</i>. Use is limited to not more than 200 ppm² and must be filtered prior to final packaging.</p>	<p>21 CFR 184.1585.</p> <p>FDA advisory opinion dated August 18, 1983.</p> <p>FDA advisory opinion dated August 18, 1983.</p> <p>21 CFR 184.1924.</p>
<p>Ethyl maltol: To stabilize¹ wine.</p>	<p>Use authorized at a maximum level of 100 ppm² in all standard wines except natural wine produced from <i>Vitis vinifera</i> grapes.</p>	<p>FDA advisory opinion dated December 1, 1986.</p>
<p>Ferrous sulfate: To clarify and stabilize¹ wine.</p>	<p>The amount used must not exceed 3 ounces per 1000 gallons (0.022 g/L) of wine.</p>	<p>21 CFR 184.1315.</p>
<p>Fumaric acid:</p> <p>To correct natural acid deficiencies in grape wine.</p>	<p>The fumaric acid content of the finished wine must not exceed 25 pounds per 1000 gallons (3 g/L). 27 CFR 24.182 and 24.192.</p>	<p>21 CFR 172.350.</p>

To stabilize ¹ wine.	The fumaric acid content of the finished wine must not exceed 25 pounds per 1000 gallons (3 g/L). 27 CFR 24.244.	21 CFR 172.350.
Gelatin (food grade): To clarify juice or wine.	None.	FDA advisory opinion dated September 8, 2016.
Granular cork: To smooth wine.	The amount used must not exceed 10 pounds per 1000 gallons of wine (1.2 g/L).	FDA advisory opinion dated February 25, 1985.
Isinglass: To clarify wine.	None.	FDA advisory opinion dated February 25, 1985.
Lactic acid: To correct natural acid deficiencies in grape wine.	27 CFR 24.182 and 24.192.	21 CFR 184.1061.
Malic acid: To correct natural acid deficiencies in juice or wine.	27 CFR 24.182, 24.192.	21 CFR 184.1069.
Malo-lactic bacteria: To stabilize ¹ grape wine.	Malo-lactic bacteria of the type <i>Leuconostoc oenos</i> may be used in treating wine.	FDA advisory opinion dated February 25, 1985.
Maltol: To stabilize ¹ wine.	Use authorized at a maximum level of 2 pounds per 1000 gallons (250 mg/L) in all standard wine except natural wine produced from <i>Vitis vinifera</i> grapes.	FDA advisory opinion dated December 1, 1986.
Milk products (pasteurized whole, skim, or half-and-half):		

<p>Fining agent for grape wine.</p> <p>To remove off flavors in wine.</p>	<p>The amount used must not exceed 2 parts of milk products per 1,000 parts (0.2 percent V/V) of wine.</p> <p>The amount used must not exceed 10 parts of milk products per 1,000 parts (1 percent V/V) of wine.</p>	
<p>Nitrogen gas: To maintain pressure during filtering and bottling or canning of wine and to prevent oxidation of wine.</p>	<p>None.</p>	<p>21 CFR 184.1540.</p>
<p>Oxygen and compressed air: Various uses in juice and wine.</p>	<p>None.</p>	
<p>Polyvinyl-polypyr-rolidone (PVPP): To clarify and stabilize¹ wine and to remove color from red wine or juice.</p>	<p>The amount used to treat the wine, including the juice from which the wine was produced, must not exceed 60 pounds per 1000 gallons (7.19 g/L) and must be removed during filtration. PVPP may be used in a continuous or batch process. The finished wine must retain vinous character and must have color of not less than 0.6 Lovibond in a one-half inch cell or not more than 95 percent transmittance per AOAC Method 11.003–11.004 (14th Ed.).³</p>	<p>21 CFR 173.50.</p>

Polyvinyl-pyrrolidone (PVP)/polyvinylimadazole (PVI) polymer: To remove heavy metal ions and sulfides from wine.	The amount used to treat the wine must not exceed 6.7 pounds per 1000 gallons (80 g/hL) of wine.	21 CFR 173.55 and FDA FCN No. 320.
Potassium bitartrate: To stabilize ¹ grape wine.	The amount used must not exceed 35 pounds per 1000 gallons (4.19 g/L) of grape wine.	FDA advisory opinion dated September 8, 2016.
Potassium carbonate and/or potassium bicarbonate: To reduce excess natural acidity in wine and in juice prior to or during fermentation.	The natural or fixed acids must not be reduced below 0.668 ounces per gallon (5 g/L).	21 CFR 184.1619 and 184.1613.
Potassium citrate: pH control agent and sequestrant in the treatment of citrus wines.	The amount of potassium citrate must not exceed 25 pounds per 1000 gallons (3 g/L) of finished wine. 27 CFR 24.182.	21 CFR 184.1625.
Potassium meta-bisulfite: To sterilize and preserve wine.	The sulfur dioxide content of the finished wine must not exceed the limitations prescribed in 27 CFR 4.22.	21 CFR 182.3637.
Potato protein isolate: Fining agent for wine.	Use must not exceed 500 ppm ² (50 g/hL) of wine.	GRAS Notice No. GRN 000447.
Silica gel (colloidal silicon dioxide): To clarify wine or juice.	Use must not exceed the equivalent of 20 pounds colloidal silicon dioxide at a 30 percent concentration per 1000 gallons (2.4 g/L) of wine. Silicon dioxide must be completely removed by filtration.	FDA advisory opinion dated September 8, 2016.

Sodium carboxymethyl cellulose: To stabilize ¹ wine by preventing tartrate precipitation.	The amount used must not exceed 0.8% of the wine.	21 CFR 182.1745.
Sorbic acid and potassium salt of sorbic acid (potassium sorbate): To sterilize and preserve wine; to inhibit mold growth and secondary fermentation.	The finished wine must not contain more than 300 ppm ² of sorbic acid.	21 CFR 182.3089 and 182.3640.
Sulfur dioxide: To sterilize and to preserve wine or juice.	The sulfur dioxide content of the finished wine must not exceed the limitations prescribed in 27 CFR 4.22(b)(1).	21 CFR 182.3862.
Tannin: To adjust tannin content in apple juice or in apple wine.	The residual amount of tannin must not exceed 24 pounds per 1000 gallons (3 g/L), calculated as gallic acid equivalents (GAE). Total tannin must not be increased by more than 150 ppm ² by the addition of tannic acid (polygalloylglucose).	FDA advisory opinion dated September 8, 2016.

<p>To clarify, or adjust tannin content of, juice or wine (other than apple).</p>	<p>The residual amount of tannin, calculated in GAE, must not exceed 6.4 GAE per 1000 gallons of wine (800 mg/L) in white wine and 24 pounds per 1000 gallons (3 g/L) in red wine. Only tannin which does not impart color may be used in the cellar treatment of juice or wine. Total tannin must not be increased by more than 150 ppm² by the addition of tannic acid (poly-galloylglucose).</p>	<p>FDA advisory opinion dated September 8, 2016.</p>
<p>Tartaric acid (L(+) tartaric acid):</p> <p>To correct natural acid deficiencies in grape juice or wine and to reduce the pH of grape juice or wine where ameliorating material is used in the production of grape wine.</p>	<p>Use as prescribed in 27 CFR 24.182 and 24.192.</p>	<p>21 CFR 184.1099 and GRAS Notice No. GRN 000187.</p>
<p>Yeast nutrients: To facilitate fermentation of juice and wine.</p> <p>Ammonium phosphate/diammonium phosphate (<i>mono-</i> and <i>di</i> basic).</p> <p>Biotin.</p> <p>Calcium pantothenate (vitamin B5).</p>	<p>The amount used must not exceed 8 pounds per 1000 gallons (0.96 g/L).</p> <p>The amount used must not exceed 25 ppb⁴.</p> <p>The amount used must not exceed 1.5 ppm².</p>	<p>FDA advisory opinion dated August 29, 2016.</p> <p>FDA advisory opinion dated August 29, 2016.</p> <p>FDA advisory opinion dated August 29, 2016.</p>

Folic acid (folate).	The amount used must not exceed 100 ppb ⁴ .	FDA advisory opinion dated August 29, 2016.
Inositol (myo-inositol).	The amount used must not exceed 2 ppm ² .	FDA advisory opinion dated August 29, 2016.
Magnesium sulfate.	The amount used must not exceed 15 ppm ² .	FDA advisory opinion dated August 29, 2016.
Niacin (vitamin B3).	The amount used must not exceed 1 ppm ² .	FDA advisory opinion dated August 29, 2016.
Pyridoxine hydrochloride (vitamin B6).	The amount used must not exceed 150 ppb ⁴ .	FDA advisory opinion dated August 29, 2016.
Soy flour (defatted).	The amount used must not exceed 2 pounds per 1000 gallons (0.24 g/L) of wine.	FDA advisory opinion dated August 29, 2016.
Thiamine hydrochloride.	The amount used must not exceed 0.005 pounds per 1000 gallons (0.6 mg/L) of wine or juice.	FDA advisory opinion dated August 29, 2016.
Yeast, autolyzed.	None.	FDA advisory opinion dated August 29, 2016.
Yeast, cell wall/membranes of autolyzed yeast.	The amount used must not exceed 3 pounds per 1000 gallons (0.36 g/L) of wine or juice.	FDA advisory opinion dated August 29, 2016.

¹ To stabilize—To prevent or to retard unwanted alteration of chemical and/or physical properties.

² Parts per million—1 ppm = 0.128 ounces per 1000 gallons = 1 mg/L = 1000 ppb.

³ Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II, AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

⁴ Parts per billion—1ppb = 0.000128 ounces per 1000 gallons = 1 mg/1000L

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8. Section 24.247 is amended by:

a. Revising the introductory text;

b. Revising the entry in the table for “Ammonium phosphate (mono- and di basic”); and

c. Removing the footnote at the end of the table.

The revisions read as follows:

§ 24.247 Materials authorized for the treatment of distilling material.

The materials listed in this section as well as the materials listed in § 24.246 are approved as being acceptable in good commercial practice for use by proprietors in the treatment of distilling material within the limitations specified in this section. If, however, the U.S. Food and Drug Administration (FDA) informs TTB that a specified use or limitation of any material listed in this section is inconsistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act, the appropriate TTB officer may cancel or amend the approval for use of the material in the treatment of distilling material.

Materials	Use	Reference or limitation
Ammonium phosphate/diammonium phosphate (<i>mono-</i> and <i>di</i> basic).	Yeast nutrient in distilling material.	The amount used shall not exceed 10 pounds per 1000 gallons (1.2 g/L). 21 CFR 184.1141a and 184.1141b.
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9. Section 24.248 is amended by:

a. Revising the introductory text;

b. Removing the entries for “Nanofiltration,” “Reverse osmosis,” and “Ultrafiltration”;

- c. Adding an entry for “Cross flow filtration”, including subentries for “Nanofiltration”, “Reverse osmosis”, and “Ultrafiltration”, at the top of the table;
- d. Revising the entries for “Osmotic transport”, “Spinning cone column”, and “Thin-film evaporation under reduced pressure”; and
- e. Removing footnote 1 at the end of the table and adding new footnotes 1 and 2.

The additions and revisions to the table and its footnotes read as follows:

§ 24.248 Processes authorized for the treatment of wine, juice, and distilling material.

The processes listed in this section are approved as being consistent with good commercial practice for use by proprietors in the production, cellar treatment, or finishing of wine, juice, and distilling material, within the general limitations of this section. If, however, the U.S. Food and Drug Administration (FDA) informs TTB that a specified use or limitation of any material listed in this section is inconsistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act, the appropriate TTB officer may cancel or amend the approval for use of the process in the production, cellar treatment, or finishing of wine, juice, and distilling material.

**PROCESSES AUTHORIZED FOR THE TREATMENT OF WINE, JUICE, AND
DISTILLING MATERIAL**

Process	Use	Reference or limitation
Cross flow filtration	Various processes and uses. ¹	
Nanofiltration ²	To reduce the level of volatile acidity in wine (used with ion exchange), to reduce the ethyl alcohol content of wine.	This process must use permeable membranes which are selective for molecules not greater than 150 molecular weight with transmembrane pressures of 250 psi or less.
Reverse osmosis ²	To reduce the ethyl alcohol content of wine and to remove off flavors in wine.	Permeable membranes that are selective for molecules not greater than 500 molecular weight with transmembrane pressures of 200 pounds per square inch (psi) and greater. The addition of water other than that originally present prior to processing will render standard wine "other than standard." Use must not alter the vinous character of the wine. May be used in combination with osmotic transport.

Ultrafiltration ²	To remove proteinaceous material from wine; to reduce harsh tannic material from white wine produced from white skinned grapes; to remove pink color from blanc de noir wine; to separate red juice and wine into low color and high color fractions for blending purposes, to reduce the ethyl alcohol content of wine.	Permeable membranes that are selective for molecules greater than 500 and not less than 25,000 molecular weight with transmembrane pressures less than 200 psi. Shall not alter vinous character.
* * * * *	* * * * *	* * * * *
Osmotic transport ²	For alcohol reduction.	(1) Use must not alter the vinous character of the wine. (2) None of the stripping solution may migrate into the wine. (3) May be used in combination with reverse osmosis.
* * * * *	* * * * *	* * * * *
Spinning cone column ²	To reduce the ethyl alcohol content of wine and to remove off flavors in wine.	Use shall not alter vinous character. For standard wine, the same amount of essence must be added back to any lot of wine as was originally removed.
* * * * *	* * * * *	* * * * *

Thin film evaporation under reduced pressure ²	To separate wine into a low alcohol wine fraction and into a higher alcohol distillate.	Use shall not alter vinous character. Water separated with alcohol during processing may be recovered by refluxing in a closed continuous system and returned to the wine. The addition of water other than that originally present in the wine prior to processing, will render standard wine other than standard wine.
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¹ In cross-flow filtration, the wine is passed across the filter membrane (tangentially) at positive pressure relative to the permeate side. A proportion of the wine which is smaller than the membrane pore size passes through the membrane as permeate or filtrate; everything else is retained on the feed side of the membrane as retentate.

² When used to remove ethyl alcohol (dealcoholization), this process must be done on distilled spirits plant premises. However, reverse osmosis and nanofiltration, under certain limited conditions, may be used on bonded winery premises if ethyl alcohol is only temporarily created within a closed system.

* * * * *

10. Paragraph (b) of § 24.250 is amended to read as follows:

§ 24.250 Application for use of new treating material or process.

(b) Documentary evidence from the U.S. Food and Drug Administration that the material is consistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act for its intended purpose in the amounts proposed for the particular treatment contemplated;

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11. Section 24.251 is added to read as follows:

§ 24.251 Salvaging accidentally diluted wine.

(a) Removal of accidentally added water without prior TTB approval. If a proprietor accidentally adds to standard wine water in excess of limitations specified in subparts F and L of this part, the accidentally diluted wine may be

returned to its original condition through the use of reverse osmosis and distillation without prior application to TTB provided that:

(1) The accidentally added water represents no more than 10 percent of the original volume of the wine;

(2) The wine is returned to its original condition by removing an amount of water equal to the amount that was accidentally added to the wine;

(3) The vinous character of the wine is not altered;

(4) The proprietor transfers the wine in bond to a distilled spirits plant for treatment; and

(5) Records are maintained in accordance with paragraph (c) of this section.

(b) Removal of accidentally added water with TTB approval. If a proprietor accidentally adds water to standard wine and the accidentally added water represents more than 10 percent of the original volume of the wine, then the proprietor must request permission from TTB prior to treating the wine. A proprietor may submit an application requesting permission to treat the wine to remove the water and return the wine to its original condition. The removal of water may not be conducted until the appropriate TTB officer has approved the request. The application, which is to be submitted to the appropriate TTB officer, must be in writing, must provide evidence of the exact amount of water accidentally added to the wine and an explanation of how the water was accidentally added, and must specify the method the proprietor will use to remove the water from the wine. In approving any request under this section, the

appropriate TTB officer may require the proprietor to take steps to prevent future accidental additions of water to wine. In evaluating any request under this section, the appropriate TTB officer may consider as a factor whether the proprietor has demonstrated good commercial practices, taking into account the proprietor's prior history of accidental addition of water to wine and of compliance with other regulations in part 24.

(c) Records. The proprietor must, with respect to removals of water from wine authorized under this section, maintain records that document the accidental addition of water, the use of any treatment or process to remove the water from the wine, and the fact that only the amount of water that was accidentally added to the wine was removed as a result of the treatment or process.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383–1384, as amended (26 U.S.C. 5382))

Signed: June 16, 2016.

John J. Manfreda,

Administrator.

Approved: October 25, 2016.

Timothy E. Skud,

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

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