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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 24

[Docket No. TTB–2016–0010; T.D. TTB–185; Re: Notice No. 164]

RIN 1513–AB61

Wine Treating Materials and Related Regulations

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

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is amending its regulations pertaining to the production of wine to add to the list of materials and processes authorized for the treatment of wine and of the juice from which wine is made, and to expand the authorized uses of certain materials already authorized under the regulations. TTB is finalizing amendments to the regulations proposed in a notice of proposed rulemaking, Notice No. 164, with some changes in response to comments received. Adding these wine treating materials and processes to the TTB regulations will increase the acceptability in export markets of wine produced using these materials and processes.

DATES: This final rule is effective August 24, 2022.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

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I. Background

A. TTB Authority

TTB authorizes the use of certain wine treating materials and processes under the authority of chapter 51 of the Internal Revenue Code of 1986, as amended (IRC), 26 U.S.C. chapter 51. Specifically, certain provisions of the IRC apply to the production of ''natural wine,'' which is defined at 26 U.S.C. 5381 as the product of the juice or must of sound, ripe grapes or other sound, ripe fruit, made with such cellar treatment as authorized under the IRC at 26 U.S.C. 5382. Section 5382(a) of the IRC (26 U.S.C. 5382(a)) 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) authorizes the Secretary of the Treasury (Secretary) to prescribe, by regulation, limitations on the preparation and use of methods and materials for clarifying, stabilizing, preserving, fermenting, and correcting wine and juice. In addition, section 5387(a) of the IRC (26 U.S.C. 5387(a)), which authorizes the production of agricultural wine from agricultural products other than the juice of fruit, provides that 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.

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 certain administrative and enforcement authorities to TTB through Treasury Order 120–01.

The regulations promulgated under these authorities are set forth in part 24 of title 27 of the Code of Federal Regulations (27 CFR part 24). The TTB regulations at 27 CFR 24.246 list materials authorized for the treatment of wine and juice; 27 CFR 24.247 lists materials authorized for the treatment of distilling material used in the production of wine; and 27 CFR 24.248 lists processes authorized for the treatment of wine, juice, and distilling material. The materials and processes listed in these regulatory sections 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 and distilling material, within limitations provided.

B. Process for Approval of Wine Treating Materials

Industry members wanting to use a treating material or process not specifically authorized in part 24 may request authorization to do so. TTB may administratively approve the use of treating materials and processes not listed in the regulations, either as an experiment under 27 CFR 24.249 or for continual use (acceptable in good commercial practice) under 27 CFR 24.250. Applicants for such approvals must submit to TTB a request describing the material or process and the purpose, manner, and extent to which the material or process is to be used; certain samples and test results; and any other relevant information, as described in the regulations. If the request is for the approval of a material, the applicant must also submit documentary evidence of the U.S. Food and Drug Administration (FDA) approval of the material for its intended purpose in the amounts, along with the recommended minimum and maximum amounts of the material, if any. Consistent with §§ 24.246, 24.247, and 24.248, TTB may approve the use of treating materials

and processes that are determined to be acceptable in good commercial practice. In Notice No. 164, TTB explained that it considers good commercial practice to include 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 but not creating an erroneous impression about the character and composition of the wine.

When TTB approves the continued commercial use of a treating material or process under § 24.250, it provides public notice of such approval on its website at *https://www.ttb.gov/wine/treating-materials.* The listing of such administrative approvals on the TTB website affords all industry members the opportunity to use an administratively approved wine treating material or process pending future rulemaking.

For several reasons, 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. One reason is that when TTB administratively approves wine treatments or processes for continued commercial use under § 24.250, TTB is making an initial determination that the treatment is consistent with ''good commercial practice.'' The subsequent rulemaking process allows industry members and other members of the public an opportunity to publicly comment on, and specifically to confirm or refute, the initial determination that the use of a material or process is consistent with good commercial practice. TTB can then determine whether to add the material or process to its regulations.

Administrative approval of a wine treatment under § 24.250 does not guarantee acceptance in foreign markets of any wine so treated. Therefore, conducting rulemaking to add wine treating materials and processes to the regulations may also result 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 . . . 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. Through the rulemaking process, TTB provides such public notice and opportunity to comment on wine treating materials and processes that had been administratively approved. As a result, incorporation of the treating materials and processes in the regulations provides domestic winemakers with greater flexibility in producing wines for sale in foreign markets.

C. Consultation With U.S. Food and Drug Administration

TTB also 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. See 21 U.S.C. 321(s), 21 CFR 170.30. The use of a food additive in food must be authorized by FDA either through a food additive regulation in 21 CFR or an effective food contact notification (FCN).[1] 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).[2] For the purpose of this rulemaking, TTB is using 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.

[1] *https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications.*

[2] *https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices.*

II. Publication of Notice of Proposed Rulemaking

On November 22, 2016, TTB published in the **Federal Register** (81 FR 83752) a notice of proposed rulemaking, Notice No. 164, proposing to amend its regulations to incorporate 15 wine and juice treating materials and the combined use of two existing wine treatment processes it had administratively approved. TTB also proposed some clarifying and editorial changes. In response to requests by commenters, TTB reopened the comment period for 90 days and then subsequently extended it for another 90 days. The comment period finally closed on April 9, 2018. TTB received 33 comments from major trade organizations, suppliers of wine treating materials and processes, winemakers, the public, and the European Union. The comments generally support the treating materials and processes proposed in Notice No. 164. Notice No. 164 and the comments received may be viewed in their entirety in Docket No. TTB–2016–0010 at the *Regulations.gov* website (*www.regulations.gov*). The primary proposals, comments received, and TTB responses to those comments are discussed in the following sections of this document. The clarifying and editorial changes to the regulations are described in detail in Notice No. 164, and unless subject of comments received, are incorporated in the final regulations below and not further discussed here.

III. Scope of Rulemaking and Petition for Additional Changes

On March 5, 2015, the Wine Institute, a wine industry trade association, petitioned TTB to amend §§ 24.246 and 24.247 to replace many of the numerical limits for wine treating materials and processes with a usage standard of ''good manufacturing practice.'' Wine Institute noted in its petition that the current provisions generally limit the authorized usage of a material to the particular use of the material by the industry member who originally petitioned for its use. It also submitted a comment to Notice No. 164 and reiterated its request for ''a default limit of good manufacturing practice (GMP) for those [treating] materials unless otherwise dictated by health concerns.''

TTB agrees that the current process, as described above, results in TTB's authorizing materials at specific usage levels reflecting the parameters detailed in requests by winemakers, and therefore reflects winemakers' actual use, or expressed interest in use, and TTB's evaluation of wine or juice to which the materials and processes have been applied, rather than potential use. This reflects TTB's longstanding application of ''good commercial practice'' as that term is described above. TTB intends to publish separate rulemaking to obtain public comment on the broader approach proposed in the Wine Institute's petition. TTB is not addressing the entirety of the petition in this rulemaking as it would entail many more amendments to the relevant regulations than were proposed in Notice No. 164. In this final rule, TTB is addressing the proposals regarding materials and processes that already had been the subject of notice and comment under Notice No. 164.

IV. Discussion of Comments

A. Comment Overview

TTB received 33 comments in response to Notice No. 164, of which 3 were requests for extension of the comment period (Wine Institute (2 requests), and David Douglas). The remainder were comments submitted by or on behalf of: Six members of the public (Alice Feiring, Dr. Robert Kreisher (2 comments), Heather Nenow, Coleman Reardon, and Samantha Hunter); 13 wine industry members (vineyards and/or wineries) (Adelsheim Vineyard, Bear Creek Winery; Clover Hill Winery, Deerfield Ranch, Domaine Serene, Don Sebastiani and Sons, E&J Gallo Winery, Firestone Vineyard, Halter Ranch Vineyard, South Coast Winery Resort and Spa, Toni Stockhausen, Wine by Joe, WX Brands); 2 trade organizations (Enzyme Technical Association and Wine Institute); 4 companies that produce wine treating materials or processes (Beverage Supply Group, Erbslöh Geisenheim (2 comments), ConeTech, and Laffort USA); 1 industry consultant (Richard Gahagan); and the European Union (2 comments).

Eleven of the commenters submitted essentially the same letter containing no substantive differences (Adelsheim Vineyard, Bear Creek Winery, Deerfield Ranch Winery, Domaine Serene, Don and Sons, Firestone Winery, Halter Ranch Vineyard, Laffort, South Coast Winery Resort and Spa, Wine by Joe, and WX Brands). These comments will be referred as the ''11 form letter comments'' for ease of reference.

B. General Support for the Regulatory Amendments

The 11 form letter comments expressed support for amending the regulations to incorporate the proposed additional wine treating materials, stating that these additions would positively affect their ability to export their wine and allow them to continue to grow their business in export markets by offering wines with better stability and quality. They also provided specific support for certain of the materials, and their comments are included in the comment discussion for each of these materials below. They further noted that the materials they addressed in their comment are used in multiple countries, including all countries following the International Organization of Vine and Wine (OIV), in good commercial practice at dose rates like those suggested by TTB in Notice No. 164.

The Wine Institute also expressed general agreement that the administratively approved wine and juice treating materials and processes proposed for authorization in Notice No. 164 ''have accumulated sufficient analytical data and should be added to §§ 24.246 and 24.248 as appropriate.''

C. General Comment of Opposition

One commenter, Alice Feiring, expressed discontent with the number of authorized wine and juice treating materials for wine, stating that they ''interfere with the taste and liveliness of the wine.'' The commenter asserted that ''none of these additives—other than sulfite addition . . . —are evaluated for their health impact and allergen potential,'' and that ''tannins and enzymes are the primary materials that trigger allergic reactions.'' The commenter pointed to the proposal in Notice No. 164 to add polyvinylpyrrolidone (PVP) to the list of authorized wine and juice treating materials in § 24.246 and raised concerns regarding the safety of its use, which TTB addresses in the discussion of PVP later in this document. The commenter further suggested that TTB consider requiring the labeling of ingredients in wine.

TTB Response. As discussed in Notice No. 164, all proposed wine and juice treating materials authorized for use under § 24.246 must have documentary evidence from the FDA that the 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. Therefore, TTB disagrees with the assertion that the wine and juice treating materials currently authorized in § 24.246 and proposed in Notice No. 164 for addition to the authorized list are not evaluated for their impact on health, and TTB notes that the table in § 24.246 includes references to the relevant FDA regulations and advisory opinions for each material. Further, TTB consulted with FDA on the proposed amendments in Notice No. 164 prior to its publication, and the materials proposed in Notice No. 164 have been found to be consistent with the FD&C Act.

Concerning the labeling of ingredients in wine, TTB is separately considering rulemaking regarding ingredient labeling, as noted in Treasury's February 2022 report on ''Competition in the Markets for Beer, Wine, and Spirits,'' [3] issued in response to Executive Order 14036, ''Promoting Competition in the American Economy.''

D. Wine Treating Materials

Below is a summary of the actions TTB is taking in this final rule, including a discussion of, and response to, comments received regarding the wine treating materials that were the subject of TTB proposals in Notice No. 164.

1. Blends and Other Combinations of Approved Treating Materials

TTB proposed to include in § 24.246(b) a general, clarifying statement that approved materials may be used in a blend or otherwise in combination with other approved materials, provided that each material is used for its specified use and in accordance with any limitation specified for that use.

Comments. In its comment, Wine Institute agreed that approved wine treating materials may be blended or used in combination provided that each material is used in accordance with the individual limitations and allowable uses for that material.

The 11 commenters who submitted the form letter did not directly address the proposed language pertaining to blends; however, they did comment on the use of blends for yeast nutrients. These commenters stated in part that yeast nutrient blends mitigate the risk of sluggish or stuck fermentation.

TTB Response. TTB agrees that blends of authorized wine treating materials, including yeast nutrients, are consistent with good commercial practice, provided that the use of each material conforms to the conditions specified for that material (that is, the reason or

[3] *home.treasury.gov/system/files/136/Competition-Report.pdf.*

purpose for its use and the references and limitations that apply to its use). Accordingly, TTB is finalizing the proposal on blends in § 24.246.

2. Yeast Nutrients

In Notice No. 164, TTB proposed to add six ''yeast nutrients'' to the list of approved treating materials and expand the approved use of a seventh that already appears on the list. Specifically, TTB proposed 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. The inclusion of these yeast nutrients was in response to a petition and to industry member requests. The specific proposals, comments, and final action are described below.

i. Use of the Term ''Yeast Nutrients''

As described in Notice No. 164, TTB and its predecessor agencies have recognized the need to supply yeast with appropriate nutrients to facilitate fermentation of juice to wine and to prevent ''stuck fermentation'' (fermentation that has halted before completion due to, among other things, high sugar levels or nutrient deficiencies). In both the current and proposed regulations, TTB has referred to these nutrients as ''yeast nutrients.''

Comments. The 11 submitters of the form letter, as well as Wine Institute and Richard Gahagan, addressed the use of the term ''yeast nutrients.'' The 11 form letter submitters requested that TTB omit the word ''yeast'' or conversely include the word ''bacteria'' in the heading used in the regulations. Wine Institute stated their belief that the term ''yeast nutrients'' is ''misleading'' and expressed a concern that ''[t]he use of the word 'nutrient' suggests there is some nutritive value to humans, which is not the case.'' Instead of ''yeast nutrients'', Wine Institute suggested TTB use the term ''Fermentation Aids'', noting that ''yeast nutrients'' serve no purpose after completion of fermentation. Rather, they ''are for the sole purpose of creating and maintaining a robust environment for yeast and/or malolactic bacteria during the fermentation process.''

Mr. Gahagan also opposed the use of the term ''yeast nutrients'' and suggested that a more appropriate heading would be ''fermentation aids'' or ''fermentation adjuncts.'' Mr. Gahagan points out that ''yeast cell walls/membranes'', which are authorized for use in § 24.246 and proposed under the heading ''yeast nutrients'' in Notice No. 164, ''are not yeast nutrients.'' Mr. Gahagan cited scientific literature in support of his argument.

TTB Response. TTB agrees with the comments and is replacing the term ''yeast nutrients'' with the term ''fermentation aids'' in the regulations, where applicable. TTB is using the term ''yeast nutrients'' and ''fermentation aid'' as synonyms throughout the rest of this document, as the former reflects the terminology used in the proposal.

ii. Specific Yeast Nutrients

In Notice No. 164, TTB proposed to add biotin (vitamin B7), folic acid, inositol (myo-inositol), magnesium sulfate, niacin (vitamin B3), and pyridoxine hydrochloride (vitamin B6) to the list of authorized materials in § 24.246 for use as yeast nutrients. TTB had previously administratively approved all six materials but had not yet included them in the list of authorized materials in § 24.246. The proposed use limitations for each material were as follows:

- Biotin: 25 parts per billion (ppb).
- Folic acid: 100 ppb.
- Inositol (myo-inositol): 2 parts per million (ppm).
- Magnesium sulfate: 15 ppm.
- Niacin (vitamin B3): 1 ppm.
- Pyridoxine hydrochloride (vitamin B6): 150 ppb.

Additionally, TTB proposed to expand the authorized use of calcium pantothenate (vitamin B5) from use solely as a yeast nutrient in apple wine to use as a yeast nutrient in all juice and wine. The use limitation of 0.1 pound of calcium pantothenate per 25,000 gallons (0.48 ppm) would remain unchanged.

Comments. The Wine Institute and the 11 form letter comments supported including all six administratively approved materials as authorized materials in § 24.246, as well as approving calcium pantothenate for use in all juices and wines. While the 11 form letter comments supported the use of the materials at the usage rates proposed in Notice No. 164, Wine Institute requested that the usage rate for the materials be ''good manufacturing practice.''

Additionally, Richard Gahagan supported the addition of magnesium sulfate to the list of authorized wine and juice treating materials in § 24.246 but concludes that the ''qualitative limits'' proposed in Notice No. 164 ''may not be adequate in all cases.'' Mr. Gahagan referenced scientific articles for his assertion that the proposed use level for magnesium sulfate ''is not adequate'' and recommended a use rate not to exceed 200 ppm (200 mg/L).

Mr. Gahagan also expressed his concern that the use rates for the proposed yeast nutrients in Notice No. 164 consist ''essentially of the Gusmer commercial product'', which in his opinion, ''would limit the United States wine industry to the use of only the Gusmer product, or products that contain no more of any one of the materials contained in Gusmer's product.'' He argued that ''commercial fermentation aid products would be excluded, severely limiting the choices of available fermentation aides [sic] to domestic winemakers.'' Mr. Gahagan referred to the proposed yeast nutrients with use rates (''quantitative limitations'') and the fact that the use rates were proposed by the petitioner. Mr. Gahagan asserted that the FDA advisory opinion of August 29, 2016, referenced in Notice No. 164, states that the proposed yeast nutrients can be used in accordance with ''good manufacturing practice.'' He further pointed to *www.ttb.gov* where the list of administratively approved yeast nutrients are listed and noted that as a use rate for the listed yeast nutrients, the website reads ''the amount used must not exceed that of good commercial practice'' and includes a reference to the appropriate FDA regulation followed by the acronym GRAS, for ''Generally Recognized As Safe.'' He further stated that ''[t]he limitations on all the fermentation aids should be good commercial practice or GRAS, rather than quantitative limits.''

TTB Response. TTB is finalizing the proposals for all seven materials, including the proposed use rates. TTB believes that additional public comment is needed to authorize a usage rate other than what was proposed in Notice No. 164 for any of the yeast nutrients, since the proposed rule did not include the prospect of different usage rates. However, TTB is considering the request to consider the yeast nutrient usage rate at ''good manufacturing practice'' for separate rulemaking in which TTB intends to address Wine Institute's petition, described above, to authorize usage rates of ''good manufacturing practice'' more broadly.

With respect to Mr. Gahagan's comment about the proposed use rate limits, under the regulatory provisions of §§ 24.249 and 24.250, TTB reviews and approves or denies proposed wine treating materials based on the information provided by the industry member who submitted the request. TTB does not have reason or resources to test experimentally treated wine containing a new wine treating material

at a use rate greater than that which is being requested. In the case of the yeast nutrients that were administratively approved subsequent to the Gusmer petition, TTB proposed in Notice No. 164 to limit the amount of usage to the amounts provided in the Gusmer petition because TTB believes it is important to place limitations on the use of vitamins and minerals as nutrients for yeast growth. This belief is consistent with FDA's fortification policy in 21 CFR 104.20, as discussed in Notice No. 164. The FDA advisory opinion cited in the proposed regulations and referred to by Mr. Gahagan does not state that vitamins and minerals used in the production of wine are limited only by good manufacturing practice. Rather, in their advisory opinion, FDA referred to its regulations in which certain vitamins and minerals may be used in accordance with good manufacturing practice [4] if they are used in accordance with the intended purpose as stated by the regulations.

As noted in Notice No. 164, many of the yeast nutrients are vitamins and minerals that are authorized for use in food, and 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. Therefore, a cross-reference to the FDA regulations is not appropriate for yeast nutrients. Notice No. 164 further states that FDA has stated to TTB that the proposed vitamins and minerals could be used for the purpose of providing nutrients to the yeast, where the levels of the vitamins and minerals remaining in the wine would be of a de minimis level, and not to fortify the wine. In the interim, TTB is placing limitations on these substances to permit their use as nutrients for yeast growth but not as a source of nutrients in the finished wine.

TTB notes that among the 11 submitters of the form letter is Laffort U.S.A., a supplier of wine treating materials. Laffort U.S.A. wrote that they support the addition of yeast nutrients proposed by TTB ''at the levels recommended by TTB.'' This support indicates that Laffort U.S.A. is not concerned that the proposed use rates for yeast nutrients would exclude any of their products from the market. Another supplier of wine treating materials (including yeast nutrients), Beverage Supply Group, commented on Notice No. 164, and while they did not specifically express support for the proposed use rates of the proposed yeast nutrients, they did not expressly voice concern that the proposed use rates are insufficient and possibly exclude their products from the marketplace.

3. Specific Wine Treating Materials

i. Acacia (Gum Arabic)

In Notice No. 164, TTB proposed to amend its regulations in § 24.246 to identify, for the purpose of clarifying and stabilizing wine, a maximum use rate of 8 pounds of acacia per 1,000 gallons (0.96 grams per liter (g/L)) of wine. Acacia (gum arabic) is listed in § 24.246 as authorized for such purposes, but currently subject to the limitation that its use not exceed 2 pounds per 1,000 gallons (0.24 g/L) of wine. TTB explained in Notice No. 164 that TTB had administratively approved several requests from industry members for use rates up to 16 pounds per 1,000 gallons of wine, but was proposing a use rate of 8 pounds per 1,000 gallons of wine as it believed that rate was consistent with the maximum rate authorized in FDA regulations at 21 CFR 184.1330. Based on that, TTB noted that any administrative approvals authorizing use rates greater than 8 pounds per 1,000 gallons of wine would be revoked.

Comments. The 11 submitters of the form letter indicated that acacia is necessary for the stabilization of coloring matter and potassium bitartrates as well as to clarify wine. They also stated that the dose rate recommended by TTB in the proposed rule is appropriate for good commercial practice. In its comment, the Wine Institute welcomed the proposal to increase the allowable level for acacia when used for its intended purpose of clarifying and stabilizing wine.

TTB Response. The regulations finalized through this rulemaking authorize the use of acacia for clarifying and stabilizing wine at a use rate of 16 pounds per 1,000 gallons of wine (1.9 g/L), or 0.19 percent, which is within the 1 percent use rate limitation set forth in the FDA regulations for these purposes. In Notice No. 164, TTB had erroneously calculated that 8 pounds per 1,000 gallons of wine was the maximum allowable within the FDA limitations. As a result, instead of 8 pounds per 1,000 gallons of wine, TTB is amending its regulations to correspond to the administrative approvals of 16 pounds per 1,000 gallons of wine, as discussed in Notice No. 164, as TTB believes this limit is consistent with good commercial practice for clarifying and stabilizing wine.

With regard to the comment that refers to acacia's use for stabilization of ''coloring matter,'' TTB notes that the stabilization of anthocyanins for color is consistent with how TTB interprets ''stabilization'' under § 24.246.

ii. Bakers Yeast Mannoprotein

TTB proposed 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, for the purpose of stabilizing wine from the precipitation of potassium bitartrate crystals. TTB had already administratively approved the use of bakers yeast mannoprotein for this purpose and with that limit.

Comments. The 11 commenters who submitted the form letter stated their support of TTB's proposal to add bakers yeast mannoprotein to the list of authorized treating materials contained in § 24.246 to stabilize wine from the precipitation of potassium bitartrate crystals. The commenters noted that bakers yeast mannoprotein is an efficient alternative for the stabilization of red wines and that it is appropriate for good commercial practice at the dose rates proposed by TTB.

The Wine Institute suggested GMP as the appropriate limit for bakers yeast mannoprotein, without a numerical limit, but stated that, if numerical limits are to be required, the proposed limit is ''too low.'' The Wine Institute stated that ''a quick review of recommended usage rates . . . by Suppliers of this material to the Industry suggest usage rates up to 1500 mg/L as a more appropriate limit.''

The European Union (EU), in its comment, informed TTB that the EU does not have a fixed limit for bakers yeast mannoproteins, ''which means that their use is based on the best manufacturing practice criteria.'' They further state that the proposed limit for bakers yeast mannoproteins ''may be insufficient for tartaric stabilization thus creating a possible barrier to trade.''

TTB Response. TTB received no additional comments from industry members regarding the usage rates, and has not received requests from industry members for approval to use bakers yeast mannoprotein at a rate higher than 400 mg/L. TTB notes that the proposed use for bakers yeast mannoprotein in TTB Notice No. 164 (not to exceed 400 mg/L) is consistent with the use rate considered by FDA in GRAS Notice No. GRN 000284. TTB does not approve the use of a material at a rate greater than that which FDA has determined is consistent with the food additive requirements under the FD&C Act.

[4] FDA defines ''good manufacturing practice'' in the context of food additives and GRAS substances in 21 CFR 172.5, 174.5, 182.1, and 184.1.

Considering this and the rulemaking record before it, TTB does not believe there is an adequate basis for establishing a limit different from that proposed in Notice No. 164, but will consider the comments of the European Union and the Wine Institute as suggestions for further broader rulemaking relating to GMP. This rulemaking finalizes the proposed use of bakers yeast mannoprotein to stabilize wine from the precipitation of potassium bitartrate crystals at an amount not to exceed 400 mg/L.

iii. Beta-Glucanase Having an Enzyme Activity Derived From *Trichoderma harzianum* and Beta-Glucanase Having an Enzyme Activity Derived From *Trichoderma longibrachiatum*

TTB proposed in Notice No. 164 to add beta-glucanase derived from *Trichoderma harzianum,* at a use rate not to exceed 30 parts per million (ppm) of wine, as an approved treating material in § 24.246 for the purpose of clarifying and filtering wine. *Trichoderma harzianum* had been administratively approved prior to the proposed rulemaking. Beta-glucanase derived from *Trichoderma longibrachiatum* is currently listed in § 24.246 as approved for use for clarifying and filtering wine at a rate not to exceed 3 grams per hectoliter of wine (30 ppm), and in Notice No. 164 TTB also solicited comments on whether Beta-glucanase derived from *Trichoderma longibrachiatum* is still relevant and should be retained as an authorized treatment.

Comments. The form letter submitted by 11 commenters specifically addressed beta-glucanase, as did comments from the Wine Institute, the Enzyme Technical Association, and an individual commenter. The 11 submitters of the form letter stated that the use rate of beta-glucanase proposed in Notice No. 164 is appropriate for good commercial practice to filter wine, whether the enzymatic activity is derived from *Trichoderma harzianum* or *Trichoderma longibrachiatum.* They also proposed that beta-glucanase should be authorized for use in juice prior to fermentation. In support of this, the commenters wrote that mold growth, specifically from *Botrytis cinera,* on grapes increase the content of glucans in the resultant wine. The commenters claimed that the glucans ''can render the wine difficult or impossible to filter using available filter media.'' Adding beta-glucanase to the juice or wine ''will allow the reduction of glucan levels and improved filterability.'' The commenters noted that unfiltered wines ''can potentially have negative flavor profiles due to instabilities.''

Wine Institute recommended using GMP as a use rate for beta-glucanase. In the absence of GMP, Wine Institute recommended a use rate of 80 mg/L based on a review it performed of usage rates recommended by suppliers of this material to the industry. Wine Institute also noted TTB's comment in Notice No. 164 about the agency inadvertently stating that the amount of beta-glucanase derived from *Trichoderma harzianum* used must not exceed 300 ppm, and suggested that industry members are currently using beta-glucanase at higher use levels than 30 ppm because suppliers recommend a level higher than 30 ppm and because TTB administratively approved usage up to 300 ppm. As a result, Wine Institute argued that reducing the authorized use rate of beta-glucanase from an amount not to exceed 300 ppm to an amount not to exceed 30 ppm may cause difficulty to winemakers and impact the quality of resulting wines. With regard to beta-glucanase derived from *Trichoderma longibrachiatum,* Wine Institute supported retaining its authorized use.

The Enzyme Technical Association supported the addition of *Trichoderma harzianum* as a source of beta-glucanase. However, the association recommended TTB align the use rate of beta-glucanase derived from *Trichoderma harzianum* and that derived from *Trichoderma longibrachiatum,* and that the usage rate limitation for both should be ''good manufacturing practice.'' The association indicated that the proposed use rate limit of 30 ppm for beta-glucanase derived from *Trichoderma harzianum* is insufficient. It expressed its position that the FDA GRAS Notice No. GRN 000149, which TTB cites for its support of a 30 ppm limitation on beta-glucanase derived from *Trichoderma harzianum,* actually supports a higher use rate. Enzyme Technical Association argued that the range provided in GRAS Notice No. GRN 000149 ''was not set as a maximum use'' and stated that ''what was not discussed in the FDA No Questions Letter is the wide safety margin of the beta-glucanase enzyme preparation that was included in the notifier's original submission.'' It further stated that ''[A] wide safety margin suggests that the enzyme preparation can be used well outside the range of 30 ppm with no toxic effects.'' Enzyme Technical Association ''agrees that beta-glucanase enzymatic activity derived from *Trichoderma longibrachiatum* (also known as *T. reesei*) is still relevant for and used in wine treatments.''

In its second comment submitted in response to Notice No. 164, Erbslöh Geisenheim suggested that TTB add the microorganism species *Penicillium funiculosum* (synonym: *Talaromyces versatilis*) as a third source besides *Trichoderma longibrachiatum* and *Trichoderma harzianum* for the entry ''Enzymatic activity, intended for clarifying and filtering wine.'' It noted that FDA already considers *Penicillium funiculosum* as GRAS for ''use in various food applications in the US.'' It also stated that both the International Oenological Codex and the European Commission recognize *Penicillium funiculosum* as a wine treating material.

TTB Response. After considering the comments, TTB is finalizing regulations that remove any specific use rate limitation other than that set forth in the FDA regulations at 21 CFR 184.1250. In effect, this implements the limitation that has applied during the time TTB had inadvertently authorized 300 ppm rather than 30 ppm, as described above, as use of the material above the 30 ppm rate would still have been subject to any limit set forth in FDA regulation. Similarly, TTB is also finalizing its proposal in Notice No. 164, to add to the regulations authorization for beta-glucanase derived from *Trichoderma harzianum* as an approved treating material in § 24.246 for the purpose of clarifying and filtering wine, with the only use rate limitation specified by a reference to FDA GRAS Notice No. GRN 000149. TTB has confirmed with FDA that a limitation of ''good manufacturing practice'' would be consistent with both 21 CFR 184.1250 and GRAS Notice No. GRN 000149, and that additional advisory opinions specifying that would be unnecessary. With regard to the use of the materials in juice, TTB is authorizing the use of both beta-glucanase derived from *Trichoderma harzianum* and beta-glucanase derived from *Trichoderma longibrachiatum* in juice, which is consistent with GRAS Notice No. GRN 000149 and 21 CFR 184.1250,[5] respectively.

With respect to the use of *Penicillium funiculosum,* TTB notes that it has not received any requests from winemakers to use this microorganism as a source of beta-glucanase for clarifying or filtering wine. Therefore, TTB has not had the opportunity to analyze wine treated with *Penicillium funiculosum* and cannot add it to its list of approved wine treating materials at this time. However, TTB would consider requests from

[5] 21 CFR 184.1250 describes a type of a cellulase that is also known as endo-1,4-beta-glucanase.

individual industry members under §§ 24.249 and 24.250 for use of *Penicillium funiculosum* as a wine treating material.

iv. Chitosan

In Notice No. 164, TTB proposed to authorize chitosan for the removal of spoilage organisms from wine at a usage rate not to exceed 10 grams per 100 liters (or 10g/hL) of wine.

Comments. The 11 submitters of the form letter agreed with TTB's proposal that chitosan should be authorized for use in the treatment of wine to remove spoilage organisms such as *Brettanomyces* from wine. They stated that the ''unchecked growth of *Brettanomysces* [sic] organisms in wine can lead to highly negative flavor profiles'' and that chitosan is ''an efficient and effective treatment to destroy these spoilage organisms.'' Further, submitters of the form letter confirmed that chitosan is consistent with good commercial practice at the levels proposed by TTB.

In its comment, Wine Institute welcomed the proposed addition of chitosan to the list of allowable treating materials but suggested that GMP is a more appropriate usage limit.

In his comment, Richard Gahagan supported the inclusion of chitosan but stated that the limitation should be ''GRAS, or if TTB decides on a quantitative limit, 100 g/hL would be consistent with the OIV limitation.'' Mr. Gahagan's comment regarding the authorized use of chitosan with OIV limitations was consistent with that of the EU, which stated that the TTB proposed use rate of 10 g/hL for chitosan is ''10 times lower than the EU limit,'' and indicated that the use rate proposed by TTB for chitosan ''could create a trade barrier.'' (TTB notes that OIV's use rate for chitosan was raised in 2015, to a rate not to exceed 500 g/hL of wine.)

TTB Response. Since TTB's publication of Notice No. 164, TTB has received numerous requests to experiment with chitosan at levels greater than 10 g/hL of wine. The most recent requests for experimentation sought to use chitosan at a rate of no more than 500 g/hL. TTB approved the experimentation of those requests because in GRAS Notice No. GRN 000397, FDA had ''no questions'' with regard to the stated intended use rate of 10 to 500 g/hL of wine. After the evaluation of numerous samples of wine experimentally treated with chitosan at rates exceeding 10 g/hL and including 500 g/hL, TTB administratively approved an increased use rate of chitosan not to exceed 500 g/hL of wine in 2021.

After considering comments from Wine Institute, the EU, and Mr. Gahagan supporting an increased level of chitosan, the use range specified in GRAS Notice No. 000397, and TTB's experience with recent administrative approvals, TTB is amending § 24.246 to include chitosan from *Aspergillus niger,* with a use rate not to exceed 500 g/hL of wine, for use in removing spoilage organisms, such as *Brettanomyces,* from wine.

v. L(+) Tartaric Acid

Tartaric acid is currently listed in § 24.246 as a material authorized for the treatment of wine and juice for the purpose of correcting natural acid deficiencies in grape juice or wine and to reduce the pH of grape juice or wine. In Notice No. 164, TTB proposed 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 (which allows for L(+) tartaric acid obtained as a byproduct of wine production) or the method specified for L(+) tartaric acid in GRAS Notice No. GRN 000187 (which allows L(+) tartaric acid manufactured using an enzyme from immobilized *Rhodococcus ruber* cells). TTB also proposed to add the citation for the FDA GRAS notice in the ''Specific limitation'' column.

Comments. In its comment, the EU stated that it and the OIV both authorize the use of L(+) tartaric acid with limits of 2.5g/L and 4g/L, respectively. The EU argued that ''[t]hese limits are justified by the assessment made by JECFA fixing the acceptable daily intake (ADI) is between 0 and 30mg/kg of body weight.'' Accordingly, the EU does not believe that GMP is an appropriate use rate for L(+) tartaric acid. The EU further stated that an excess of L(+) tartaric may ''modify the natural and essential characteristics of the wine'', resulting in a possible breach of the Article 80(3)(d) of Regulation No. 1380/2013, which states that oenological practices shall ''allow the preservation of the natural and essential characteristics of the wine and not cause a substantial change in the composition of the product.''

In her comment, Toni Stockhausen argued that ''synthetically derived L(+) Tartaric Acid, or L(+) Tartaric Acid (alternate method) per FDA GRAS notice GRN 000187 . . . should not be considered Good Manufacturing Practice for use in winemaking in the USA.'' In support of this, Ms. Stockhausen stated: (1) That FDA GRAS Notice No. GRN 000187 for L(+) tartaric acid ''does not comment on the source of the maleic acid or on the safety of potentially unconverted maleic acid or other contaminants unique to the alternate production method;'' (2) ''Despite GRN 000187, issued in 2006, in 10 years the FDA has not updated the list of direct food substances affirmed as generally regarded as safe;'' and, (3) ''For the purposes of exportation, jurisdictions including the European Union have confirmed or amended their food safety regulations to specify the source of Tartaric Acid as wine or grape derived, including the most recent European Pharmacopeia (9th Edition, effective January 1, 2017).''

In its comment, Wine Institute stated that it understands that ''synthetic (L(+)) tartaric acid, which was administratively approved by TTB,'' is not currently being used for the production of wine within the United States.

TTB Response. TTB is finalizing in this rulemaking document the proposal in Notice No. 164 to include in the TTB regulations a reference to tartaric acid manufactured using an enzyme from immobilized *Rhodococcus ruber* cells (as described in FDA GRAS Notice No. GRN 000187) to correct natural acid deficiencies in grape juice/wine and to reduce the pH of grape juice/wine. TTB believes that this form of tartaric acid is the form commenters refer to as ''synthetic.'' The regulatory text uses the spelling ''L-(+)-tartaric acid,'' as TTB understands that this is the scientifically preferred spelling for the material, rather than the ''L(+) tartaric acid'' spelling used in the proposed rule document.

In response to the comments submitted by the EU and Wine Institute, TTB notes that with regard to the use rates for tartaric acid, the current regulations refer to TTB regulations at 27 CFR 24.182 and 24.192 that provide additional detail about its use, and to FDA regulations in 21 CFR 184.1099. The uses prescribed in the TTB regulations do not authorize a use rate that would ''modify the natural and essential characteristics of the wine.'' TTB did not propose to change the limitations on the use of tartaric acid, and is not changing those limits at this time. However, TTB will consider including the more limited use rates in any subsequent rulemaking for additional comment.

In her comment, Ms. Stockhausen claimed that the EU only allows tartaric acid derived from wine or grapes. TTB notes that in its comments on the proposal in Notice No. 186, the EU only addressed its belief that GMP was not an appropriate use rate for L(+) tartaric

acid. The EU did not distinguish between L(+) tartaric acid derived from wine or grapes and L(+) tartaric acid manufactured using *Rhodococcus ruber* cells. Therefore, TTB does not believe that the EU objects to TTB's proposal to allow the alternate method of producing L(+) tartaric acid.

In response to Ms. Stockhausen's comments regarding GRAS Notice No. GRN 000187, the FDA has stated to TTB that GRAS Notice No. GRN 000187 does not specifically state the source of maleic acid, and that maleic acid may be an impurity in the starting material (*i.e.,* maleic anhydride), or it can be a byproduct of the reaction of maleic anhydride and hydrogen peroxide that is used to produce tartaric acid. GRAS Notice No. GRN 000187 does specify that the content of maleic acid in the final tartaric acid must be less than or equal to 0.05 percent. FDA also noted that the GRAS Notice process is an alternative to GRAS affirmation petitions, and that the FDA regulations do not provide a comprehensive list of GRAS substances.

vi. Polyvinylpyrrolidone (PVP)/ Polyvinylimidazole (PVI) Polymer

TTB proposed to add polyvinylpyrrolidone (PVP)/ polyvinylimidazole (PVI) polymer (terpolymer of 1-vinylimidazole, 1-vinylpyrrolidone, and 1,2-divinylimidazolidinone; CAS 87865–40–5 [6]) to remove heavy metal ions and sulfides from wine to the list of authorized wine and juice treating materials in § 24.246.

Comments. In their comment, the 11 submitters of the form letter expressed support for the proposal in Notice No. 164 to add polyvinylpyrrolidone (PVP)/ polyvinylimadazole (PVI) polymer to the list of authorized wine and juice treating materials in § 24.246 to remove heavy metal ions and sulfides from wine at a level not to exceed 80 grams per 100 liters of wine. They stated that PVP/PVI polymer would ''provide the US wineries with an effective tool to eliminate these metals'', and further stated that the ''current US regulations provide unfair trade advantage for non-US wine producers in both domestic and international markets.''

The 11 commenters of the form letter also recommended that the approval of PVP/PVI be extended to use in juice and must. They argued that this will give wineries the ability to ''remove excessive copper (from vineyard treatments) before starting fermentation or the early stages.'' They also stated that adoption of this recommendation ''would align the US regulation with other countries.''

One commenter, Alice Feiring, raised concerns regarding the safety of PVP. She described PVP as a material that should not be authorized for use in the production of wine, stating that it ''is classified as 'expected to be toxic or harmful,' by the Environment Canada Domestic Substance List.''

TTB Response. TTB is finalizing the use of PVP/PVI polymer as proposed in TTB Notice No. 164, for use at a level not to exceed 80 grams per 100 liters of wine to remove heavy metal ions and sulfides from wine. TTB did not propose the use of PVP/PVI in juice and has not had the opportunity to analyze juice treated with PVP/PVI. Accordingly, TTB is not including such authorization in its regulations at this time, but will consider for future action.

With regards to the comment regarding the Canadian classification of PVP, TTB notes that under the Canada Food and Drug Regulations (see C.R.C., c 807 B.02.100(b)(xii)(D)), PVP may be used in the production of wine ''in an amount that does not exceed 2 parts per million in the finished product.''

vii. Potato Protein Isolates

In Notice No. 164, TTB proposed 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 treating materials contained in § 24.246.

Comments. In their form letter, 11 commenters supported the addition of potato protein isolate to the list of authorized treating materials in § 24.246 and stated that ''potato protein isolate is an effective fining agent for both juice and wine to remove phenolic components effecting [sic] astringency and bitterness, as well as to aid in settling juice and wine . . .'' at the use rate of 500 ppm (50 g/hL), which is the proposed use rate in wine, not juice. These commenters suggested that TTB authorize the use of potato protein isolate in the use of juice because ''it is equally effective in application.'' They also stated that in its first additional correspondence to GRAS Notice No. GRN 000447, the FDA considered the use of potato proteins in wine-must, which the commenters noted is ''considered as 'grape juice' prior to fermentation.'' According to the commenters, ''Many winemakers choose to use fining products on juice in preference to wine as the process is more efficient and ha[s] less impact on resulting wine flavor.''

In its comment, the Wine Institute indicated its support of the addition of potato protein isolates to the list of authorized treating materials contained in § 24.246. It also recommended the use rate of good manufacturing practice for the use of potato protein isolates as a ''clarification'' material.

Erbslöh Geisenheim indicated its support of the addition of potato protein isolates to the list of authorized treating materials contained in § 24.246, noting that proteins from plant origins, including potatoes, have been authorized by the International Oenological Codex as a wine and juice treating material. It further stated, ''Vegetable based fining agents have become increasingly important for the production of beverages that are suitable for a vegetarian or vegan diet.''

TTB Response. TTB is finalizing the proposal to authorize fractionated potato protein isolate for use at a rate of 500 ppm or 50 grams per 100 liters (50 g/hL) of wine, as a fining agent. TTB believes the use of fractionated potato protein isolate in juice should be subject to public comment, and plans to include such use among other proposals in a separate rulemaking.

viii. Sodium Carboxymethyl Cellulose

TTB proposed to add sodium carboxymethyl cellulose (CMC) to the list of authorized wine and juice treating materials in § 24.246 at a level not to exceed 0.8 percent of the wine, to stabilize wine from tartrate precipitation.

Comments. In their form letter, 11 commenters supported TTB's proposal in Notice No. 164 to add CMC to the list of authorized wine and juice treating materials contained in § 24.246. These commenters stated that the 0.8 percent use rate proposed by TTB is appropriate for good commercial practice. They also stated that CMC ''is one of many tools the wine industry can use to stabilize wines, depending on unique wine chemistry and consumer preferences.''

Wine Institute supported the addition of CMC to the list of authorized wine and juice treating materials; however, they recommended a use rate of GMP. Wine Institute recommended that if TTB does not adopt GMP, it should decrease the authorized amount of CMC from proposed 0.8% (8,000 mg/L) to 0.1% (1,000 mg/L), which according to Wine Institute, is the standard in international markets. It is Wine Institute's belief that the use of CMC at the maximum proposed level of 8,000 mg/L ''could create quality issues in wines.''

TTB response. As noted in Notice No. 164, FDA regulations at 21 CFR 182.1745 state that CMC is GRAS when used in accordance with good manufacturing practice. In light of this

[6] CAS = Chemical Abstracts Service Registration Number.

and the concern expressed in the Wine Institute's comment, this final rule amends the proposal to remove a specific use rate other than that contained in the reference to the FDA's regulations in 21 CFR 182.1745.

E. Proposed Processes for the Treatment of Wine, Juice, and Distilling Material

TTB proposed 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. A discussion of the specific proposals, comments received, and TTB responses follows.

1. Cross Flow Filtration

TTB proposed to expand the authorized use of nanofiltration and ultrafiltration in § 24.248 (Processes authorized for the treatment of wine, juice, and distilling material) 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 color from blanc de noir wine; and to separate red wine into high color and low color wine fractions for blending purposes. Because both nanofiltration and ultrafiltration are capable of reducing alcohol content in wine, the proposed liberalization will provide industry members with more tools to reduce the alcohol content of wine.

Comments. In its comment, Wine Institute agreed with the proposal in Notice No. 164 to group nanofiltration, ultrafiltration, and reverse osmosis under the general category of ''cross flow filtration'' and welcomed the expansion of authorized uses for this category to include reduction of alcohol content.

In his comment, Dr. Robert Kreisher disagreed with TTB's proposal to expand the authorized uses of nanofiltration and ultrafiltration to include dealcoholization. Dr. Kreisher indicated that TTB considered nanofiltration for purposes of alcohol reduction in 2007 and found that such a process is not consistent with good commercial practice because ''nanofiltration permeate contained too great a quantity of volatile esters and fixed acids.'' Dr. Kreisher further stated that ultrafiltration has the same problems as nanofiltration, at a greater magnitude. If authorized, Dr. Kreisher advised TTB that it should be made clear that nanofiltration, ultrafiltration, and reverse osmosis may only be used in combination with distillation.

TTB Response. This rulemaking finalizes TTB's proposal in Notice No. 164 to expand the use of nanofiltration and ultrafiltration to include dealcoholization (reduction of alcohol).

In 2007, TTB reviewed a petition for the use of nanofiltration and ultrafiltration for purposes of removing off-flavors in wine. It did not review the processes for the purpose of alcohol reduction. However, TTB reviewed nanofiltration and ultrafiltration for purposes of alcohol reduction in 2013 and found that on a preliminary basis nanofiltration and ultrafiltration were acceptable for alcohol reduction pending future rulemaking.

In Notice No. 164, TTB proposed amending § 24.248 to state that nanofiltration, ultrafiltration, and reverse osmosis must be conducted on distilled spirits plant premises when used to remove ethyl alcohol (dealcoholization). The proposed amendment also provided a specific exemption to this rule for reverse osmosis and nanofiltration if ethyl alcohol is only temporarily created within a closed system. In this rulemaking document, TTB is adopting these amendments as final.

2. Reverse Osmosis in Combination With Osmotic Transport

TTB proposed to amend the table of authorized processes in § 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.

Comment. Wine Institute expressed its support of the proposal and also requested that TTB expand the authorized use of osmotic transport to include removal of off flavors, indicating that this would maintain consistency between reverse osmosis and osmotic transport.

TTB Response. TTB is finalizing the proposal as set forth in Notice No. 164 to amend § 24.248 to allow reverse osmosis and osmotic transport to be used in combination with the other. TTB is not expanding the authorized use of osmotic transport to remove off flavors at this time, and intends to include that proposal in separate rulemaking as TTB believes that additional public comment is needed. TTB would consider individual industry member requests under §§ 24.249 and 24.250 for use of osmotic transport to remove off flavors from wine.

3. Ultrafiltration

In Notice No. 164, TTB proposed amending § 24.248 to allow the use of 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. TTB had previously administratively approved the use of ultrafiltration to separate red grape juice into low and high color fractions, and the proposed amendment would amend the table at § 24.248 accordingly. However, TTB had not administratively approved the use of ultrafiltration to separate high and low colored fractions of discolored white grape juice, so, in Notice No. 164, TTB did invite comments on whether this practice constitutes good commercial practice.

Comments. In its comment, Wine Institute welcomed TTB's proposal to authorize the use of ultrafiltration to separate red grape juice into low and high color fractions. Wine Institute also made two recommendations for the ''Reference or limitation'' column for ultrafiltration in § 24.248. The first recommendation was to change the phrase ''greater than 500 and less than 25,000 molecular weight'' to ''not less than 500 and not greater than 25,000'' molecular weight. This change, which Wine Institute implied would be an ''edit'', would have the effect of including molecular weights of ''500'' and ''25,000'' as opposed to excluding them, which is what the current regulatory language does. Wine Institute's second recommendation was to allow transmembrane pressure up to 500 psi rather than limit the transmembrane pressure to less than 200 psi. Wine Institute stated that ''limiting the transmembrane pressure to 200 psi incorporates obsolete technology into the regulation'' and allowing transmembrane pressure up to 500 psi will ''allow use of recent improvements in technology that allow more effective use of Ultrafiltration . . . without altering vinous character.''

TTB Response. TTB is finalizing in this rulemaking its proposal to expand the use of ultrafiltration to separate red grape juice into low and high color fractions. TTB does not consider the language change suggested by Wine Institute to be an editorial change, because the change would effectively allow the inclusion of molecular

weights of 500 and 25,000, which are currently not permitted and were not proposed to be allowed in Notice No. 164. TTB also did not propose in Notice No. 164 an increase to the transmembrane pressure from less than 200 psi to 500 psi. TTB believes further notice and comment on these proposed substantive changes is needed. TTB would consider requests from industry members under §§ 24.249 and 24.250 to use membranes that are selected for weights outside what is currently authorized and to increase the authorized limit on transmembrane pressure for ultrafiltration.

4. Use of Wood To Treat Natural Wine

TTB proposed a new 27 CFR 24.185 to maintain in one location all regulatory provisions pertaining to the treatment of wine with wood. Section 24.185(a) clarifies TTB's current policy 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, has not been burned or blackened).

Proposed § 24.185(b) states TTB's position on the use of wood essences and extracts in the production of wine. In the proposal, wood preparations made with an alcohol solution stronger than 24 percent alcohol by volume would be considered ''essences'' and must be used in accordance with § 24.85. Wood essences and extracts must be consistent with the food additive requirements of the FD&C Act for that purpose and could only be used in ''other wines'' in accordance with § 24.218.

TTB also proposed 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. Additionally, the proposal would remove the reference to oak chips from § 24.246 and include it in the new § 24.185.

Comment. In response to the proposals related to the use of wood to treat natural wine, Wine Institute expressed concern with the language in proposed § 24.185(a) ''that would not allow the use of charred barrels in winemaking.'' Wine Institute pointed to the standard of identity in TTB regulations for ''Bourbon whisky'', which requires use of charred new oak containers (see 27 CFR 5.22(b)(1)(i)) and to the longstanding use of bourbon barrels by both winemakers and brewers and requested ''equal regulatory treatment with respect to barrel requirements across all alcohol types and sectors.''

Wine Institute also noted that TTB did not propose language indicating how it will determine whether wood has been charred. Wine Institute noted that the proposed regulation would allow ''toasting'', which does not include ''undergoing combustion.'' Wine Institute refuted this by arguing that ''during the toasting process, minor blisters may occur on the wood, which can be significantly darker in color than the rest of the wood and thus suggests—inaccurately—that combustion has occurred.'' For this reason Wine Institute believed that a color test would be ''insufficient to determine if combustion, and thus charring, has occurred'' and asked TTB to clarify how it would ''identify improperly 'charred' wood containers.''

TTB response. TTB notes that, in part, the proposed change in Notice No. 164 regarding the treatment of wine with wood stems from current § 24.246, which authorizes the use of uncharred and untreated oak chips or particles to smooth wine. TTB proposed to liberalize the current restriction on the treatment of wine with wood by authorizing the use of any wood that is consistent with the food additive requirements under the FD&C Act (not just oak) and to allow wood that has been toasted to be used for the purpose of smoothing wine. It was not TTB's intent to indicate that used distilled spirits barrels that were charred prior to use for storage of distilled spirits could not be used to store wine. TTB has considered Wine Institute's comment and has determined that the proposed language in § 24.185 may cause confusion. TTB has also determined that the restriction on charred wood as a treatment for wine is no longer necessary because one concern with charred wood was that it may, depending on the amount of charring, remove color from wine. However, TTB regulations have for many decades authorized the use of activated carbon to remove color from wine. Accordingly, TTB is finalizing new § 24.185 as proposed, with the exception that charred wood that is consistent with the requirements under the FD&C Act may be used to treat natural wine. Also, if charred wood is used to treat wine, it cannot remove color from the wine. TTB is retaining the restriction that the wood must not be otherwise treated.

F. Wine Spirits

TTB proposed to amend § 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. The proposals included amendments to:

- Incorporate the terms of section 5373(a) of the IRC related to standards for the production of wine spirits (that is, spirits distilled from fresh or dried fruit, or the wine or wine residue therefrom), to clarify that natural wine or special natural wine to which sugar has been added after fermentation may not be refermented to develop alcohol from the added sugar and then used to produce wine spirits;
- Specify that wine spirits derived from special natural wine (that is, a wine produced from a base of natural wine and to which natural flavorings are added) may be used only in the production of a special natural wine if those spirits retain any flavor characteristics of the special natural wine; and
- Specify that spirits derived from authorized alcohol reduction treatments may be used as wine spirits, if such spirits are distilled at a rate of 100 degrees proof or more (rather than the general IRC standard of 140 degrees proof or more), and if the spirits conform to the other terms of section 5373(a) of the IRC.

TTB also proposed the following non-substantive technical amendments:

- Moving the sentence allowing the use of wooden storage tanks used for the addition of spirits for the baking of wine to a new § 24.185 that is related solely to the use of wood to treat natural wine; and
- Reorganizing the entire § 24.225 to improve readability and clarity.

Comment. Wine Institute agreed with the proposals set out in Notice No. 164 for § 24.225 and welcomed the ''use of clarifying and simplified language to amend the regulation.'' Wine Institute believed that TTB's proposal of allowing the byproducts of alcohol reduction to be used as wine spirits if they are 100 degrees proof or more ''will provide a useful opportunity for the by-products of the alcohol reduction process.'' Wine Institute also stated that it ''welcomes the clarifying language concerning wine spirits produced from special natural wine.''

TTB Response. TTB is finalizing all the amendments to § 24.225 as proposed in Notice No. 164. However, TTB is lowering the degrees of proof for which spirits byproducts of alcohol reduction processing deemed as wine spirits may be distilled from the proposed ''100 degrees of proof or more'' to ''not less than 90 degrees proof.'' As discussed in

the preamble of Notice No. 164, 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 exceptions for other wine spirits ''if regulations so provide.'' The IRC allows for regulations to provide for distillation at less than 140 degrees of proof, and TTB did not receive any comments objecting to its original proposal of ''100 degrees of proof or more.'' TTB has previously authorized experiments for the use of the byproduct of spinning cone column at 90 degrees of proof for use as wine spirits. Because of its experience with the experimental use of lower-proof byproducts of alcohol reduction methods, and because TTB believes the use of such byproducts are consistent with the intent of the IRC, TTB is incorporating the 90 degrees of proof rate into its regulations to provide winemakers greater flexibility in their winemaking processes.

G. Accidental Water Additions

TTB proposed to add what would have been 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. The proposed text set forth the 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. The proposal also stated that the appropriate TTB officer could 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 specified that, in evaluating any request under this section, TTB may consider as a factor whether the proprietor has demonstrated good commercial practices, taking into account the proprietor's prior history of accidental additions of water to wine and of compliance with other regulations in part 24.

Comment: In its comment, the Wine Institute expressed its support for the proposal 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. It also agreed with ''the conditions of usage of reverse osmosis and distillation as outlined'' in the proposed regulations for the purpose of removing accidentally added water. However, Wine Institute pointed out that the regulations were proposed for ''new'' § 24.251, which already exists.

Additionally, Wine Institute expressed its support for language in proposed § 24.186(a), which provides that wine shall remain ''standard wine'' if water is accidentally added to standard wine in an amount that does not exceed 1 percent of the total volume of the wine, and the proprietor need not take any action to correct the wine. Wine Institute also suggested amending § 24.186(b), which allows for the correction of accidental water additions, to allow ''the addition of grape juice concentrate to correct an accidental dilution of grape wine.'' Wine Institute argued that since grape juice and grape juice concentrate is authorized to be added to standard wine (see 27 CFR 24.186), TTB should authorize the addition of grape juice and grape juice concentrate to wine that has been accidentally diluted with water. Wine Institute expressed its belief that water accidentally added can be completely or partially accounted for by an appropriate amount of juice concentrate because water is necessary to reconstitute juice concentrate back to original Brix. It argued that this approach eliminates the need for processing (such as reverse osmosis) that, according to Wine Institute, is expensive and can potentially impact the quality of the wine. Wine Institute further suggested that the process proposed in § 24.251 be used on a portion of the wine if concentrate does not fully account for the accidental water addition.

Clover Hill Winery expressed concern that the authority of removing accidentally added water from wine under the standards as proposed could be abused by winemakers to fortify wines by distilling ''slightly past the original concentration.'' With no record of this distillation, Clover Hill Winery stated ''there would be no red flags at the regulatory agencies and customers would be none the wiser.''

In its comment, the EU quoted the EU–US agreement [7] on wine in article 3, which provides that ''the term wine shall cover beverages which contain no added water beyond technical necessity.'' As stated in their comment, the ''EU considers adding water intentionally to wine products as fraud.'' They further noted, ''[I]n EU, any addition of water for facilitating the solution or dispersion of oenological products must be reported in a register held by the producer.'' It is for these reasons that the EU recommended that ''any accidental addition of water should be reported to the competent authority and duly recorded even if it is in the context of its subsequent removal.'' The EU further commented that ''the blending of a watered wine with a non-watered wine is not considered by EU as an acceptable solution to reduce the proportion of added water within the limit of 1 percent, this limit being accepted only in the context of the addition of water for facilitating solution or dispersion of oenological products.'' They also corrected a statement made in Notice No. 164 by stating that ''concentration techniques including reverse osmosis are allowed in EU for the enrichment of musts used to produce any category of wine under the conditions referred to in Annex VIII(I)(B)(1)(b) to regulation (EU) No 1308/2017.''

TTB Response. In Notice No. 164, TTB referenced having 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. TTB also stated that it has not approved these requests because, in accordance with § 24.218, the accidental addition of water renders the wine an ''other than standard wine.'' Further, § 24.218 provides that other than standard wine must be segregated from standard wine, thus generally prohibiting the blending of other than standard wine with standard wine.

TTB proposed in new § 24.186 to permit the blending of other than standard wine with standard wine to reduce the amount of accidentally added water to 1 percent or less of the total volume of the blended wine. The intent was that the resulting wine would be considered to be standard wine.

In response to the comment received by the EU, TTB has reconsidered this proposal and is removing it from § 24.186 in this final rulemaking document. Accordingly, this final rule will not allow for the ''salvage'' of wine by blending the accidentally diluted wine (other than standard wine) with a standard wine. However, in response to the Wine Institute's suggestion of allowing the addition of juice concentrate to wine that has been diluted with water, TTB has added language to proposed § 24.251 (which is redesignated as § 24.252 in this document) that authorizes the salvage of wine that has been diluted with water by adding concentrate under certain conditions.

TTB is codifying these provisions in a new section, § 24.252. TTB originally proposed them in § 24.251. However,

[7] *https://www.ttb.gov/agreements/us-eu-wine-agreement.pdf.*

that section was added by a rulemaking subsequent to the publication of Notice No. 164. TTB notes that the provisions in § 24.252 only apply to wine that contains water in excess of the limits provided for standard wine in part 24 that was ''accidentally added,'' not ''intentionally.'' TTB also notes that the recordkeeping requirements in § 24.252 provide that the industry member retain 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. Because the regulations already address these matters, TTB does not believe that there is a need to amend the proposed regulations to further clarify that the water must be ''accidentally'' added in order to take advantage of the provisions of § 24.252, nor does TTB believe that additional recordkeeping requirements are necessary.

In response to Clover Hill Winery's comment, TTB notes that in general, wine spirits are authorized to be added to standard wine (see 27 CFR part 24, subpart K). It is unclear to TTB what is meant by ''distill slightly past the point of concentration.'' Currently, there are no labeling requirements in 27 CFR part 24 that require an industry member to indicate on the label of their product that it contains wine spirits. In fact, such practices are generally prohibited for wines that are required to be covered by a Certificate of Label Approval (COLA) under TTB's regulations in 27 CFR part 4.

Labeling concerns aside, the issue at hand is that alcohol that was removed from the permeate stream resulting from reverse osmosis is distilled and returned to the wine. As provided in the proposed regulations, the wine must be returned to its original condition by removing an amount of water equal to the amount that was accidentally added to the wine. ''Returned to its original condition'' includes alcohol content. TTB is adding clarifying language to the provisions of § 24.252 to address this issue.

H. Other Proposed Regulatory Amendments

In addition to the changes discussed previously, TTB Notice No. 164 included the following proposed regulatory amendments.

1. Technical Amendments to the List of Authorized Wine and Juice Treating Materials

i. General Amendments to § 24.246

TTB proposed numerous technical and clarifying changes to § 24.246. First, TTB proposed to amend the heading in paragraph (a) of § 24.246 to read ''Wine and juice'' rather than just ''Wine.'' TTB also proposed a number of technical changes to the table in § 24.246. A significant portion of these technical changes involve 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 were only in U.S. Common (English) units or SI (International Standard, or metric) units, TTB proposed adding the other unit of measure for reference purposes, where appropriate. Other technical changes in the proposed rule include: (1) Adding a footnote reference after each use of ppm and ppb in the chart to address parts per million and parts per billion, respectively; (2) including a definition of the word ''stabilize'' at the end of the chart; (3) adding a third column to the table in § 24.246 titled ''FDA reference'' to provide references to relevant FDA regulations in title 21 of the CFR, FDA GRAS Notices, and FDA advisory opinions; and (4) updating references to FDA opinions.

Comments. Wine Institute submitted the only comment specifically referencing the technical amendments to § 24.246. In its comment, Wine Institute expressed its support of TTB's proposal of ''expressing units first in U.S. common units and then in SI units'' for the specified limitations of use in the list of authorized wine and juice treating materials listed in § 24.246. Wine Institute ''appreciates the fact that the limits are expressed using both conventions'', and suggested ''that a common SI unit form, *i.e.* mg/L or g/L, be expressed wherever possible.'' Wine Institute argues that ''mg/L or g/L'' is a ''more correct from a scientific perspective than 'ppm' or 'ppb.' '' Wine Institute also stated that ''in some instances, limits are expressed in grams per hectoliter or similar; use of mg/L would be more consistent and more useful and relevant to the Industry.''

TTB Response. TTB is amending its regulations to add the appropriate SI unit to the specified limitations of use in the list of authorized wine and juice treating materials listed in § 24.246. TTB notes that many of the limitations in the table in § 24.246 include both common and SI units. Adding the actual SI units to the remaining limitations in the table, in addition to the footnote regarding the relationship between ppm or ppb and the common SI units, would not change the substance of the limitations and would be useful to industry members and provide consistency within the table.

ii. Activated Carbon

In the entry for activated carbon in § 24.246, TTB proposed to amend one of the entries in the ''Materials and use'' column for clarity by revising the phrase ''remove color in wine and/or juice'' to read ''remove color from wine and/or juice.''

Comments. Although Wine Institute stated that the simplified proposed language for activated carbon would assist in clarification, it was uncertain as to why a limit on the use of activated carbon is necessary, provided that the wine retains its vinous character after the decoloring process is complete. Instead, Wine Institute suggested GMP as an appropriate limit under the belief that ''[t]he need to limit color removal is unnecessary.''

TTB Response. TTB is finalizing its proposal for the entry for activated carbon in § 24.246, and notes that Notice No. 164 did not include a specific proposal to change the use rate of activated carbon. TTB intends to seek comment on the Wine Institute recommendation in separate rulemaking. As a result, TTB is not adopting the recommendation at this time, but will consider requests from individual industry members under §§ 24.249 and 24.250 to use different levels of activated carbon to remove color from juice and/or wine as needed.

iii. Ammonium Phosphate (*mono-* and *di-* basic)

TTB proposed to revise the name of the material to ''Ammonium phosphate/diammonium phosphate (*mono* and *di* basic)'' and place the entry under a new entry for ''Yeast nutrients'' in the table in § 24.246. (TTB also proposed a conforming change revising the name of the material in § 24.247.)

Comments. Wine Institute expressed its belief that the current use rate of ammonium phosphate ''is insufficient in certain circumstances.'' Wine Institute stated ''[a]n addition of 8lbs. DAP per 1000 gallons of juice results in an addition of approximately 200 mg/L of Nitrogen to the juice.'' Wine Institute referred to scientific articles (Butzke et

al. (U.C. Davis, 1998))[8] that suggested ''[i]n juices with high Brix levels, . . . as much as 350 mg/L of Nitrogen will be required for a healthy fermentation, thus it is possible that if the high Brix juice is naturally deficient in Nitrogen, then an addition of 8lbs/1000 gallons may be insufficient.''

In her comment, Heather Nenow expressed her concern that the current authorized use rate of ammonium/diammonium phosphate at 8 pounds per 1000 gallons of wine is insufficient to finish fermentation with grapes grown in certain regions of the country. Ms. Nenow referred to uncited studies that indicate yeast-assimilable nitrogen of 250 to 350 ppm is required to finish fermentation. According to Ms. Nenow, 1 pound of diammonium phosphate added to juice provides 22 ppm of yeast-assimilable nitrogen. With a limit of 8 pounds per 1000 gallons for addition of diammonium phosphate, the maximum increase of yeast-assimilable nitrogen the winemaker can add is 176 ppm, which is well below the 250-to-350 ppm of yeast-assimilable nitrogen that Ms. Nenow indicated is necessary to complete fermentation. She recommended a use rate for diammonium phosphate of 15 pounds per 1000 gallons of wine.

TTB Response. TTB is revising the name of the material to ''Ammonium phosphate/diammonium phosphate (*mono* and *di* basic)'' and adding it to the new entry ''Fermentation aid'' in the table in § 24.246 (as noted above, for clarity, TTB is replacing the term ''Yeast nutrients'' with the term ''Fermentation aids'' in the regulations). TTB notes that it has not yet received requests from winemakers to use ammonium phosphate at levels higher than proposed. TTB plans to include this recommendation in separate rulemaking in relation to Wine Institute's recommendation of GMP.

iv. Casein, Potassium Salt of Casein

In the ''Specific limitation'' column, TTB proposed to remove the references to FDA's GRAS opinions. The opinions were from 1960 and 1961, and copies were no longer available from either TTB or FDA.

Comments. The 11 submitters of the form letter stated that casein, which is currently authorized for use to clarify wine under § 24.246, should also be authorized for use in grape juice. They argued that the use of casein in juice is as effective as its use in wine. They further stated that ''[m]any winemakers choose to use fining products on juice in preference to wine as the process is more efficient and ha[s] less impact on resultant wine flavor.''

TTB Response. TTB notes that it has not received applications from winemakers submitted under § 24.250 for the approval of the use of casein as a clarifying agent for juice. As a result, TTB did not propose to extend its authorized use to include juice in Notice No. 164. TTB believes that additional notice and opportunity for comment is necessary, and plans to include this recommendation in separate rulemaking. Thus, TTB is not authorizing the use of casein in grape juice in the production of wine at this time, but will consider requests from individual industry members under §§ 24.249 and 24.250 for the use of casein as a treatment material for grape juice.

v. Technical Amendments to Other Specific Wine Treating Materials

TTB also proposed to make the following technical changes to the current entries in the table in § 24.246:

- Albumen. In the ''Specific limitation'' column, TTB proposed to revise the words ''of solution'' in the second sentence to read ''of wine.''
- Calcium carbonate. In the ''Materials and use'' column, TTB proposed to add the abbreviation ''$CaCO_3$'' to the material name, to revise the phrase ''and juice'' to read ''or juice'' in the first use entry, and to revise the phrase ''A fining agent'' to read ''As a fining agent'' in the second use entry.
- Citric acid. In the ''Materials and use'' column, TTB proposed revising the phrase ''deficiencies in wine'' to read ''deficiencies in juice and wine.''
- Copper sulfate. In the ''Specific limitation'' column, TTB proposed to revise the phrase ''sulfate added (calculated as copper)'' to read ''sulfate (calculated as copper) added to wine.''
- Dimethyl dicarbonate. For purposes of clarity, in the ''Materials and use'' column, TTB proposed to add the abbreviation ''(DMDC)'' after the material name and also proposed to remove the phrases ''dealcoholized wine'' and ''low alcohol wine'' from the entry to reduce redundancy.
- Ferrocyanide. TTB proposed to remove ''ferrocyanide'' from the list of authorized wine treating materials because 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.
- Milk products. Because milk products are currently approved for use as fining agents in all wines, TTB proposed to remove the phrase ''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.
- Oxygen and compressed air. In the ''Materials and use'' column, TTB replaced the words ''May be used in juice and wine'' with the words ''Various uses in juice and wine.''
- Polyvinylpolypyrrolidone (PVPP). In the ''Materials and use'' column, TTB proposed removing the phrase ''black wine'' because this term for a very dark red wine is no longer commonly used by industry members; the material will still be allowed in red wines, which covers so-called ''black wines.''
- Sorbic acid and potassium salt of sorbic acid. In the ''Materials and use'' column, TTB proposed adding the words ''potassium sorbate'' in parentheses immediately after the material name because ''potassium salt of sorbic acid'' is commonly referred to as ''potassium sorbate.''
- Sulfur dioxide. TTB proposed to correct the entry for sulfur dioxide to include its use in juice.
- Thiamine hydrochloride. TTB proposed to move the material thiamine hydrochloride under a new heading, ''Yeast nutrients.''

Comments. In its comment, Wine Institute agreed with the proposed clarifying changes for albumen, ammonium phosphate (mono- and di basic), calcium carbonate, casein, citric acid, copper sulfate, dimethyl dicarbonate, ferrocyanide compounds, milk products, oxygen and compressed air, polyvinylpolypyrrolidone (PVPP), sorbic acid, sulfur dioxide, and thiamine hydrochloride.

TTB Response. This rule will finalize the technical changes to albumen, calcium carbonate, citric acid, copper sulfate, dimethyl dicarbonate, ferrocyanide compounds, milk products, oxygen and compressed air, polyvinylpolypyrrolidone (PVPP), sorbic acid, sulfur dioxide, and thiamine hydrochloride as proposed in Notice No. 164.

2. Application for Use of New Treating Material or Process

TTB proposed a technical amendment to clarify the requirements in § 24.250 for applications for use of new wine treating materials or processes. The amendment would require evidence 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.'' TTB believes the proposed language is

[8] Butzke, C.E. 1998. Survey of yeast assimilable nitrogen status in musts from California, Oregon and Washington. American Journal of Enology and Viticulture. 49(2):220–224.

clearer than the current language which requires proof of FDA ''approval of the material.'' TTB received no comments specifically related to this proposed amendment. Therefore, TTB is adopting the amendment as proposed in Notice No. 164 as final.

I. Other Issues for Public Comment and Possible Regulatory Action Discussed in Notice No. 164

In Notice No. 164, TTB invited public comments on a number of additional potential changes to part 24. Most of these issues had been raised in petitions for rulemaking or arose in connection with wine treatment approval requests under § 24.249 or § 24.250. The issues in question, and the specific points on which TTB requested public comments, are outlined below.

1. Alcoholic Oak Extract

In 2008, Oak Tannin Technologies submitted a petition to amend the TTB 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 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 [9] except agricultural wine.[10]

In Notice No. 164, TTB sought 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 advised that a manufacturer of alcoholic oak extract must contact FDA and go through the FDA pre-market review process.

Comment. In its comment, Clover Hill Winery indicated its support for the use of alcoholic oak extract in the production of standard wines because it ''may be beneficial to smaller wineries.'' However, they also expressed concern that the authorized use of alcoholic oak extract in standard wine would detract ''from the individuals who take time to age in barrels or with oak substitutes.'' To resolve this concern and dispel possible consumer confusion, Clover Hill Winery offered a ''middle ground'' suggestion, which would include a statement on the label indicating whether or not wine was aged in oak or with alcoholic oak.

TTB Response. TTB appreciates Clover Hill Winery's comment and will take it into consideration in any future decisions regarding the use of alcoholic oak extract. TTB notes that as of the date of this document, the use of alcoholic oak extract as a stabilizing, enriching, and integrating agent has not gone through the FDA pre-market review processes. Therefore, TTB is not amending its regulations to allow the use of alcoholic oak extract at this time.

2. Lactic Acid

In 2007, Hyman, Philips, & McNamara, P.C. petitioned TTB to amend §§ 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 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 certain other countries allow the addition of lactic acid before fermentation. Further, the petitioner noted that lactic acid is less expensive and more reliably available than tartaric acid.

In Notice No. 164, TTB did not propose any changes to the regulations concerning the use of lactic acid. However, TTB invited comments regarding whether or not the use of lactic acid prior to fermentation is good commercial practice in the production of natural wine.

Comments. Wine Institute noted that L(+) tartaric acid, malic acid, citric acid, and lactic acid are commonly grouped together in the regulations of other wine producing countries as allowed for acidification purposes. Wine Institute thus suggested that the limitation on use of lactic acid be expanded to allow its use in both juice and wine.

TTB Response. TTB's understanding of Wine Institute's comment is that it was responding to the request for comment in support of allowing the use of lactic acid for use prior to fermentation of natural wine. TTB believes that the Wine Institute's suggestion would benefit from additional public comment and plans to include it in a separate rulemaking document. TTB would also consider requests from individual industry members under §§ 24.249 and 24.250 for the use of lactic acid in juice prior to fermentation.

3. 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. In 2014, Constellation Wines U.S. Inc. (Constellation) 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. In Notice No. 164, TTB invited 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. TTB did not, however, propose any amendments to add these uses to the list of authorized uses for reverse osmosis.

TTB stated that if commenters believed that the use of reverse osmosis for these purposes is consistent with good commercial practice, their comments should explain their position in detail, as well as provide guidelines/standards concerning how much water (maximum percentage) may be removed. If commenters believed that the use of reverse osmosis for these purposes is not consistent with good commercial practice, their comments should explain their position in detail.

Comments. In its comment, Wine Institute expressed strong support for the use of reverse osmosis as described in Notice No. 164. It stated that this process ''is consistent with good commercial practice'' and suggested that it be added to the list of allowable uses for reverse osmosis. Wine Institute

[9] 27 CFR 24.10 defines ''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.''

[10] 27 CFR 24.10 defines ''agricultural wine'' as ''Wine made from suitable agricultural products other than the juice of grapes, berries, or other fruit.''

stated that the practice of using reverse osmosis to improve the phenol flavor and character of wine and reduce the water content of wine ''is allowed in other wine producing countries such as Australia and New Zealand,'' and argued that ''the lack of ability in the U.S. to use the technology in the proposed manner places the U.S. Industry at a significant competitive disadvantage.'' Wine Institute further stated ''Australia and New Zealand do not set limits on the amount of water that can be removed.'' Rather than setting a numerical use rate on the reverse osmosis for the proposed uses, Wine Institute stressed its desire to base a use rate/limitation on the resultant wine needing to retain vinous character.

In his comment, Coleman Reardon also expressed support for the use of reverse osmosis as requested by Constellation. Mr. Reardon argued that the concentration of standard wine via reverse osmosis would result in wine producers using more grapes in the production of wine, which would benefit grape growers. He also stated that ''[i]ncluding less water in the production of wine would also inherently increase the flavor of wine's other ingredients and characteristics.'' Mr. Reardon further argued that the U.S. is at an international disadvantage by not allowing the proposed use of reverse osmosis because such practice is authorized in some other countries.

In his second comment to Notice No. 164, Dr. Robert Kreisher opposed the proposed use of reverse osmosis and disagreed with Constellation's assertion that wine resulting from reverse osmosis to improve the phenol flavor and character of wine and reduce the water content ''is considered to be standard wine but with reduced levels of alcohol and water.'' Dr. Kreisher stated that Constellation's assertion was incorrect because, under current regulation, the concentration of wine via reverse osmosis is not authorized and, therefore, such a practice does not result in a standard wine.

Dr. Kreisher also argued that Constellation's statement that concentration of wine via reverse osmosis will result in ''reduced levels of alcohol and water'' is inaccurate. Dr. Kreisher indicated that concentration of wine cannot result in both a reduction of alcohol and water. He stated that reverse osmosis passes water (through a membrane) preferentially to alcohol and thus reduces water content, while concentrating (increasing) alcohol in the wine. Therefore, the alcohol in the retentate, *i.e,* ''wine'', is increased.

Dr. Kreisher also refuted Constellation's assertion ''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'' and that ''[t]he expanded use of reverse osmosis would provide winemakers with better ability to regulate the alcohol content of wines.'' He argued that the alcohol content of wine would only be regulated upward when reverse osmosis is used and further indicated that the claim that foreign countries authorize such practices is incorrect.

Finally, Dr. Kreisher argued that the prohibition on the concentration of wine to improve phenolic flavor and character and to reduce the water content does not subject anyone to unfair competition because wine produced with the use of such practices ''may not be sold in any major market, including the U.S.'' Dr. Kreisher stated ''[t]his isn't unfair, it's parity.''

In her comment, Alice Feiring opposed the proposed use of reverse osmosis, stating that such a practice would be used ''to cover up sloppy and unclean winemaking.''

TTB Response. TTB has decided not to set out regulations pertaining to this issue in this rulemaking. However, TTB will consider seeking additional comment in separate rulemaking.

4. Ultrafiltration To Separate White Grape Juice

In Notice No. 164, TTB discussed an industry member's request 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. TTB sought comment on whether the use of ultrafiltration to separate discolored wine for blending would be acceptable in good commercial practice. In its request for comment, TTB stated that a comment should explain in detail the commenter's position as to why the use of ultrafiltration in this manner is or is not acceptable in good commercial practice.

Comments. In its comment, E&J Gallo Winery (Gallo) acknowledged that TTB's request for comments on this matter was in response to a request the agency received from Gallo. Gallo responded that ''ultrafiltration should be permitted to be used for both discolored white grape juice and discolored white wine.'' In support of its position, Gallo noted that ''unprocessed discolored white grape juice and/or discolored white wine can currently be blended with red grape juice and/or red grape wine without any limitations.'' It further argued that ''[u]sing a processing step to separate white juice into color fractions should not alter where it can subsequently be used as is currently allowed today.''

In his second comment in response to Notice No. 164, Dr. Robert Kreisher expressed support for extending the authorized use of ultrafiltration to separate discolored white wine. He further argued that the use of ultrafiltration gives winemakers greater control over the wine they produce.

TTB Response. Because TTB did not receive any negative comments in its request for comments, the agency is authorizing the use of ultrafiltration to separate white grape juice into low and high color fractions.

5. Additional Yeast Nutrients

In 2007, TTB received a petition from Gusmer Enterprises Inc. (Gusmer) requesting approval of eight vitamins and minerals for use as yeast nutrients in the production of wine—cobalamin (vitamin B12), iodine (potassium iodide), iron, manganese sulfate, nickel, potassium chloride, riboflavin (Vitamin B2), and zinc sulfate. Prior to the publication of Notice No. 164, TTB had not administratively approved these vitamins and minerals under § 24.250. In Notice No. 164, TTB sought 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.

Comments. In response to TTB's request for comment on the eight vitamins and minerals, Wine Institute said that it has ''no position on whether any of the other materials identified in the Gusmer Enterprises, Inc. petition should be approved as authorized wine treatment materials.''

In its comment, Beverage Supply Group stated support for Gusmer's petition, specifically the use of zinc sulfate and manganese sulfate as yeast nutrients. Beverage Supply Group expressed their belief that the use of zinc sulfate and manganese sulfate is consistent with good commercial practice and also provided scientific data that they believe supports allowing the use of these two materials as yeast nutrients.

TTB Response. TTB did not receive comments supporting the addition of cobalamin (vitamin B12), iodine (potassium iodide), iron, nickel, potassium chloride, and riboflavin (vitamin B2), to the list of authorized wine and juice treating materials in § 24.246. TTB also has not had an opportunity to analyze wine or juice

treated with these substances. Accordingly, TTB does not believe it has enough information to add these vitamins and nutrients to the list of authorized wine and juice treating materials at this time. However, TTB would consider requests from individual industry members under the procedures of §§ 24.249 and 24.250 for use of any of these materials to aid in the fermentation of wine.

6. Comments on Matters on Which TTB Did Not Seek Comments

i. Flowers and Botanical Wines

Comment. In her comment, Samantha Hunter asked TTB to ''highlight'' flower and botanical wines to ''preserve historical methodologies and treatments in [w]inemaking.'' Ms. Hunter further suggested that TTB add ''flowers or botanicals'' to the definition of ''essences.'' She also suggested that TTB amend its regulations pertaining to ''other wine'' to allow wine to be made ''by blending wines or co-fermenting flowers with fruits or, juice.''

TTB Response. TTB notes that wine made with flowers, such as dandelions, are considered ''agricultural wines'' under its regulations in 27 CFR part 24, subpart I. Wine derived from flowers may be blended with wine made from fruit; TTB considers this type of wine to be an ''other than standard wine.'' TTB will propose clarifying language to resolve this issue in future rulemaking. With regard to adding flowers and botanicals to the regulations pertaining to essences, TTB will consider this issue for future rulemaking.

ii. Malolactic Bacteria

Comments. In their form letter, 11 commenters notified TTB that the type of malolactic bacteria authorized by § 24.246 (*Leuconostoc oenos*) for use in wine is no longer current. The commenters cited a scientific article which proposes assigning *Leuconostoc oenos* to a new genus, *Oenococcus oeni.* The 11 commenters, who are mostly winemakers, stated that *Oenococcus oeni* ''was adopted by the wine industry and the U.S. regulations should be updated to reflect that.'' The 11 commenters also expressed concern over competing with wines produced in other countries because those producers are authorized to use other types of malolactic bacteria, such as those belonging to *Leuconostoc, Lactobacillus,* and *Pediococcus* genus. They believed that this creates an unfair trade advantage for wines produced in other countries and stated that ''[a]ligning the designation of the authorized bacteria with current OIV standards as outlined in document OIV–Oeno 328–2009, Oeno 494–2012 (*https://www.oiv.int/public/medias/4054/e-coei-1-balact.pdf*) would provide U.S. wine producers with relative competitive equality in all trade markets.''

In his comment, Richard Gahagan stated that he does not believe that malolactic fermentation should be limited to *Leuconostoc oenos.* He stated that ''taxonomists have reclassified this organism to *Oenococcus oeni* (Dicks, Dellaglio and Collins (1995).'' He also stated that researchers from University of California Davis isolated three genera of lactic acid bacteria (*Lactobacillus, Leuconostoc,* and *Pediococcus*) from California wine (references to scientific articles were provided).

TTB Response. TTB is amending its regulations to add the name *Oenococcus oeni* as a synonym for *Leuconostoc oenos.* TTB has considered these comments and notes that the agency received several requests in the past to experiment with a different type of malolactic bacteria than that which is authorized for use in § 24.246, namely, *Lactobacillus plantarum.* In the responses to these previous requests, TTB stated that although the use of *Leuconostic oenos* as a stabilizing agent in wine is considered GRAS by FDA, the Bureau has been unable to ascertain that *Lactobacillus plantarum* is likewise considered GRAS by FDA. Therefore, TTB did not approve commercial use of *Lactobacillus plantarum.* In 2021, FDA did evaluate *Lactobacillus plantarum* in GRAS Notice No. GRN 000953, but only for use in ''conventional foods, such as yogurt and other dairy products, soy products, chewing gum, and confectionary snacks.'' Alcohol beverages were not among the uses evaluated. As a result, TTB is still not approving commercial use of *Lactobacillus plantarum* in wine.

TTB has not received requests to experiment with malolactic bacteria belonging to the genera *Leuconostoc, Lactobacillus,* or *Pediococcus.* Further, because these types of malolactic bacteria were not discussed in the proposed rule, the public has not had the opportunity to review a proposal on this matter. Accordingly, TTB is not incorporating the commenters' recommendations in this final rule but plans to include them in future rulemaking.

iii. Pea Protein

Comments. The 11 submitters of the form letter, in addition to the Wine Institute and Erbslöh Geisenheim (in its first comment), all commented that they support the addition of pea protein to the list of authorized wine and juice treating materials in § 24.246 as a source of plant protein. It is TTB's understanding that pea protein is intended to be used as a clarifying material. The 11 submitters of the form letter stated that: ''Current US regulations provide unfair trade advantage for non-US wine producers in both domestic and international markets.'' The Wine Institute's comment agreed with this assertion. The 11 commenters further argued that pea protein should be in the list of authorized treating materials because TTB has received ''multiple'' submissions from wineries requesting experimentation under § 24.246.

TTB Response. Since the publication of Notice No. 164, TTB has administratively approved the use of pea protein as a fining agent and to remove off flavors from wine and juice. Because TTB did not propose pea protein for such uses in Notice No. 164, the public has not had sufficient opportunity to comment. TTB is not adding pea protein to the list of approved treating materials in § 24.246 at this time but will include it in a future rulemaking document.

iv. Potassium Polyaspartate

Comment. In its comment, the Wine Institute suggested that TTB consider the addition of potassium polyaspartate to the list of approved materials. It stated that ''potassium polyaspartate has recently been approved for use in winemaking in the European Union as a tartrate stabilization tool, similar to CMC.''

TTB Response. TTB understands that the potassium polyaspartate that the Wine Institute is recommending for addition to the authorized list of wine treating materials is ''potassium polyaspartate A–5D K/SD.'' Since the publication of Notice No. 164, the FDA has evaluated potassium polyaspartate for use as a wine stabilizer (see GRAS Notice No. GRN 000770) and TTB has administratively approved its use to stabilize wine by preventing tartrate crystal precipitation. However, because Notice No. 164 did not include a proposal to add this material to the authorized list of wine treating materials, TTB believes the public needs an opportunity to comment. TTB plans to include potassium polyaspartate in a separate rulemaking document.

v. Use of Spinning Cone Column for Adding the Original Water Back to Wine

Comment. In its comment, ConeTech argued that the ''Reference or limitation'' column for spinning cone column in § 24.248 should be amended to allow for addition of the original

water that was removed via spinning cone column back to the wine, with the resulting wine being considered standard wine. ConeTech supplied arguments in its comments for the addition of this proposal to the final rule.

TTB Response. TTB administratively approved the process proposed by ConeTech subsequent to the publication of Notice No. 164. Because TTB has not aired this proposal for public comment, it is not incorporated in this final rule, but TTB plans to include it in a separate rulemaking document.

vi. Use of Spinning Cone Column on Winery Premises

Comment. In its comment, Clover Hill Winery recommended that TTB authorize the use of spinning cone column for purposes of alcohol reduction on winery premises rather than requiring it be used on a distilled spirits plant premises.

TTB Response. Spinning cone column is considered to be a distillation process. In general, statutory requirements require that distillation processes take place on distilled spirits plant premises. Therefore, TTB is not authorizing the use of spinning cone column on winery premises.

vii. Thin-Film Evaporation

Comment. In its comment, Wine Institute suggested that TTB authorize the use of thin-film evaporation to separate juice into low Brix and high Brix fractions. It claims that such an authorization ''would conform the allowable use of Thin-film evaporation to the allowable use of thermal gradient processing.''

TTB Response. Because TTB did not air this proposal for public comment in Notice No. 164, it is not incorporated in this final rule, but TTB plans to include it in a separate rulemaking document.

Regulatory Analysis and Notices

Executive Order 12866

It has been determined that this rule is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), TTB certifies that these final regulations will not have an economic impact on a substantial number of small entities. This final 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 application to TTB. This rule allows for certain treatments, under limited circumstances, without the submission of an application to TTB. TTB estimates that the 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 rule as wineries subject to part 24 still will be required to maintain those usual and customary records.

Pursuant to section 7805(f) of the IRC (26 U.S.C. 7805(f)), the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business, and no comments were received.

Paperwork Reduction Act

Regulations in this document contain current collections of information that have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and assigned control numbers 1513–0057, titled ''Letterhead Applications and Notices Related to Wine (TTB REC 5120/2),'' and 1513–0115, titled, ''Usual and Customary Business Records Relating to Wine (TTB REC 5120/1).'' Any 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.

In conjunction with Notice No. 164, TTB submitted revisions to OMB control numbers 1513–0057 to OMB for review. That revision accounted for the anticipated reduction in the number of respondents as a result of the proposal to no longer require proprietors to submit an application to TTB prior to correcting accidentally diluted wine. The proposal was included in Notice No. 164 and is adopted as final in this document. The revision and its connection to the proposed regulatory amendments are described in detail in Notice No. 164, which also solicited comments regarding the information collection revision. TTB received no comments in response to the revision, which OMB has now approved.

Administrative Procedure Act

TTB finds good cause under 5 U.S.C. 553(d)(3) to dispense with the effective date limitation in 5 U.S.C. 553(d)(3). A 30-day delayed effective date is unnecessary because the regulatory changes in this final rule that authorize the use of wine treating materials are optional, and making the changes effective immediately upon publication will give wineries the option of using these newly-approved materials and processes as soon as possible.

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 above in the preamble, TTB amends 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''.

The revision reads as follows:

§ 24.10 Meaning of terms.

* * * * *

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

§ 24.85 [Amended]

■ 3. Section 24.85 is amended by:
■ a. In the first sentence adding the word ''wood,'' after the word ''berries,''; and
■ b. Removing the parenthetical authority citation at the end of the section.

■ 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 with any wood that is consistent with the food additive requirements under the Federal Food, Drug, and Cosmetic Act. 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), or charred and the wood must not be otherwise treated. If wine is treated with charred wood, the wood may not remove color from the wine.

(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. Wood essences and extracts must be consistent with the requirements of the Federal Food, Drug, and Cosmetics Act for that purpose and may be used only in ''other wine'' in accordance with § 24.218. This paragraph (b) 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.

■ 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 removal of the accidentally added water from the wine in accordance with § 24.252.

■ 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 the 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 90 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 premises only for the production of nonbeverage wine products.

■ 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 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 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.

TABLE 1 TO PARAGRAPH (c)—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 16 pounds per 1,000 gallons (1.9 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 (300 mg/L), and the finished concentrate must have no detectable level of the material.[2].	FDA advisory opinion dated September 8, 2016.
Activated carbon:		
To assist precipitation during fermentation	27 CFR 24.176	FDA advisory opinion dated September 8, 2016, which states that the activated carbon must meet the specifications in the Food Chemicals Codex and be removed from the wine.
To clarify and purify wine	The amount used to clarify and purify wine must be included in the total amount of activated carbon used to remove excessive color from wine and/or juice. 27 CFR 24.241 and 24.242.	FDA advisory opinion dated January 26, 1979, which states that the activated carbon must meet the specifications in the Food Chemicals Codex and be removed from the wine.
To remove color from wine and/or juice from which wine is produced.	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.	FDA advisory opinion dated January 26, 1979, which states that the activated carbon must meet the specifications in the Food Chemicals Codex and be removed from the wine.
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 184.1155 FDA advisory opinion dated July 26, 1985.
Ascorbic acid *iso*-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 (generally recognized as safe) Notice No. GRN 000284.
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 (4.79 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 *Aspergillus niger:* To remove spoilage organisms such as *Brettanomyces* from wine.	The amount used must not exceed 0.04 pounds per 1 gallon (500 g/100 L) of wine.	GRAS Notice No. GRN 000397.
Citric acid:		
To correct natural acid deficiencies in certain juice or wine.	See 27 CFR 24.182 and 24.192	21 CFR 184.1033.
To stabilize [1] wine other than citrus wine	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.

TABLE 1 TO PARAGRAPH (c)—MATERIALS AUTHORIZED FOR TREATMENT OF WINE AND JUICE—Continued

Materials and use	Specific TTB limitation (if applicable)	FDA reference
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 (6mg/L).[2] The residual level of copper in the finished wine must not exceed 0.5 ppm (0.5 mg/L).[2].	21 CFR 184.1261.
Defoaming agents (polyoxyethylene 40 monostearate, silicon dioxide, dimethylpoly-siloxane, sorbitan monostearate, glyceryl monooleate and glyceryl dioleate): To control foaming, fermentation adjunct.	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 ppm (10 mg/L).[2].	21 CFR 173.340 and 184.1505.
Dimethyl dicarbonate (DMDC): To sterilize and stabilize [1] wine.	DMDC may be added to wine in a cumulative amount not to exceed 200 ppm (200 mg/L).[2].	21 CFR 172.133.
Enzymatic activity: Various enzymes and uses, as shown in the following entries:.	The enzyme preparation used must be prepared from nontoxic and nonpathogenic microorganisms..	
Carbohydrase (*alpha*-Amylase): To convert starches to fermentable carbohydrates.	The amylase enzyme activity must be derived from:.	
	Aspergillus niger, Aspergillus oryzae, Bacillus subtilis, or barley malt; or.	FDA advisory opinion of August 18, 1983. 21 CFR 173.130.
	from *Rhizopus oryzae;* or	21 CFR 184.1027.
	from *Bacillus licheniformis.*	
Carbohydrase (*beta*-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 *Aspergillus niger, Aspergillus oryzae,* or.	FDA advisory opinion dated August 18, 1983. 21 CFR 173.130. 21 CFR 173.110.
	from *Rhizopus oryzae,*	
	or from *Rhizopus niveus.*	
Carbohydrase (pectinase, cellulase, hemicellulase): To facilitate separation of juice from the fruit.	The enzyme activity must be derived from *Aspergillus aculeatus*..	FDA advisory opinion dated December 19, 1996.
Catalase: To clarify and stabilize [1] wine	The enzyme activity must be derived from *Aspergillus niger* or bovine liver.	FDA advisory opinion dated August 18, 1983. 21 CFR 184.1034.
Cellulase: To clarify and stabilize [1] wine and facilitate separation of the juice from the fruit.	The enzyme activity must be derived from *Aspergillus niger*.	FDA advisory opinion dated August 18, 1983.
Cellulase (beta-glucanase): To clarify and filter wine and juice.	The enzyme activity must be derived from *Trichoderma longibrachiatum* or *Trichoderma harzianum*..	For beta-glucanase derived from *Trichoderma longibrachiatum,* 21 CFR 184.1250. For beta-glucanase derived from *Trichoderma harzianum,* GRAS Notice No. GRN 000149.
Glucose oxidase: To clarify and stabilize [1] wine.	The enzyme activity must be derived from *Aspergillus niger*.	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 (500 mg/L).[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 *Aspergillus niger*.	FDA advisory opinion dated August 18, 1983.
Protease (general): To reduce or to remove heat labile proteins.	The enzyme activity must be derived from:	FDA advisory opinion dated August 18, 1983.
	Aspergillus niger or *Bacillus subtilis;* or	21 CFR 184.1027.
	from *Bacillus licheniformis*	
Protease (Bromelin): To reduce or remove heat labile proteins..	The enzyme activity must be derived from pineapple (*Ananas comosus* (L.) or *Ananas bracteatus* (L.)).	FDA advisory opinion dated August 18, 1983.
Protease (Ficin): To reduce or remove heat labile proteins.	The enzyme activity must be derived from fig (*Ficus spp.*).	21 CFR 184.1316.
Protease (Papain): To reduce or remove heat labile proteins.	The enzyme activity must be derived from papaya (*Carica papaya* (L.)).	21 CFR 184.1585.
Protease (Pepsin): To reduce or remove heat labile proteins.	The enzyme activity must be derived from porcine or bovine stomachs.	21 CFR 184.1595, FDA advisory opinion dated August 18, 1983.
Protease (Trypsin): To reduce or remove heat labile proteins.	The enzyme activity must be derived from porcine or bovine pancreas.	FDA advisory opinion dated August 18, 1983.

TABLE 1 TO PARAGRAPH (c)—MATERIALS AUTHORIZED FOR TREATMENT OF WINE AND JUICE—Continued

Materials and use	Specific TTB limitation (if applicable)	FDA reference
Urease: To reduce levels of naturally occurring urea in wine to help prevent the formation of ethyl carbamate.	The enzyme activity must be derived from *Lactobacillus fermentum*. Use is limited to not more than 200 ppm (200 mg/L) and must be filtered prior to final packaging.[2].	21 CFR 184.1924.
Ethyl maltol: To stabilize[1] wine	Use authorized at a maximum level of 100 ppm (100 mg/L) in all standard wines except natural wine produced from *Vitis vinifera* grapes.[2].	FDA advisory opinion dated December 1, 1986.
Fermentation aids: To facilitate fermentation of juice and wine..		
Ammonium phosphate/diammonium phosphate (*mono*- and *di* basic).	The amount used must not exceed 8 pounds per 1000 gallons (0.96 g/L).	FDA advisory opinion dated August 29, 2016.
Biotin (vitamin B7)	The amount used must not exceed 25 ppb (25 ng/mL).[3].	FDA advisory opinion dated August 29, 2016.
Calcium pantothenate (vitamin B5)	The amount used must not exceed 1.5 ppm (1.5 mg/L).[2].	FDA advisory opinion dated August 29, 2016.
Folic acid (folate)	The amount used must not exceed 100 ppb (100 ng/mL).[3].	FDA advisory opinion dated August 29, 2016.
Inositol (myo-inositol)	The amount used must not exceed 2 ppm (2 mg/L).[2].	FDA advisory opinion dated August 29, 2016.
Magnesium sulfate	The amount used must not exceed 15 ppm (15 mg/L).[2].	FDA advisory opinion dated August 29, 2016.
Niacin (vitamin B3)	The amount used must not exceed 1 ppm (1 mg/L).[2].	FDA advisory opinion dated August 29, 2016.
Pyridoxine hydrochloride (vitamin B6)	The amount used must not exceed 150 ppb (150 ng/mL).[3].	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.
Ferrous sulfate: To clarify and stabilize[1] wine	The amount used must not exceed 3 ounces per 1000 gallons (0.022 g/L) of wine.	21 CFR 184.1315.
Fractionated potato protein isolates: Fining agent for wine.	Use must not exceed 500 ppm[2] (50 g/hL) of wine.	GRAS Notice No. GRN 000447.
Fumaric acid:		
To correct natural acid deficiencies in grape wine.	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.	21 CFR 172.350.
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 and 24.192	21 CFR 184.1069.
Malolactic bacteria: To stabilize[1] grape wine	Malolactic bacteria of the type *Leuconostoc oenos* (*Oenococcus oeni)* 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 (240 mg/L) in all standard wine except natural wine produced from *Vitis vinifera* grapes.	FDA advisory opinion dated December 1, 1986.
Milk products (pasteurized whole, skim, or half-and-half):		
Fining agent for grape wine	The amount used must not exceed 2 parts of milk products per 1,000 parts (0.2 percent V/V) of wine.	
To remove off flavors in wine	The amount used must not exceed 10 parts of milk products per 1,000 parts (1 percent V/V) of wine.	

TABLE 1 TO PARAGRAPH (c)—MATERIALS AUTHORIZED FOR TREATMENT OF WINE AND JUICE—Continued

Materials and use	Specific TTB limitation (if applicable)	FDA reference
Nitrogen gas: To maintain pressure during filtering and bottling or canning of wine and to prevent oxidation of wine.	None	21 CFR 184.1540.
Oxygen and compressed air: Various uses in juice and wine.	None.	
Polyvinylpolypyrrolidone (PVPP): To clarify and stabilize [1] wine and to remove color from red wine or juice.	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.	21 CFR 173.50.
Polyvinylpyrrolidone (PVP)/polyvinylimidazole (PVI) polymer (terpolymer of 1-vinylimidazole, 1-vinylpyrrolidone, and 1,2-divinylimidazolidinone; CAS 87865–40–5 (Chemical Abstracts Service Registration Number)): 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.	FDA FCN No. 000320.[4]
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.
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.		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 (300 mg/L) of sorbic acid.[2].	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 (150 mg/L; 0.150 g/L) by the addition of tannic acid (polygalloylglucose).[2].	FDA advisory opinion dated September 8, 2016.
To clarify, or adjust tannin content of, juice or wine (other than apple).	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 ppm (150 mg/L; 0.150 g/L) by the addition of tannic acid (poly-galloylglucose).[2].	FDA advisory opinion dated September 8, 2016.
Tartaric acid (L-(+)-tartaric acid):		
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.	Use as prescribed in 27 CFR 24.182 and 24.192.	21 CFR 184.1099 and GRAS Notice No. GRN 000187.

[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] Parts per billion—1ppb = 0.000128 ounces per 1000 gallons = 1 mg/1000L.

[4] An effective food contact notification (FCN) applies only to the food contact substance that is the subject of the FCN and is applicable only to the manufacturer/supplier listed within the notification.

■ 8. Section 24.247 is amended by:
■ a. Revising the introductory text;
■ b. Removing the entry in the table for ''Ammonium phosphate (*mono-* and *di* basic'' and adding the entry for ''Ammonium phosphate/diammonium phosphate (*mono*-and *di* basic)'' in its place; and
■ c. Removing the footnote at the end of the table and the parenthetical authority citation at the end of the section.

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 (*mono*-and *di* 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.
* * *	* * *	* * *

■ 9. Section 24.248 is amended by:
■ a. Revising the introductory text;
■ b. Adding in alphabetical order an entry for ''Cross flow filtration'', including subentries for ''Nanofiltration'', ''Reverse osmosis'', and ''Ultrafiltration'';
■ c. Removing the entry for ''Nanofiltration'' following the entry ''Metal reducing matrix sheet processing'';
■ d. Revising the entry for ''Osmotic transport'';
■ e. Removing the entry for ''Reverse osmosis'' following the entry ''Osmotic transport'';
■ f. Revising the entry for ''Spinning cone column'';
■ g. Removing the entry for ''Thin-film evaporation under reduced pressure'' and adding the entry ''Thin film evaporation under reduced pressure'' in its place;
■ h. Removing the entry for ''Ultrafiltration'' following the entry ''Thin film evaporation under reduced pressure'';
■ i. Revising footnote 1 and adding footnote 2; and
■ j. Removing the parenthetical authority citation at the end of the section.

The additions and revisions 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..	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.
Reverse osmosis[2]	To reduce the ethyl alcohol content of wine and to remove off flavors in 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.
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 and white 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 less than 25,000 molecular weight with transmembrane pressures less than 200 psi. Shall not alter vinous character.

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

Process	Use	Reference or limitation
* *	* *	* * *
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.

[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. Amend § 24.250 by:
■ a. Revising paragraph (b); and
■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

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

* * * * *

(b) *Data required.* The application must include 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.

* * * * *

■ 11. Section 24.252 is added prior to the undesignated center heading ''Bottling, Packing, and Labeling of Wine'' to read as follows:

§ 24.252 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 subpart F of this part and this subpart, the accidentally diluted wine may be returned to its original condition through:

(1) The use of reverse osmosis and distillation without prior application to TTB provided that:

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

(ii) 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;

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

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

(v) Records are maintained in accordance with paragraph (c) of this section; or

(2) By adding juice concentrate under the conditions outlined in § 24.180 without prior application to TTB provided that:

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

(ii) The solids content of the finished wine do not exceed 21 percent by weight;

(iii) The proprietor complies with any State or local rules regarding the addition of juice concentrate; and

(iv) 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 this part.

(c) *Records.* The proprietor must, with respect to removals of water from wine and addition of concentrate 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 or that only an amount of concentrate sufficient to make up for the amount of water accidentally added is used.

Signed: August 17, 2022.

Mary G. Ryan

Administrator.

Approved: August 18, 2022.

Thomas C. West, Jr.

Deputy Assistant Secretary (Tax Policy).

[FR Doc. 2022–18060 Filed 8–23–22; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 870 and 872

[Docket ID: OSM 2021–0008; S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520]

RIN 1029–AC83

Abandoned Mine Land Reclamation Fee

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), and the Department of the Interior are adopting as final the interim final rule published on January 14, 2022, making amendments to the departmental regulations governing the Abandoned Mine Reclamation Fund (AML Fund) to be consistent with the Infrastructure Investment and Jobs Act (IIJA), which included the Abandoned Mine Land Reclamation Amendments of 2021 (the 2021 amendments). The final rule adopts the changes to the regulations reflecting the extension of our statutory authority to collect reclamation fees for an additional 13 years and the 20 percent reduction in fee rates. In addition, the final rule adopts the changes to the regulations reflecting the statutory extension of the dates when moneys derived from these fees will be available for distribution to eligible States and Tribes as grants. The final rule adopts the interim final rule with two revisions to correct grammatical errors. The final rule also corrects two additional grammatical errors in the regulations which were unaffected by the interim final rule.

DATES: Effective August 24, 2022.

FOR FURTHER INFORMATION CONTACT: Harry Payne, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Mail Stop 4558, Washington, DC 20240; Telephone (202) 208–5683. Email: *hpayne@osmre.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. How did the reclamation fee work before the 2021 amendments?

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA) created the AML Fund, which is funded primarily by a reclamation fee (also known as the AML fee) assessed on each ton of coal produced in the United States and that, among other things, provides funding to eligible States and Tribes for the reclamation of coal mining sites abandoned or left in an inadequate reclamation status as of August 3, 1977. As originally enacted, section 402(a) of SMCRA set the reclamation fee at 35 cents per ton (or 10 percent of the value of the coal, whichever was less) for coal other than lignite produced by surface mining methods, 15 cents per ton (or 10 percent of the value of the coal, whichever was less) for coal other than lignite produced from underground mines, and 10 cents per ton (or 2 percent of the value of the coal, whichever was less) for lignite. Section 402(b) of SMCRA first authorized collection of reclamation fees for 15 years following the date of SMCRA's enactment (August 3, 1977). Subsequently, the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, 104 Stat. 1388, section 6003(a)) extended our fee collection authority through September 30, 1995, followed by the Energy Policy Act of 1992 (Pub. L. 102–486, 106 Stat. 2776, 3056, section 19143(b)(1) of Title XIX), which extended our fee collection authority through September 30, 2004. A series of short interim extensions in appropriations and other acts further extended our fee collection authority through September 30, 2007.

The Surface Mining Control and Reclamation Act Amendments of 2006 (the 2006 amendments) were signed into law on December 20, 2006, as part of the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432, 120 Stat. 2922). The 2006 amendments extended our fee collection authority under section 402(b) through September 30, 2021, and reduced the reclamation fee rates in section 402(a) by 10 percent for the period from October 1, 2007, through September 30, 2012, and an additional 10 percent from the original levels for the period from October 1, 2012, through September 30, 2021. Therefore, the fee rates from October 1, 2012, through September 30, 2021, required coal mine operators to pay 28 cents per ton (or 10 percent of the value of the coal, whichever was less) for coal other than lignite produced by surface mining methods, 12 cents per ton (or 10 percent of the value of the coal, whichever was less) for coal other than lignite produced from underground mines, and 8 cents per ton (or 2 percent of the value of the coal, whichever was less) for lignite. OSMRE notified operators in writing of the change in fee rates resulting from the 2006 amendments in January and September 2007. 73 FR 67576, 67578. On November 14, 2008, the Department promulgated final regulations at 30 CFR parts 870 and 872 to codify these changes and other revisions made by the 2006 amendments (73 FR 67576).

B. How did the 2021 amendments change the reclamation fee and the annual AML grant distributions?

The 2021 amendments, signed into law on November 15, 2021, as part of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, 135 Stat. 429), commonly known as the Bipartisan Infrastructure Law (BIL), extended our fee collection authority under section 402(b) through September 30, 2034, and reduced reclamation fee rates in section 402(a) by 20 percent from the prior rates. Therefore, for the calendar quarter beginning October 1, 2021, the current rates require operators to pay 22.4 cents per ton (or 10 percent of the value of the coal, whichever is less) for coal other than lignite produced by surface mining