



July 13, 2022

Robert Koch
President, CEO
Wine Institute
425 Market Street., Suite 100
San Francisco, California 94105

James Trezise
President
Wine America
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Re: Docket No. FDA-2020-P-1523

Dear Mr. Koch and Mr. Trezise:

This letter responds to your citizen petition (FDA-2020-P-1523) requesting that the Food and Drug Administration (FDA, or we) amend subparagraph (c)(6) in 21 CFR § 101.9 to permit the use of an accurate “quantitation and summation of sugars” approach as an approved method for calculating total carbohydrate content in wine and wine-based beverages, henceforth referred to as “wine.” See Citizen Petition from Robert Koch, President, CEO, Wine Institute and James Trezise, President, WineAmerica, dated June 8, 2020, submitted to the Division of Dockets Management, Food and Drug Administration (“Petition”) at page 1.

Your petition asserts the following in support of your requests:

1. Wine producers disclose nutritional information to consumers, either as required by regulation or voluntarily in response to consumer requests.
2. The Handbook 74¹ analytical method for carbohydrates in wine is inaccurate and significantly overstates the level of carbohydrates in wine by including non-carbohydrate compounds (e.g., organic acids and glycerol) that should not be counted as carbohydrates. This overstatement disproportionately harms wine in the marketplace.

¹ Merrill AL and Watt BK. Energy value of foods: basis and derivation, revised. United States Department of Agriculture, Agriculture Handbook No. 74. 1973.

3. Summation of sugars, as noted in Handbook 74,¹ is an appropriate method for calculating the level of carbohydrates in wine, providing accurate information for consumers and the trade.

Your petition also provides additional information to support these assertions (Petition at pages 4 and 8).

In accordance with 21 CFR § 10.30(e)(3), and for the reasons stated in section II of this response, we are denying your requests. This letter sets out the basis for our determination that the “carbohydrate determination by difference” method (described below) must continue to be used for the purpose of total carbohydrate declarations in wine under the Federal Food, Drug, and Cosmetic Act (FD&C Act).² A wine under 7% alcohol by volume is subject to the labeling regulations of the FD&C Act. Wines at or above 7% alcohol by volume are subject to the product labeling regulations of the Alcohol and Tobacco Tax and Trade Bureau (TTB).

I. Background

FDA’s regulation, at 21 CFR § 101.9(c)(6), specifies that total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food. This means that any substances in a food that are not classified as protein, total fat, moisture, and ash under our regulations in 21 CFR § 101.9(c) such as organic acids are part of total carbohydrate for the purpose of nutrition labeling. In responding to your petition, we will call this method the carbohydrate determination by difference method.

Our regulation, at 21 CFR § 101.9(c)(6)(iv), defines sugar alcohols as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). Separately, our regulation, at 21 CFR § 101.9(c)(1)(i)(F), lists the calorie value of eight sugar alcohols (i.e., isomalt, lactitol, xylitol, maltitol, sorbitol, hydrogenated starch hydrolysates, mannitol, and erythritol) ranging from 0 to 3.0 calories per gram (g).

² As noted in your petition, the FD&C Act’s product labeling requirements only apply to the labeling of wine products with less than 7% alcohol by volume (Compliance Policy Guide 510.450, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-510450-labeling-diluted-wines-and-cider-less-7-alcohol>). The menu labeling requirements at 21 CFR 101.11 also specify that covered restaurants have information available upon request about standard menu items, including any wine, that includes total carbohydrates. Your petition at pages 1 and 11 cites 27 CFR 4.39(a)(1) as the regulation that applies as a basis for asserting that you need a different method to calculate carbohydrate content to avoid labeling your product with a statement that you assert is inaccurate. However, you do not elaborate adequately as to the basis for your assertion of inadequacy. We note that we are unable to opine on how any label declarations will be considered under regulations that are issued by the TTB. We also note that our response is only applicable to products when regulated by FDA.

II. Responses to the Action Requested in Your Petition

a. Amend our regulation 21 CFR §101.9(c)(6) to specify that the total carbohydrate content for wine may be calculated by use of the quantitation and summation of sugars method

Your petition (at pages 1 and 2) requests that we amend 21 CFR § 101.9(c)(6) to read as follows:

“Carbohydrate, total” or “Total carbohydrate”: A statement of the number of grams of total carbohydrate in a serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement “Contains less than 1 gram” or “less than 1 gram” may be used as an alternative, or if the serving contains less than 0.5 gram, the content may be expressed as zero. Except as authorized below, ~~T~~total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food. This calculation method is described in A. L. Merrill and B. K. Watt, “Energy Value of Foods—Basis and Derivation,” USDA Handbook 74 (slightly revised 1973) pp. 2 and 3, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section). Total carbohydrate content for wine may be calculated by use of the quantitation and summation of sugars method.

The petition asserts that the Handbook 74¹ analytical method (i.e., the carbohydrate determination by difference method) for carbohydrates in wine is inaccurate and significantly overstates the level of carbohydrates in wine by including non-carbohydrate compounds (e.g., organic acids and glycerol) that should not be counted as carbohydrates (Petition at page 2).

In support of this assertion, the petition provides the data on wine composition from the website, Waterhouse,³ in Tables 1 and 2 (Petition at pages 4 and 8). This website describes that most of the data was collected and written by students of the class, Natural Products of Wine, in 2004 and supplemented by additional student reports in 2015 and 2016. No peer-reviewed original research articles are cited in the petition or on the website for the data. The petition does not explain explicitly which laboratory method was used to generate the data presented in Tables 1 and 2. For example, it is unclear how the petition obtained “sugar” 0.11 g/glass in Table 1 and “sugars (true carbohydrates)” 0.74 g/5 ounce (oz) serving in Table 2 and what is included in these terms. In addition, it is unclear how carbohydrate overstatement of 308 percent was obtained for red wine in Table 2. The petition referenced the book by Amerine et al.⁴ in

³ Waterhouse, What’s in Wine? <https://waterhouse.ucdavis.edu/whats-in-wine/red-wine-composition>. 2005.

⁴ Amerine MA, Cruess WV, and Berg HW. The Technology of Wine Making 4th Edition: Avi Pub Co. 1980.

connection with Table 2 (Petition at page 8), but the petition did not provide an electronic file or a copy of the book or any relevant chapter(s) of the book. For these reasons, we conclude that Tables 1 and 2 do not have reliable, pertinent data from which we can draw a conclusion about the usefulness of the data in evaluating the petition's claim that the carbohydrate determination by difference method significantly overstate the level of carbohydrates in wine.

b. The petition asserts that organic acids are a large contributor to error in the calculation of the carbohydrate content in wine, with most prevalent being tartaric acid, and that tartaric acid is not fully available for human metabolism and should be removed from the carbohydrate and calorie declaration

The petition notes that the determination of carbohydrate in Handbook 74¹ (i.e., the carbohydrate determination by difference method) has been shown to be generally satisfactory for estimating energy values of foods, but states that the authors of the Handbook 74¹ acknowledged that in addition to the true carbohydrates, this difference fraction may include such compounds as organic acids (Petition at page 4). The petition elaborates that grapes, from which wine is made, are one of the high organic acid-containing foods, with the most prevalent acid being tartaric acid, and that Handbook 74¹ pointed out that calories present in tartaric acid are probably biologically unavailable to a large extent (Petition at page 10).

The petition referenced a document by Leonardelli et al.⁵ in stating that tartaric acid is present in relatively large amounts in grape wine (20 - 45% of the organic acid concentration in grapes is tartaric) (Petition at page 5). The petition also references statements in Handbook 74¹ that a separate value should be used for calculating the energy contribution of organic acids than carbohydrates because they have a different heat of combustion, and that tartaric acid is "thought to be either excreted unchanged or destroyed by micro-organisms" (Petition at page 5). The petition thus stated that since tartaric acid calories "should not be included in the overall caloric content of the wine, there is no basis for including tartaric acid in the total wine carbohydrate declaration" (Petition at page 5).

As explained in subsection II. a. of this response, the petition does not provide electronic files or copies of any peer-reviewed original research articles on the laboratory analysis of individual organic acid content of wine to substantiate its claim that organic acids are a large contributor to error in the calculation of the carbohydrate content in wine, with the most prevalent being tartaric acid. An article by Rovio et al.⁶ that we found suggests that tartaric acid content of wine in their

⁵ The petition writes "Leonardelli, M. J. (2013). Acidity in Wine: The importance of management through measurement. Retrieved from Grape and Wine Institute: <http://gwi.missouri.edu/publications/2013spring.pdf>." This website does not exist. We found the document at the following URL: <https://vinosigns.dk/wp-content/uploads/2017/09/Measuring-Acids-in-Wine.pdf>.

⁶ Rovio S, Sirén K, and Sirén H. Application of capillary electrophoresis to determine metal cations, anions, organic acids, and carbohydrates in some Pinot Noir red wines. Food Chemistry 2011;124:1194-1200.

study was 0.2 g – 0.3 g per 5 fluid (fl) oz. Even if calories present in tartaric acid are biologically unavailable to a large extent, the removal of such a small amount of tartaric acid from carbohydrate determination is unlikely to make a difference in the carbohydrate or calorie declaration per 5 fl oz of wine, especially if the value is rounded for the declaration on the label as described by 21 CFR § 101.9(c)(1) and (c)(6). For these reasons, we decline to remove tartaric acid from the carbohydrate or calorie declaration for wine under the FD&C Act.

c. The petition asserts that glycerol is the other large contributor to the error in the calculation of the carbohydrate content and that glycerol is not a sugar alcohol

The petition asserts that glycerol is the other large contributor to error in the calculation of the carbohydrate content and that glycerol is not a sugar alcohol, and thus, not a carbohydrate on the basis that sugar alcohols are composed of 5- or 6- carbon chains, since they are derived from 5-carbon or 6-carbon sugars, but glycerol is a 3-carbon polyol (Petition at page 5). Furthermore, the petition states that FDA appears to have recognized that glycerol is not a sugar alcohol because glycerol is not one of sugar alcohols that are listed in the calorie value of sugar alcohols in 21 CFR § 101.9(c)(1)(i)(F) (Petition at page 6). The petition also notes that in addition to the structural differences between sugars and glycerol, the metabolism of sugars is different from that of glycerol (Petition at page 6).

Our regulation, at 21 CFR § 101.9(c)(1)(i)(F), lists the calorie value of eight sugar alcohols (isomalt, lactitol, xylitol, maltitol, sorbitol, hydrogenated starch hydrolysates, mannitol, and erythritol) ranging from 0 to 3.0 calories per g. Because the calorie values of these sugar alcohols were known and they were different than the general calorie value for carbohydrate, 4 calories per g, at the time of the rulemaking in 2014 (79 FR 11879) and 2016 (81 FR 33742), the specific calorie values were established in the regulation.

Our regulation, at 21 CFR § 101.9(c)(6)(iv), defines sugar alcohols as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). We have not yet promulgated a regulation to identify which specific polyols, including glycerol, are sugar alcohols beyond the eight sugar alcohols for which specific calorie values are established at 21 CFR § 101.9(c)(1)(i)(F). However, we recognize that the yeast metabolism of sugars of grapes during the wine making process results in the production of glycerol and other substances in wine,⁷ and glycerin (i.e., glycerol) is generally recognized as safe when used in accordance with good manufacturing practice at 21 CFR § 182.1320.

⁷ Goold HD, Kroukamp H, Williams TC, et al. Yeast's balancing act between ethanol and glycerol production in low-alcohol wines. *Microbial Biotechnology* 2017;10(2):264-278.

As explained in section II. a. of this response, the petition does not provide electronic files or copies of any peer-reviewed original research articles on the laboratory analysis of glycerol content of wine to substantiate its claim that glycerol is the other large contributor to error in the calculation of the carbohydrate content in wine.

d. Use of AOAC 985.09 and AOAC 2013.12 for the quantitation and summation of sugars method

Furthermore, the petition requests that FDA allow for the use of summation of sugars as the determination of carbohydrate in wine instead of the carbohydrate determination by difference method (Petition at page 1 and 10). The petition explains that methods for accurate measurement of sugars now exist, and the methods are recognized as the AOAC⁸ official methods for use in the wine industry, and these methods do not include organic acids, glycerol, or any other interfering components in the measurement. The petition referenced AOAC 985.09 and AOAC 2013.12 (Petition at pages 8-10).

AOAC 985.09

AOAC 985.09 is defined for the determination of glucose and fructose in wine as measured by a spectrophotometer as the amount of reduced nicotinamide-adenine dinucleotide phosphate formed through the enzymatic reactions using enzymes hexokinase, glucose-6-phosphatase dehydrogenase, and phosphoglucose isomerase and the coenzyme nicotinamide-adenine dinucleotide phosphate.⁹ FDA considers AOAC 985.09 to be insufficient for the summation of total carbohydrate in wine because this method quantifies only glucose and fructose. Although glucose and fructose are the primary monosaccharides present in wine, it appears that the presence of other carbohydrates that we are aware of (e.g., sugar alcohols)¹⁰ are not quantified by this method.

AOAC 2013.12

AOAC 2013.12 is defined for the determination of sugars, glycerol, organic acids, and phenolic compounds, and termed, in the context of this method, as total carbohydrates. Using AOAC 2013.12, samples can be analyzed to quantify total sugars (undefined), glycerol, organic acids, and phenolic compounds, or the samples can be first treated with ion-exchange resin to remove organic acids and with polyvinylpyrrolidone to remove phenolics. This method, however, does not define or distinguish among individual sugars, reducing sugars, and organic acids. In addition, it is not specified within the method if AOAC 2013.12 can be used for quantification of sugar alcohols other than glycerol in wine.

⁸ AOAC International, <https://www.aoac.org/about-aoac-international/>

⁹ Henniger G and Mascaro L. Enzymatic-ultraviolet determination of glucose and fructose in wine: Collaborative Study. J Assoc Off Anal Chem 1985;68:1021-1024. This article is referenced in AOAC Official Method 985.09 Glucose and Fructose in Wine.

¹⁰ See *supra*, note 6

The “First Action” AOAC 2013.12 method that the petition referenced included a multi-laboratory study on six wine and wine-based materials.¹¹ The method as reported lacks validation data including the characterization of method accuracy, precision, and selectivity. In addition, concentrations of total sugars (undefined), glycerol, organic acids, and phenolic compounds are reported as g/100 milliliters (mL) total carbohydrates against an external glucose calibration curve. Based on the data publicly available, AOAC 2013.12 would not be an appropriate method to quantify all carbohydrate sources in wine, without additional validation.

We decline to adopt AOAC 985.09 or AOAC 2013.12 for wine as an exception to the carbohydrate determination by difference method under the FD&C Act based on the insufficient and unvalidated information provided in the petition.

In addition, the overestimation of carbohydrate in wine by the carbohydrate determination by difference method may be much less than what the petition purports. Based on the information that the petition presents in Table 2 (which we find deficient in pertinent information for our evaluation, as explained in section II. a. of this response), if there is, in fact, an overestimation in the amount of carbohydrate, it is likely to be quite small, —only about 2 g per 5 oz of wine. This amount will be further reduced to about 1 g if glycerol is counted as a carbohydrate. Thus, we find that the petition lacks adequate substantiation for the claim that the carbohydrate determination by difference method overstates the level of carbohydrates in wine, and that the methods presented in the petition are insufficient or inappropriate for use in determining total carbohydrate for the purpose of the label.

III. Conclusion

For the reasons stated in section II of this response, we are denying your request.

Sincerely,

Claudine Kavanaugh, Ph.D., MPH, RD
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
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¹¹ Kupina S and Roman M. Determination of total carbohydrates in wine and wine-like beverages by HPLC with a refractive index detector: First Action 2013.12. J AOAC Int 2014;97(2):498-505.