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Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fisher Lane Room 1061 Rockville, MD 20852

CITIZEN PETITION Carbohydrate Methodology for Wine and Wine-Based Beverages

Wine Institute is the premier organization representing California wineries in the United States and around the world. With 1,000 winery and affiliated business members, the organization initiates and advocates public policy that enhances the ability to responsibly produce, promote and enjoy wine. California represents 85 percent of U.S. wine production and over 90 percent of U.S. wine exports.

WineAmerica is the National Association of American Wineries. The organization represents wineries, state and regional winery associations, and wine industry supply companies across the country. Its mission is to encourage the dynamic growth and development of American wineries and winegrowing through the advancement and advocacy of sound public policy.

The FDA regulation governing nutrition labeling of food (21 CFR §101.9) requires the total carbohydrate content of wine to be calculated using the "by difference" method as described by Merrill and Watt in the USDA publication, *Energy Value of Foods: Basis and Derivation. Agriculture Handbook No. 74*. (Merrill & Watt, 1973), hereafter referred to as "*Handbook 74*". This method of calculating carbohydrates is not accurate for wine. Under 27 CFR §4.39 (a)(1), alcohol beverage producers are forbidden from presenting "...any statement that is false or untrue...". Carbohydrate declarations need to be accurately expressed, both to be in accordance with regulations and so as not to misrepresent or mislead consumers. On behalf of the United States wine industry, Wine Institute and WineAmerica submit this Citizen Petition in accordance with 21 CFR §10.30 and 21 CFR §10.20 to request the Commissioner of Food and Drugs to 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".

A. ACTION REQUESTED

Wine Institute and WineAmerica request the amendment of 21 CFR §101.9(c)(6) by addition of the language shown in redline to the existing text as shown here:

(6) "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, Ttotal 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.

B. STATEMENT OF GROUNDS

Wine Institute and WineAmerica request the amendment of 21 CFR 101.9(c)(6) in order to provide consumers with more accurate information about the carbohydrate content of wine than is provided by the analytical method specified in *Handbook 74* and to prevent unfair comparisons of the carbohydrate content in wine versus that in other alcoholic beverages. As explained in more detail in this petition, Wine Institute and WineAmerica submit the following as grounds for this request:

- 1. Wine producers disclose nutritional information to consumers, either as required by regulation or voluntarily in response to consumer requests.
- 2. The *Handbook 74* 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.
- 3. Summation of sugars, as noted in *Handbook 74*, is an appropriate method for calculating the level of carbohydrates in wine, providing accurate information for consumers and the trade.

1. Disclosure of Nutrition Information for Wine

While nutrition information is not currently required in the labeling of all wine, wine producers must include nutrition labeling, including carbohydrate content, on wines containing less than 7% alcohol by volume (21 CFR §101.9 (c)(6)).¹ Additionally, under an FDA regulation issued pursuant to the Patient Protection and Affordable Care Act (commonly known as the "Affordable Care Act", or "ACA"), chain restaurants and similar food establishments are required to provide to their customers upon request written information for a standard menu item that specifies the amounts of several nutrients, including total carbohydrate, in that item. The information may be provided by counter card, sign, poster, handout, booklet, loose-leaf binder, menu, or electronic device or by other similar means. (See 21 CFR 101.11(b)(2)(ii)).

¹ Wine producers may voluntarily include Serving Facts information that includes carbohydrates on labels of wine containing at least 7% alcohol by volume. See TTB Ruling 2004-1 and TTB Ruling 2013-2, available at www.ttb.gov/what-we-do/regs-guidance/rulings.





The purpose of the menu labeling requirements is to help consumers make informed choices when eating out. As always, the information made available to consumers must therefore be accurate, truthful, and not misleading.

As part of the ACA, FDA confirmed the applicability of the rule to alcoholic beverages and stated that, from a public health perspective, the requirement for nutrition labeling of alcoholic beverages "...is more likely to enable consumers to compare beverage options and make informed order selections in covered establishments" (79 Fed. Reg. at 71187). Consistent with this goal, Wine Institute and WineAmerica believe that any information provided must be accurate so as not to mislead the consumer.

In the document "Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap", four priority areas were identified for focus of additional policy activity. Of these four areas, the third is directly related to this petition: "Empower consumers to make better and more informed decisions about their diets and health...". The FDA document states that the "FDA works to ensure that consumers have access to the reliable, evidence-based information that they need to maintain and improve their health through diet and nutrition" (page 7). Further, it goes on to state, "Armed with reliable, analytically valid, and clinically meaningful, science-based diagnostic information, consumers can make more effective decisions about their lifestyles and health" (page 8, emphasis added). This petition is fully in alignment with these principles. Wine Institute and WineAmerica members seek to provide consumers with reliable, evidence-based information about the carbohydrate composition of wine.

2. Inaccuracies of the Current Handbook 74 Methodology for Wine Carbohydrate Measurement

According to 21 CFR §101.9(c)(6): "...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 *Handbook 74* and is incorporated into the regulation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The result of the calculation is often referred to simply as "carbohydrate by difference". However, *Handbook 74* acknowledges that the carbohydrate by difference method for calculating total carbohydrate has limitations. (See *Handbook 74* at 2-3.) Notably, the carbohydrate by difference method was designed to determine the energy content of foods and not to measure carbohydrates. The calculation was designed for its robustness in the energy calculations, as any errors in protein determination are offset by a higher or lower carbohydrate energy value.

Wine contains a high relative concentration of organic acids and glycerol, resulting in an inaccurate and <u>significant</u> over-estimation of total carbohydrate when estimated using the carbohydrate by difference method. Wine Institute and WineAmerica believe that the organic acids and glycerol in wine are not carbohydrates and thus should not be included as carbohydrates in nutrition information for consumers. As a result, consumers relying on declarations of carbohydrates based on results from the carbohydrate by difference method may be making ill-informed choices because they are receiving incorrect information in relation to wine.





Wine Composition

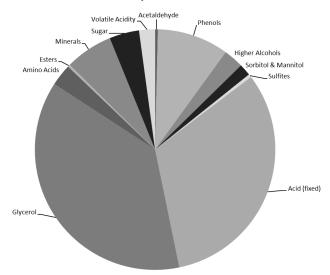
Wine is primarily composed of approximately 85% water and 13% ethanol, though the relative amounts of these two components vary inversely to a certain extent. The remaining approximately two percent is made up of a large range of substances. The compounds present in a typical red wine are outlined in the Table 1 and Figure 1. (Adapted from What's in Wine (Waterhouse, 2005))

Table 1
Minor Components of Wine

Component	g/L	g/glass
Glycerol	7	1.04
Acid (fixed)	6	0.89
Phenols	1.8	0.27
Sugar	0.75	0.11
Amino Acids	0.55	0.08
Higher Alcohols	0.5	0.07
Sorbitol & Mannitol	0.3	0.04
Sulfites	0.08	0.01
Minerals	1.2	0.18
Volatile Acidity	0.4	0.06
Acetaldehyde	0.07	0.01
Esters	0.06	0.01

Note: Strike-through values above would not be included in a "Carbohydrates by Difference" calculation.

Figure 1
Minor Components of Wine



As we examine these components in relation to the carbohydrate by difference method, the water, ethanol, minerals, volatile acidity, acetaldehyde, and esters would not be counted in the carbohydrate estimate. However, all other components in this list would be included, though some minor components would only be counted partially (e.g., higher alcohols). Significantly, the two largest "minor components" in the table above, namely fixed acids (i.e., organic acids) and glycerol, are included in the current method for calculation of carbohydrate in wine. However, Wine Institute and WineAmerica maintain that organic acids and glycerol should not be counted as carbohydrates in wine.

Organic Acids

Handbook 74 states that, "'Carbohydrate by difference' has been shown to be generally satisfactory for estimating energy values of foods" (page 3), but the authors had acknowledged on page 2 that "In addition to the true carbohydrates, this 'difference' fraction may include such compounds as organic acids." In other words, the authors acknowledged that organic acids are not true carbohydrates. On page 6, the authors confirm this, and point out that, in those foods containing abundant organic acids, a separate estimation of those acids should be made when determining energy values, because they are chemically distinct from carbohydrates and have different heats of combustion:





"...carbohydrate by difference," include(s) organic acids. In a very few foods the acids are sufficiently abundant that they should be determined separately for estimations of energy values of those foods, inasmuch as they are distinctly different chemically from carbohydrates and their heats of combustion are lower than for carbohydrates generally. ... Fruits contain organic acids in more significant amounts than other food groups. ... Citric and malic acids predominate in all fruits listed except grapes and tamarind. Tartaric acid accounts for most of the total in these two fruits. (emphasis added)

Wine is derived from grapes. As indicated in *Handbook 74*, grapes are one of the foods for which the carbohydrate by difference method will not give accurate results, in view of the abundant content of organic acids in grapes. The authors of *Handbook* 74 recognized that organic acids should not be counted as carbohydrates and that the carbohydrate by difference method is not accurate for foods with a high organic acid content. Consequently, the *Handbook 74* carbohydrate by difference method is not appropriate for wine.

Furthermore, on page 7 of *Handbook 74*, the following additional statement is made:

In certain types of processing by fermentation the total acidity of the product is increased several fold over the original content of the food. ... Some of the acid constituents of food are available to the body as a source of calories; others are known to be unavailable or of doubtful availability... tartaric acid is thought to be either excreted unchanged or destroyed by micro-organisms.

When a constituent of food is "excreted unchanged or destroyed", it follows that the calories contained in the constituent may not be fully available to the body. In this instance, although tartaric acid is present in relatively large amounts in grape wine (20-45% of the organic acid concentration in grapes is tartaric (Leonardelli, 2013)), the calories from tartaric acid will contribute minimally (if at all) to the caloric content of wine because much of the acid is excreted unchanged in the urine. 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.

Glycerol

Glycerol (glycerin) is the other large contributor to error in the calculation of the carbohydrate content of wine using the carbohydrate by difference method. Glycerol is produced by yeast during fermentation and is found in varying amounts in wine. Glycerol is a polyol, but Wine Institute and WineAmerica submit that glycerol should not be classified as a sugar alcohol and, therefore, not as a carbohydrate. Generally speaking, sugar alcohols are composed of 5- or 6-carbon chains, since they are derived from 5-carbon or 6-carbon sugars (pentoses and hexoses, respectively). Glycerol, however, is only a 3-carbon polyol.





FDA appears to have recognized that glycerol is not a sugar alcohol. In the Federal Register notice of FDA's final nutritional labeling rule, it specifies the calories per gram that are to be used for each of the "sugar alcohols". However, that list does not include glycerol. (See 21 CFR 101.9(c)(1)(i)(F) and 81 Fed. Reg. at 33979 (May 27, 2016)) In response to comments requesting that the term "polyol" be used in place of "sugar alcohol" on nutrition labels (81 Fed. Reg. at 33851-2 (May 27, 2016)), FDA states that the term "polyol" includes both sugar alcohols and non-carbohydrate polyalcohols while the term "sugar alcohol" as used by FDA includes only carbohydrates. In going on to discuss the caloric content of sugar alcohols, the FDA refers only to the sugar alcohols listed in 21 CFR 101.9(c)(1)(i)(F). As glycerol is not a sugar alcohol, it does not meet the definition of a carbohydrate, as outlined in the FDA's information sheet for Total Carbohydrate (FDA).

In addition to the structural differences between sugars and glycerol, the metabolism of these substances in the body is different. Importantly, while glucose travels through the bloodstream and is generally metabolized intracellularly in every cell in the body for energy, glycerol kinase, the predominant enzyme responsible for glycerol metabolism is primarily present in the liver, indicating that most of the glycerol would be metabolized there. While a portion of ingested glycerol, whether consumed as glycerol per se, or as a triglyceride, may be converted to glucose via gluconeogenic pathways, such is also the case for many other food components such as organic carboxylates (i.e., lactate), and amino acids (e.g., alanine, and glutamine), which are not classified as carbohydrates. Additionally, as regards the ability of the body to form glucose from glycerol, it is known that liver cells can make glucose from pyruvate and other 3-carbon compounds, such as glycerol, but this is only when carbohydrate is unavailable (Whitney, 2005). The American diet, even one which is low in carbohydrates, will always contain sufficient carbohydrates, so that the liver cells will not perform the conversion of glycerol to glucose.

When deciding to exclude the non-carbohydrate fraction of the carbohydrate by difference method, we must also consider the nature of carbohydrates as they relate to nutrition and dietary planning, which are the primary reasons for nutrition labeling of foods. The authors of *Handbook 74* stated that "'Carbohydrate by difference' has been shown to be generally satisfactory for estimating energy values of foods". They further stated that "for certain purposes, such as dietary planning for the diabetic, carbohydrate values are needed which exclude the fractions that are not potential glucose formers". This implies that any chemical that is not a glucose former -- such as glycerol -- is <u>not</u> considered to be a carbohydrate.

Wine Institute and WineAmerica acknowledge that glycerol is identified by the American Diabetes Association (ADA) as a sugar alcohol, due to its lower glycemic index than traditional carbohydrates. However, the classification of glycerol as a sugar alcohol and/or carbohydrate is disputed both among various nutrition associations and in international regulations. We also are aware that FDA has cited various companies for excluding glycerol from their carbohydrate declarations because the current FDA the regulations require the total carbohydrate content to be calculated by subtraction of the sum of the





crude protein, total fat, moisture and ash from the total weight of a product (i.e., carbohydrate by difference), and the companies in question did not adhere to this methodology. (Wellness Foods) That is why Wine Institute and WineAmerica are requesting a different carbohydrate content methodology for wine.

It should also be noted that the classification of glycerol in international nutritional labeling systems is inconsistent. In Australia and New Zealand, for example, only sugars are considered to be carbohydrates (Food Standards Australia New Zealand, 2016). In the European Union regulation regarding conversion factors for energy, they note the energy factor of 4 Calories per gram for "carbohydrates (excluding polyols)", and then indicate a different, lower energy factor for polyols (European Commission, 2011). Thus, it would appear that the neither Australia and New Zealand, nor the European Union considers glycerol to be a "true" carbohydrate.

In sum, there are several cogent reasons why glycerol should not be considered a sugar alcohol or a carbohydrate. Beside FDA's discussion in the 2016 Federal Register announcement of the revised Nutrition and Supplement Fact Labels rules, there are chemical and structural differences, differences in the manner in which glycerol is recognized and processed in the body, the emphasis in *Handbook 74* regarding excluding constituents which are not potential glucose formers, and the precedent in international regulations regarding the classification of glycerol.

Effect of Inaccuracies in the Handbook 74 Method

The Association of Official Analytical Chemists International (AOAC International) Official Method 985.10 Carbohydrate Content in Wine (AOAC, 2012e) manifests the inaccuracies of any "by difference" method, in that the reliability of the results obtained are complicated by the fact that it is not a stand-alone method, but a calculation obtained from the results of three separate AOAC methods: AOAC 920.56 Specific Gravity of Wines (AOAC, 2012c), AOAC 945.09 Extract of Beer (AOAC, 2012b), and AOAC 920.67 Ash of Wines (AOAC, 2012a). AOAC 985.10 assumes all residues obtained after evaporation that are not ash are composed of carbohydrates, which is inaccurate, as indicated earlier in this document. In a wine with very little residual sugar, which is the only source of "true carbohydrate", the inaccuracy of the carbohydrate declaration can be significant. Indeed, the resulting overstatement of the carbohydrate content of wine can be surprisingly large, resulting in an untruthful, inaccurate, and misleading declaration in the case of wine.

To illustrate this, Table 2 lists each non-sugar component in wine and compares what the total carbohydrate label declarations for wine would be using the carbohydrate by difference method and what they would be using the "true" carbohydrates contained in the wine (Waterhouse, 2005; Amerine, Cruess, & Berg, 1980). For a wine containing five grams of sugar per liter, which is quite common in the industry, the difference is a staggering 2.40 grams of "carbohydrates" per glass (a 308% increase) for a typical red wine and 2.16 grams of "carbohydrates" per glass (a 292% increase) for a typical white wine.





TABLE 2.

COMPARISON OF CARBOHYDRATE CONTENT IN RED AND WHITE WINE ACCORDING TO AOAC 985.10 (CARBOHYDRATE BY DIFFERENCE) VS. "TRUE" CARBOHYDRATES

	Red Wine, grams per 5 oz. serving	White Wir grams pe 5 oz. servi
Carbohydrate by difference		
Glycerol	1.04	1.04
Fixed Acids (Tartaric, Malic, Lactic, Citric)	0.89	0.89
Phenols	0.27	0.03
Amino Acids	0.08	0.08
Higher Alcohols	0.07	0.07
Sorbitol & Mannitol	0.04	0.04
Sulfites	0.01	0.01
Sub-total of non-sugar components	2.40	2.16
Sugars ("True" Carbohydrates)	0.74	0.74
Carbohydrate by Difference (AOAC 985.10)	3.14	2.90
Sugars ("True" Carbohydrates)	0.74	0.74
Carbohydrate Overstatement (Non-sugar components compared to "True" Carbohydrates)	308%	292%

In addition to misleading consumers, this inaccuracy in the current determination for carbohydrate in wines has led to the creation of an unfair and inequitable trade situation for wine in the domestic market. Wine Institute has observed commercials and advertising campaigns, both in print and television, claiming that beer has a significantly lower carbohydrate content than wine. When the "true" carbohydrates present in wine are compared with those in beer, these values are approximately equal.

It follows then, that efforts should be made to ensure that the carbohydrate information made available to the consumer for wine is truthful and accurate.

3. Summation of Sugars is an Accurate Approach to the Determination of Carbohydrate in Wine

Handbook 74 recognizes that superior analytical methods for carbohydrate calculation might be developed, although apparently none were technically possible at the time Handbook 74 was written for reasons including interferences from non-carbohydrate substances (Handbook 74 at 3). Fortunately, analytical technology has advanced significantly since 1973. In particular, a new method for the analytical determination of Glucose and Fructose in wine has been developed that allows for more exact calculation of the level of carbohydrates. This new method has been accepted by the AOAC as Official Method 985.09.





Handbook 74 acknowledged the possibility of a more accurate approach to carbohydrate calculation but it could not be recommended in 1973 because the analytical methodology to implement it was lacking (page 3):

Another approach has been the determination of the <u>sum of the sugars</u>, starches, and dextrins measured as total reducing sugars but exclusive of pentoses and hemicelluloses. In such cases it is fairly common to report total reducing sugars expressed as glucose based on analyses in which copper was used. For routine determinations, this procedure is not entirely satisfactory since the extent of the reduction of the copper reagent differs for the various sugars, and mixtures of sugars may be present. In addition the determination may be complicated by the presence of non-carbohydrate reducing substances. Improvements have been made in procedures involving the use of copper reagents, and progress is also being made in the development of totally different methods which may some day provide the specific information needed. (emphasis added)

In other words, in 1973 there was an absence of technology enabling the determination of sugars to provide an accurate quantitation of carbohydrate content. However, it is clear that the authors foresaw a day when analytical enhancements would enable the adoption of an accurate approach to carbohydrate analysis. For wine, that day has arrived. The new method accepted by the AOAC International allows determination of carbohydrates in wine without interference from non-carbohydrate reducing substances, thereby avoiding most, if not all, of the problems identified above.

In 1985, the AOAC granted "First Action" status to a new method (recognized in 2012 as AOAC 985.09), which allowed for the accurate quantitation of glucose and fructose in wine (AOAC, 2012d). This new method is based on an enzymatic reaction, utilizing the enzyme hexokinase to catalyze a reaction with glucose and fructose. This creates compounds that undergo further reactions to form a very specific chemical that can then be selectively analyzed using a simple spectrophotometer, common in most laboratories. This highly selective method provides a much more accurate quantitation of glucose and fructose than earlier analytical approaches. Small amounts of sucrose are present in grapes, but at wine pH, sucrose undergoes acid hydrolysis and breaks into one molecule each of glucose and fructose. This enzymatic method of analysis is widely used throughout the wine industry, and has provided accurate and economical analyses of sugars for decades (Howe, Ebeler, & Sacks, 2015).

Another method developed after the publication of *Handbook 74*, is the analysis of sugars using High Performance Liquid Chromatography (HPLC). This method overcomes the interferences present in methods in use at that time. In an effort to address the inaccuracy inherent in the carbohydrate by difference method, the Wine Institute commissioned the development of an HPLC method for the measurement of sugars, which was accepted by the AOAC as First Action 2013.12 and published in the Journal of the AOAC International in 2014. (Kupina and Roman, 2014)

Simply put, by using methodologies to accurately determine the sugar content of wines without the interferences that were present in the methods used at the time of writing of *Handbook 74*, wineries can accurately measure true carbohydrates in wine and no longer need to estimate carbohydrate content inaccurately by utilizing the *Handbook 74* "by difference" method.





There is precedent for the use of matrix-specific methods and approaches when determining nutrients in food. For example, the method for testing fat in food varies based on the food type, and the AOAC Official Methods of Analysis lists fat testing methods for more than 20 different matrices. There are a number of fat testing methods, which are completely different from one another, while for some foods, there are matrix-specific alterations to the method that are required. Therefore, to alter the methodological approach for the wine matrix would be consistent with the approach taken for other test methods and matrices when current methods result in inaccurate data.

4. Conclusion

Wine Institute and WineAmerica request on behalf of the United States wine industry that the Commissioner amend subparagraph (c)(6) in 21 CFR §101.9, Nutrition Labeling of Food, to allow the summation of sugars to be used for calculating carbohydrate content in the case of wine and wine-based beverage products.

Wine Institute and WineAmerica submit the following as grounds for this request:

- 1. Wine producers disclose nutritional information to consumers, either as required by regulation or voluntarily in response to consumer requests.
- 2. The *Handbook 74* 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.
 - a. Grapes, from which wine is made, are specifically mentioned as one of these high organic acid-containing foods, the most prevalent acid being tartaric acid.
 - b. *Handbook 74* also pointed out that calories present in tartaric acid are probably biologically unavailable to a large extent.
 - c. Glycerol (the other major contributor to inaccuracy for total carbohydrate declarations in wine), is structurally and metabolically different from "true carbohydrates".
- 3. Summation of sugars, as noted in *Handbook 74*, is an appropriate method for calculating the level of carbohydrates in wine, providing accurate information for consumers and the trade.
 - a. Methods for accurate measurement of sugars now exist.
 - b. This technology has been officially recognized in AOAC official methods, is commonly in use in wine laboratories, and provides consistent and accurate determination of total carbohydrate in wine.
 - c. Organic acids, glycerol, or any other interfering components are not included in these measurements.

As we have shown, the inaccurate method as currently prescribed disproportionately harms wine in the marketplace and is misleading to consumers.





The Wine Institute and WineAmerica respectfully ask the Commissioner to review this Citizen Petition and move to implement the requested amendment to 21 CFR §101.9(c)(6) expeditiously so that wineries may provide consistent, accurate, and fair declarations of carbohydrate content in wine to consumers, while meeting the requirements of 27 CFR §4.39 (a)(1).

C. ENVIRONMENTAL ASSESSMENT

Wine Institute and WineAmerica make a claim of categorical exclusion of an Environmental Assessment because the actions requested in this Citizen Petition are exempt from the requirement of an environmental assessment pursuant to 21 CFR §25.30(k). Furthermore, the undersigned do not believe that the actions requested in this Petition would have any environmental impact.

D. ECONOMIC IMPACT

An economic impact report is required only when requested by the Administration and such report has not been requested. 21 C.F.R. §10.30(b).

E. CERTIFICATION

The undersigned certifies, that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to Wine Institute and WineAmerica that is unfavorable to the petition.

Sincerely,

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References:

- Amerine, M. A., Cruess, W. V., & Berg, H. W. (1980). *The Technology of Wine Making 4th Edition*: Avi Pub Co.
- AOAC. (2012a). Official Method 920.67 19th Ed. In: AOAC International, Official Method of Analysis, Gaithersburg, MD.
- AOAC. (2012b). Official Method 945.09 19th Ed. In: AOAC International, Official Method of Analysis, Gaithersburg, MD.
- AOAC. (2012c). Official Method 920.56 19th Ed. In: AOAC International, Official Method of Analysis, Gaithersburg, MD.
- AOAC. (2012d). Official Method 985.09 19th Ed. In: AOAC International, Official Method of Analysis, Gaithersburg, MD.
- AOAC. (2012e). Official Method 985.10 19th Ed. In: AOAC International, Official Method of Analysis, Gaithersburg, MD.
- Food Standards Australia New Zealand (2016). Standard 1.2.8 *Nutrition information requirements*. Retrieved from https://www.legislation.gov.au/Details/F2015L00395
- European Commission (2011). Regulation No. 2011/1169, Annex XIV. On the provision of food information to consumers. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&rid=1
- FDA. Nutrition Facts Label: Total Carbohydrate. Retrieved from https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/factsheets/Total_Carbohydrate.pdf
- Howe, P. A., Ebeler, S. E., & Sacks, G. L. (2015). A Review of Thirteen Years of CTS Winery Laboratory Collaborative Data. *American Journal of Enology and Viticulture*, ajev.2015.14119. doi:10.5344/ajev.2015.14119
- Kupina, S, & Roman, M, (2014). *Determination of Total carbohydrates in Wine and Wine-Like Beverages* by HPLC with a Refractive Index Detector: First Action 2013.12. Journal of AOAC International. Vol. 97, No. 2, 2014.
- Krasny, L. (2003, November/December, Wellness Foods). *Carb Claims: What can you say?*. Retrieved from Keller Heckman: https://www.khlaw.com/Files/3183 carbclaims.pdf
- 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
- Merrill, A. L., & Watt, B. K. (1973). *Energy Value of Foods: Basis and Derivation. Agriculture Handbook No. 74*. Washington DC: U.S. Department of Agriculture.
- Waterhouse, A. L. (2005). What's in Wine? Retrieved from http://waterhouse.ucdavis.edu/whats-in-wine/red-wine-composition
- Whitney, A., & Rolfes, S.R. (2005). *Understanding Nutrition*. 10th Edition, 2005. Thomson Wadsworth.