



1212 New York Avenue, NW Suite 425
Washington, DC 20005
www.wineamerica.org

Telephone: 202-783-2756
Fax: 202-347-6341
E-mail: info@wineamerica.org

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Chief, Regulations and Procedures Division
Alcohol and Tobacco Tax and Trade Bureau
Attn: Notice No. 41, P.O.Box 14412
Washington, DC 20044-4412

Dear Alcohol and Tobacco Tax and Trade Bureau:

Thank you for the opportunity to comment on Notice No. 41, Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages. Our comments, concerns, and the rationale to forego rulemaking are listed below.

Sincerely,

Bill Nelson, President
WineAmerica

Submitting Organization

WineAmerica is the National Association of American Wineries. With over 800 members in 48 states, it is the only winery trade association with national membership. The mission of WineAmerica is to encourage the dynamic growth and development of American wineries and winegrowing through the advancement and advocacy of sound public policy.

Overview

The ANPRM seeks, among other things, comments on potentially expanding the required information present on alcoholic beverage labels which, if the Bureau chooses to do, would have multiple negative effects on wineries and consumer understanding.

The consumer, for whom this is intended, would receive very little, if any benefit from the proposed additional information. This information may actually be detrimental to the consumer by detracting from important existing information such as the Government Warning, the sulfite statement and alcohol content while causing the potential for information overload. For wine, most of the additional information under consideration is well defined and limited by the standards of identity for the particular

wine. These standards do not allow significant variation and the consumer may obtain the necessary information by consultation of general references either in print or on the Internet.

American wineries would face significantly increased costs of doing business which could jeopardize the viability of many small wineries across the nation. Our contention is that this information provides very little if any practical consumer information, will clutter the look of wine labels and undermine the important aesthetics of those labels, will require each winery to redesign each of their labels, may engender extensive and expensive analysis costs on an annual basis and will require expensive label reprinting annually for each wine.

Wineries are Primarily Small Businesses and the TTB Should Determine the Impact of the Proposed Changes on the Affected Industry

The United States Small Business Administration (SBA) provides the definition of what constitutes a small business based on size standards. Wineries are considered small if they employ less than 500 employees. Based on 2002 data from the SBA, 98% of all wineries met the SBA small business definition. This is consistent with the recent history of wine production in the United States which has been characterized by an enormous increase in the number of small, family run operations. Since 1980, the number of wineries has quadrupled, from 919 in 1980 to 3,726 in 2004. Of these, more than 95% qualify for favorable treatment under the small producer tax credit.

This increase, primarily in the number of small businesses, has been fostered by explicit Congressional and TTB policy including passage of a small producer tax credit in 1990 helping wineries producing less than 250,000 gallons, latitude for simplified small winery reporting of excise tax obligations and differential rates for the Special Occupational Tax. To establish a new and onerous labeling policy would seriously undermine these small businesses and have proportionally greater impact on small wineries. Additional labeling requirements, for at best questionable information purposes, would be against stated Congressional policies. The TTB should balance the regulatory goals of greater consumer information against the burden such rules would place on small wineries. This is especially cogent when one considers that the vast majority of important information is easily accessible to consumers through other means than product labeling. The cost to implement the proposed label changes would be prohibitive. These costs include expensive label redesign, required laboratory analysis and printing and regulatory compliance costs for more frequent printing and submission of smaller batches of slightly differentiated labels. It is our belief that the consumer has more than adequate information describing wines under the present regime.

Congress has also generally fostered small businesses through the Regulatory Flexibility Act (RFA) by requiring agencies to take the needs of small businesses into account when promulgating rules. (Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996).) We would encourage the TTB to comply with the RFA when it drafts the proposed rule. In our opinion, the proposed changes contemplated by the TTB would have a significant impact on a substantial number of small wineries. Therefore, the TTB should comply with section 603 of the RFA and prepare an Initial Regulatory Flexibility Analysis (IRFA) in an effort to determine the true impact of any labeling changes on the industry. Our organization has endeavored to provide the TTB with size and cost data in this comment letter to help facilitate the preparation of the IRFA. We would be pleased to provide the TTB with any additional information necessary to demonstrate how the proposed labeling changes will affect our industry.

Specific Issues:

Nutrition Labeling

WineAmerica opposes nutritional labeling on wine labels. Wine is not a food consumed for primarily nutritional purposes. Wine has no fat or protein. Caloric content in wine would normally be derived from a simple relationship with the wine's alcoholic content which is required (at least within fairly narrow ranges) to be indicated on each wine label. The primary source of calories in a wine is from the alcohol unless the wine is very sweet. The vast majority of wines are either dry or only slightly sweet. A consumer interested in wine calories could easily consult the Internet or reference works to determine approximate ranges for types of wines to determine a wine's nominal caloric content. For example the web site [weightlossforall.com](http://www.weightlossforall.com) (<http://www.weightlossforall.com/carbohydrates-wine.htm> accessed July 28, 2005) states: "There is not much difference between the carbohydrate content in most wine so we have only listed a few. Carbohydrates are not the main source of energy in wine its the alcoholic levels that contain most of the calories."

In reality this issue is much more complicated and confusing because considerable medical evidence indicates that consumption of alcohol is not associated with weight gain and may even be associated with weight loss. (See <http://www2.potsdam.edu/hansondj/AlcoholCaloriesAndWeight.html> accessed 9/13/2005 and references included with that page). This is because alcohol consumption appears to increase metabolic rate, the biochemical pathway for alcohol consumption is different than other nutrients, and consumption of moderate amounts of alcohol such as that contained in wine may affect the absorption efficiency of other foods consumed at the same time. (Lawrence Feinman, Absorption and utilization of nutrients in alcoholism; *Alcohol Health & Research World*, Summer, 1989, Eric Jequier, Alcohol intake and body weight: a paradox; *American Journal of Clinical Nutrition*, Vol. 69, No. 2, 173-174, February 1999) Suffice it to say that nutritional labeling of wine may mislead more than inform the public. In addition, allowing nutritional labeling may give the improper and misleading impression that wine has nutritional value.

As the TTB has previously observed, partial information can have the effect of misleading the consumer. Wine labels simply do not contain enough space to reasonably inform the consumer of the complexities and subtleties inherent in nutritional labeling of beverages containing alcohol. Even if sufficient space was available, it could subtract from the essential mandatory components required on all wine labels. The TTB has always taken a strong stance against misleading the consumer, as evidenced by the issue of health claims on labels when the TTB stated "...labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects of alcohol consumption." (27 CFR Section 4.39 h.2) Nutritional labeling should also have a similar burden of providing accurate and balanced information. If additional nutritional information is desirable, the consumer could be directed to more complete sources of nutritional data on alcoholic beverages, either company web sites or more general third party documents and sources.

Nutritional labeling would be prohibitively costly for America's smaller wineries. Wineries do not manufacture wine to specification. It is the natural product of grapes which are quite variable by lot, vintage year, grape variety and blend. Small wineries frequently produce small quantities of many types of wine. Typical costs for analytical laboratories to perform nutritional analysis are approximately \$750. In addition, there are delays associated with getting these analyses done, additional printing costs for labels which may now change from year to year (typically \$200 per label type), regulatory costs for approval of labels, and an initial, very expensive, investment in changed label design in order to accommodate new label "real estate."

WineAmerica's position is that nutritional labeling is inherently misleading because it is unbalanced and does not provide a true and accurate picture of the product's metabolic effects. The TTB would be better served by establishing additional standards of identity for products, like light beer, claiming differentiation from the ordinary.

Alcohol and Serving Facts Labels

There is general, though not universal, agreement that a typical glass of wine contains 5 oz. of wine. This is so even though size, shape and configuration of wine glasses varies widely from the usual tulip shaped glass to tumblers, flutes, and in some restaurants even fruit jars. Some believe that the 187 ml. bottle represents a single serving of wine even though its content is more than 25% greater than a 5 oz. glass. Notwithstanding limits imposed by TTB standards of identity, the proposed icon illustration for alcohol equivalence is grossly misleading to the consumer. Wine can vary from as little as 7% to as much as 24% alcohol by volume. Spirits products can vary from 5% or even lower to 90% or even higher. To glibly suggest that 1.5 oz. of spirits is somehow the same as 5 oz. of wine is completely misleading. A shot glass of 1.5 oz. of 160 proof spirits contains almost 3.5 times as much alcohol as 5 oz. of wine. To suggest that these drinks are equivalent is extremely misleading and possibly dangerous.

Current alcohol content labeling should be adequate for wine because it provides sufficient consumer information. While wine labeled table wine can vary by a factor of two, the way table wine is consumed, normally with food, has an even greater effect on the actual adsorption and rate of adsorption of the alcohol in that wine. There is also great individual variation in the efficiency of wine alcohol absorption to the blood stream. Most individuals have had previous experience with wine consumption, understand the different categories of wine, can tell from the label when a wine contains higher alcohol such as varietal wines which exceed 14%, and therefore can adequately determine an appropriate amount for their consumption. Furthermore, the consumer is comfortable with alcohol by volume and understands the implications of that measure. To introduce another measure such as ounces of pure alcohol will serve to confuse virtually all consumers and is inherently a disservice. Mandatory and unnecessary additional label information will just add to clutter and confusion without helping the consumer.

Ingredient Labeling

Previous rulemaking experience of the TTB, outlined in the ANPRM, addressed this issue and there is no new information indicating that the net effect on the consumer of ingredient labeling would be more beneficial than misleading. Wine is the natural result of fermentation of the underlying fruit by yeast. TTB regulations with very tightly drawn standards of identity and limitations on additives ensure that standard wines are essentially direct products of fruit and as such are adequately described to the consumer. Just as fresh peaches and watermelons are not required to list their "ingredients" (seed, water, sunlight, soil, fertilizer, pesticides) it makes no sense to require a listing of ingredients for wine. Such a listing only adds to the clutter of labels, greatly increases the costs for small wineries, and further undermines the consumer's ability to discern what label information is meaningful by the addition of words conveying little worthwhile information.

Allergen Labeling

While the recently passed Food Allergen Labeling and Consumer Protection Act of 2004 provides a number of requirements for the labeling of food in order to protect consumers with food allergies, the act does not directly apply to beverage alcohol products. Report language accompanying the legislation directs the TTB to apply allergen labeling to beverage alcohol products "*as appropriate.*"

To our knowledge there are no known cases of individuals with serious food allergies to wine. Wine is not produced from any of the eight major food allergens listed by the Act, but may contain trace residues of some of them due to fining with allergenic agents. It is the nature of proteinaceous fining agents that they are normally denatured and precipitated by the fining process. That is the whole idea behind using these agents to clarify wine. Whether any appreciable protein epitopes survive the fining process, and in what quantity, is an open question. The FDA, through its Food Advisory Committee, has established a working group to advise it on approaches to establishing thresholds for major food allergens. This group prepared a report and met with the committee in July 2005 to discuss that report.

The committee was clearly anxious to determine safe thresholds for incidental content of allergens especially since they wished to provide guidance for labeling of processing aids. Unfortunately, the committee determined that the available science at this time is very limited and does not provide reasonably determined thresholds below which there are no risks. Some allergic individuals seem to be exquisitely sensitive to food allergies. Testing for the lower limit of their response in a scientifically meaningful way is a real challenge. Most of the testing, limited to begin with, has been done at much higher levels to determine who might have a food allergy rather than what is the lowest level capable of producing an observed response. Furthermore, the question of whether there exists an individual with higher sensitivity, or alternatively, what safety factors should be applied, adds to the difficulty. It is unclear whether this committee will be able to recommend threshold levels or even indicate that there are reasonable levels below which some of these allergens do not pose risks before the effective date of the legislation.

Given this level of confusion and the inability of the FDA to provide clear threshold guidance to the TTB, WineAmerica believes that the TTB should hold off on consideration of any requirements for allergen labeling of wine and other beverage alcohol which has been fined with applicable food proteins until the FDA completes its findings on thresholds. Because the scientific work which is necessary to underpin such findings is difficult and expensive, it may be several years until that information is at hand.

International Harmonization

In the increasingly international environment for which American wineries now operate there are great operating efficiencies and savings which could be achieved if international harmonization of labeling requirements were implemented and products bottled and labeled under United States standards could be suitable for sale in other countries without requiring costly re-labeling. These savings would be especially dramatic for smaller wineries exporting a portion of their product, a practice which is becoming evermore common as wineries are able to participate in the USDA Market Access Program. Various international trade bodies are working on facilitating harmonization and we support those efforts. To achieve harmonization it is critically important that consensus be reached on key issues of labeling requirements. Frivolous, inappropriate, or even minimally utilitarian requirements imposed by one country could undermine the consensus process.

Agency and International Harmonization

Congress has long recognized that the public interest in label information for alcoholic beverages is substantially different than for other foods. Congress chose not to include authority for alcoholic beverage label requirements in the Federal Food, Drug, and Cosmetic act. Clearly, the complexities and limitations of standards of identity and the nature of these beverages as products of fermentative

transformation justify the Congressional action of providing a different regulatory scheme. The TTB is the expert agency for wine labeling and should continue to regulate in light of its accumulated expertise.

The TTB has also requested recommendations on harmonizing regulations with other countries. Many wineries producing and labeling wine in this country also export part of their production. To the extent that TTB regulations and the regulations of other major wine producing and importing countries correspond and require common labeling standards, such harmonization would facilitate business and increase winery interest in export trade.

Cost Estimates

While every winery situation is different, there is no doubt that mandatory label changes will generate very high costs for America's more than three thousand wineries. We estimate that redesigning labels will involve one time costs of about \$2,000 to \$5,000 for each general label style. While some wineries only have one label style with different information depending on the type of wine, many have three or more. Therefore, the label redesign costs are likely to range from a low of \$2,000 to a high of \$15,000 for typical wineries. In many cases the label redesign will require the production of new dies for cutting labels in different shapes.

On an ongoing basis, some of the proposals for detailed mandatory information will require annual analysis and reprinting of labels in smaller and more frequent lots. The printing costs required for printing each label each year in smaller lots could easily be in the range of \$200 - \$300 per label. Typically very small wineries have around 15 labels, so they would have to invest between \$3,000 and \$5,000 each year in extra printing costs.

Additional analysis costs will be engendered by some of the proposed changes. While wineries already perform alcohol testing, no small winery does nutritional testing. The cost of nutritional label analysis from independent laboratories is about \$750 per sample. For the 15 labels average of smaller wineries the cost would exceed \$12,000 per year.

Allergen testing could also entail significant analytical costs. Such tests, even if they were available at this time, might cost \$100 or more for each sample of each allergen. In some cases this might mean \$300 per wine. For 15 wines, that additional cost is about \$4,000. Most wineries might shy away from the additional costs and may choose to label all their wines "may have been fined with egg, milk or fish proteins" which if universally adopted will be effectively useless information for those with allergies. If all of these factors are summed, a typical small winery might face costs of about \$20,000 per year and a one time cost of around \$10,000. For small family businesses this is an enormous burden.

Beyond the direct costs to wineries, consumers may also suffer from a lack of choice and be subjected to increased prices, as the direct costs will force wineries to limit or even shutdown some of their operations and possibly pass on some of these new input costs to the consumer.

The net effect would make it more difficult for American wineries to compete with foreign imports, which already have a strong hold in many local markets.

Conclusion

While the proposed label changes would be extremely costly, especially for small wineries, there are very few benefits for the consumer and indeed there are overriding concerns that the consumer might easily be misled by such additional information. Caloric labeling is fundamentally flawed and

misleading; carbohydrates do not vary much in typical wines and are pretty much in accordance with the wine's standard of identity. The alcohol content of wine is already required to be stated on the label. More exact specification of alcohol content and caloric content is not beneficial because there is so much physiological variation in rate of uptake especially when wine is consumed, as it normally is in conjunction with food. Allergens present in wine as a result of fining agent residuals are there in only miniscule quantities. No one has yet demonstrated or documented a significant health risk to consumers from food allergen residues in wine. Since the FDA has not been able to establish threshold levels for the safe presence of those allergens it does not make sense to mislead the public that a particular wine may have been processed with egg or milk. The TTB should use its discretion under the law to await FDA determination of thresholds for food allergens, a process which may take several years.

We have previously commented to TTB on the use of graphic icons purporting to claim that one kind of drink is equivalent to another. Use of such graphic symbolism is patently misleading since the alcohol content and method of use of each beverage varies so much even within the broad beverage types. Certainly 1.5 oz. of a 130 proof drink is vastly different than 1.5 oz. of a 40 proof drink. Wine may vary from 7% to as much as 24%. Beer too has great variation. Consumers need to pay greater concern to what it is they are drinking, under what circumstances, how quickly and whether that consumption is accompanied by food. Downing shots of high proof alcohol at a bar or even drinking directly from the bottle at a party, is certainly much riskier behavior than the consumption of two glasses of wine over a long dinner. False analogies are likely to be more misleading than informative. The public may need education about safe and sensible drinking but it should not be misled into false complacency by glib images.

Harmonization with other countries is a reasonable goal and we recommend that the TTB explore such opportunities.

WineAmerica, on behalf of over 800 wineries throughout the country, urges the TTB to forego rulemaking on labeling at this time.