November 15, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0921 and RIN 0910-AG35,
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

To Whom It May Concern:

The California Association of Winegrape Growers (CAWG), a statewide organization representing winegrape growers, and Wine Institute, the public policy trade association of California wineries, submits the following comments regarding proposed rule (RIN 0910-AG35) to establish standards for the growing, harvesting, packing, and holding of produce for human consumption. CAWG's 721 grower members represent a majority of California's 540,000 winegrape acres. Many of Wine Institute's over 1,000 winery members are small, family businesses, with about 70% of our members producing under 5,000 cases of wine a year. Wine Institute's members also include large, family-owned and publicly traded companies, responsible for 85% of US wine production. The California wine industry generates more than 300,000 jobs in the state and over 800,000 nationwide. We are pleased to submit these comments to the FDA in response to its proposed rulemaking to establish FSMA-based standards for the growing, harvesting, packing, and holding of produce for human consumption. Both CAWG and Wine Institute believe that winegrapes should be exempt from regulation under the proposed rule

CAWG and Wine Institute respectfully request the following:

- That proposed Section 112.1 distinguish between grapes and winegrapes; and
- That proposed Section 112.2 recognize winegrapes as part of the list of produce that is rarely consumed raw.

The proposed produce regulations first identify "grapes" as produce that is covered (proposed Section 112.1). The provisions at Section 112.2 further identify produce that is NOT covered by the proposed regulations, and includes an "exhaustive list" that does not include winegrapes. Further, the regulation

provides an exemption for covered produce that requires the grower to maintain documentation that the covered produce received commercial processing that adequately reduces the presence of microorganisms of public health significance:

> (b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:
>
> (1) The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;
>
> (2) You must establish and keep documentation in accordance with the requirements of subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and
>
> (3) The requirements of this subpart and subpart Q of this part apply to such produce.

CAWG and Wine Institute fully support FDA's efforts to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption. However, we disagree with FDA's inclusion of grapes in its proposed list of produce that are covered by the regulations because winegrapes are not consumed raw and the documentation burden imposed on winegrape growers to maintain an exemption under proposed Section 112.2 is unreasonable.

<u>Winegrapes Are Not Consumed Raw</u>

Proposed section 112.1 (b)(1) expressly includes "grapes" as covered by FSMA, subject to exemptions and qualified exemptions. Winegrapes, however, are very different from the table grape varieties that are sold at supermarkets for raw consumption. While winegrapes are edible, most of the grapes converted to wine aren't of the kind preferred for raw consumption. Generally, winegrapes are not grown or selected for raw consumption, but rather selected for properties that make good wine. Winemakers select specific grape varietals based on skin, color, and texture, among other things. Virtually all winegrapes are grown, harvested, and then delivered for processing at a winery, which is generally exempt from FSMA rules.

Winegrapes are grown for the specific purpose of making wine and distilled alcoholic beverages, and winegrapes have no significant commercial value as a product for fresh consumption. Some winegrapes may be crushed to make juice and concentrate, but typically these products are later used by commercial and home winemakers. Depending upon market conditions, growers of raisin and table grape varieties may elect to sell some of their crop to processors who produce wine, concentrate, juice, vinegar and brandy. But, growers of winegrape varietals do not have comparable flexibility to sell into the fresh market.

While table grapes and winegrapes, generally, belong to the same plant species, Vitis vinifera, significant distinguishing features, resulting from selective breeding, differentiate table and winegrapes. Table grape cultivars tend to have large, seedless fruit with relatively thin skin. Winegrapes are smaller, usually seeded, and have relatively thick skins (a desirable characteristic in winemaking, since much of the aroma in wine comes from the skin). Winegrapes also tend to be very sweet: they are usually harvested at the time when their juice is approximately 23% – 28% sugar by weight.

Depending upon prevailing market prices, some growers of raisin and table grape varieties will sell into the winery market, but the converse is not true. Growers of winegrape varietals do not sell their grapes into the fresh market. According to table 1 of the *California Grape Crush Report 2012*, raisin and table grape varieties accounted for only 6.15% and 2.26%, respectively, of the 4.39 million tons of grapes crushed in California for wine, brandy, other distilled products, juice and concentrate.

The California Table Grape Commission reports the top table grapes by volume shipped for 2010-11 are Autumn Royal, Autumn King, Blanc Seedless/Pristine®, Crimson Seedless, Flame Seedless, Princess, Red Globe, Ruby Seedless, Scarlet Royal, Sugranineteen/Scarlotta Seedless®, Sugraone, Summer Royal, Thompson Seedless, and Vintage Red. Of these listed table grape varieties, only two (Princess and Thompson Seedless/Sultanina) are approved by the U.S. Alcohol and Tobacco Tax and Trade Bureau for use as varietal designations for American wines (27 CFR Section 4.91, et seq).

According to information available on the University of California Integrated Viticulture website (http://iv.ucdavis.edu/Viticultural_Information/?ds=351&reportnumber=516&catcol=2603&categorysearch=Raisin%20Grape%20Production), about 95% of California raisins are currently produced from 'Thompson Seedless' grapes, followed by 'Fiesta' 3% and 'Zante Currant' 1.5%. While some wineries may purchase these varieties to crush and process into wine, in California, they are not specifically grown as winegrapes.

Of the grape varieties produced for the fresh table grape market or for raisins, only a handful are also recognized as winegrape varietals, and as winegrape varietals they represent a small portion of the total amount of grapes crushed for wine. The single exception is Thompson Seedless which is the most

versatile of grapes in terms of market opportunities. Thompson Seedless is utilized as fresh, raisin, wine (and distilled alcohol products), and concentrate. However, Thompson Seedless represented only 5.3% of the total amount of grape tonnage crushed in 2012. Typically, the first choice of Thompson Seedless growers is to sell their harvest as raisins or table grapes.

For a comprehensive listing of grape varieties, FDA can use the National Grape Registry, which also includes descriptive information about those varieties. The list can be found at website: http://ngr.ucdavis.edu/varietylist.cfm.

Winegrapes Are Not Grown In the Same Manner as Table Grapes

Winegrapes aren't grown in the same manner as table grapes. As previously stated, winegrape varietals lack the characteristics desired for raisin and table grapes. Moreover, there are distinct differences in cultural practices between wine, table and raisin grapes. Generally, winegrape vineyards utilize a variety of cultural practices, which include different irrigation practices and trellis systems, distinct from those used in raisin and table grape vineyards. For example, winegrape growers rigorously manage irrigation schedules to limit the availability of water during the growing cycle to ensure optimal flavor development and smaller grape berry sizes (which is undesirable for fresh table grapes or raisins). Finally, harvest methods for winegrapes are very different than those used for table and raisin grapes. Once winegrapes are harvested for processing into wine, brandy, juice or concentrate, they are rendered unsuitable for fresh table or raisin grape markets.

In addition to cultural practices which distinguish the production of wine, table and raisin grapes, there are important geographic distinctions to consider. The production of table and raisin grapes in California is concentrated in a few counties. According to the *California Grape Acreage, 2012 Crop* report, prepared by the U.S. Department of Agriculture National Agricultural Statistics Service, California Field Office, five counties – Fresno, Kern, Madera, Riverside and Tulare – contain 99.1% of all California raisin grape acres. Those same five counties, plus Kings County, represent 98.6% of all table grape acres. In contrast, the six counties where table and raisin grape production is concentrated account for 22% of the state's total reported winegrape acres. Thus, FDA can reasonably conclude that the overwhelming majority of grape production occurring outside these counties is dedicated to winegrapes.

A Snapshot of the Winegrape Industry:

Based on reported data found in table 1 of the *California Grape Crush Report 2012*, from the U.S. Department of Agriculture National Agricultural Statistics Service, California Field Office, the 25 specific winegrape varieties listed below account for 96.4% of all winegrapes crushed in 2012. The 10 varieties noted with an asterisk accounted for 62.8% of all winegrapes crushed in 2012. CAWG is unaware of any commercial production of the listed varieties below for fresh consumption.

White Wine Varieties	Red Wine Varieties
Burger	Barbera
Chardonnay*	Cabernet Sauvignon*
Chenin Blanc	Grenache
French Colombard*	Malbec
Gewurztraminer	Merlot*
Muscat Blanc	Petit Verdot
Muscat of Alexandria	Petite Sirah
Pinot Gris*	Pinot Noir*
Sauvignon Blanc*	Rubired*
Symphony	Ruby Cabernet
Triplett Blanc	Syrah*
Viognier	Zinfandel*
White Riesling	

The 25 winegrape varieties above represent by volume the most important winegrapes produced in California, however, there are many other established winegrape varieties grown in California that have no significant value as table or raisin grapes. Eighteen varieties of winegrapes (Albarino, Alicante Bouchet, Cabernet Franc, Carignane, Carnelian, Gamay, Grenache Blanc, Pinot Blanc, Primitivo, Roussanne, Sangiovese, Semillon, Tannat, Tempranillo, Touriga Nacional, and Verdelho) account for an additional 2.4% of winegrapes crushed and processed into a finished product. Together, the 43 above listed winegrape varieties account for 98.8% of winegrapes crushed in California in 2012. However, this is not a complete listing of all winegrapes produced in California. CAWG encourages FDA to reference the annual *California Grape Crush Report*, from the U.S. Department of Agriculture National Agricultural Statistics Service, California Field Office, to find a comprehensive listing of winegrape varieties produced in the state.

A Small Portion of Winegrapes Reach the Consumer Market:

Some winegrapes do eventually get sold for human consumption, but this is rare. In 2012, the California Table Grape Commission recorded a combined total of 2,520 boxes of French Colombard and Carignane shipped as fresh table grapes. These are generally recognized as winegrape varietals. In contrast, California ships approximately 100 million boxes of table grapes annually (the Table Grape Commission reported 101 million boxes shipped in 2012). Thus, the 2012 shipments of French Colombard and Carignane as table grapes represent less than .002% of total fresh California table grape shipments.

Winegrape Growers Cannot Meet Documentation Requirements of FDA Exemption

In order to be exempt from the produce rules, proposed Section 112.2 states that winegrape growers must qualify for an exemption by proving that the winegrapes received commercial processing that adequately reduces the presence of microorganisms of public health significance and identifying the recipient of the covered produce that performs the commercial processing.

Invoices and records usually accompany the delivery of winegrapes to wineries, but those records do not usually go further to identify that the winery that received the winegrapes applied "commercial processing that adequately reduces the presence of microorganisms of public health significance." Winegrapes delivered to a winery are generally directly converted to wine, but a grower will usually not be privy to the specific production processes that the crop undergoes nor who performs them. Further, winegrapes delivered to a winery may be crushed and converted to grape must at the first facility, then transferred to another winery for fermentation and additional processing, without any knowledge by the grower. Yet while the winery may be exempt from many FSMA provisions, the winegrape grower under the proposed rules would be obligated to maintain records that authenticate microbiological processes that are outside the scope of a winegrape grower's knowledge.

CAWG and Wine Institute believe that these record-keeping obligations impose an unreasonable burden on the winegrape grower and are not in the public interest. Over the course of human history, wine has been valued because it is free from harmful pathogens and was often added to water due to its antimicrobial properties. Obviously, today's consumers value wine for different reasons, but we are unaware of any reports in the United States of human illness attributable to microbial hazards found in wine or in winegrapes. Congress has recognized that alcoholic beverage production is already heavily regulated and has not posed a food health risk. Generally, human pathogens are unable to survive at wine pH levels and ethanol concentrations.[1] Fermentation of winegrapes results in a wine that is inhospitable to disease-producing microorganisms due to wine's acid environment and ethanol content. Acid interferes with cell pH homeostasis and the denaturing action of alcohol interrupts cell membranes of bacteria, resulting in the rapid release of intercellular constituents. Pathogenic microbes are eliminated. The only ones left are yeast, lactic acid bacteria and acetobacter, which pose no human health risks. It is generally accepted that wine is also bactericidal to foodborne pathogens.[2]

Most commercially available grape wines have a pH balance ranging between 3.0 and 3.9, with 3.5 being a typical value. And, as defined by the U.S. Alcohol Tobacco Tax and Trade Bureau, the alcohol content of standard grape wines may range from 7 to 24-percent alcohol content by volume. In practice, the

[1] "Contribution of Wine Components to Inactivation of Food-Borne Pathogens," J.G. Waite, M.A. Daeschel, Journal of Food Science, Volume 72, Issue 7, pages M286-M291, September 2007

[2] "Wine is Bactericidal to Foodborne Pathogens," T. Moretro, M.A. Daeschel, Journal of Food Science, Volume 69, Issue 9, pages M251-M257, December 2004.

average alcohol content of commercially available wines ranges from 10.5 to 15-percent alcohol by volume.

Winegrapes destined not for wine but for facilities that will convert the fruit into commercial juice and concentrate are subject to the juice HACCP requirements of part 120 (21 CFR part 120).

Conclusion:

In summary, we want to emphasize the following key points:

- Grape varieties known as winegrape varietals are rarely consumed raw and have little to no commercial value as table or raisin grapes. The *California Grape Crush Report*, issued annually by the U.S. Department of Agriculture National Agricultural Statistics Service, California Field Office, provides a good, comprehensive listing of the most significant varieties of winegrapes produced in California.
- Winegrape varieties are distinguishable from other raisin and table grape varieties, and once winegrapes are harvested for processing into wine, juice, or concentrate, they cannot be sold into table or raisin markets.
- Cultural practices and geographic considerations distinguish the production of wine, table and raisin grapes.
- The overwhelming volume of winegrapes are crushed by processors to make wine and beverage brandy, but a small portion of California winegrapes may be crushed to make concentrate and juice, two products which are often subsequently used in commercial and hobby winemaking.
- Generally, human pathogens are unable to survive at wine pH levels and ethanol concentrations and wine is also bactericidal to foodborne pathogens. Grape wine is inherently free of active microbial pathogens that may be harmful to humans.
- Winegrapes delivered for processing into juice or grape concentrate enter facilities that are subject to the juice HACCP requirements of part 120 (21 CFR part 120).
- A small but significant quantity of raisin and table grape varieties are crushed for wine and beverage brandy, but little to no established California winegrape varieties are sold into fresh table or raisin grape markets.

For all these reasons, CAWG and Wine Institute propose the following amendments to proposed sections 112.1 and 112.2 that will distinguish winegrapes from table grapes and recognize winegrapes as part of the list of produce that is rarely consumed raw. These changes would not change the obligations that a grower would have for grapes that it grows primarily for raw consumption, but would exempt winegrapes from the provisions of the produce rule.

§ 112.1 What food is covered by this part?

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. (b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following: (1) Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes**, not including winegrapes**, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon; and (2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list—arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, ***winegrapes for conversion into wine, juice, and concentrate,*** winter squash (acorn and butternut squash), and yams …

Thank you for providing us with an opportunity to comment upon FDA's proposal. We stand ready to assist FDA in these important endeavors and, if you have any questions regarding our submission, please do not hesitate to call: California Association of Winegrape Growers, 916-379-8995, or Wine Institute, 415-512-0151.

Sincerely,

John Aguirre
President, CAWG

Robert Koch,
President and CEO, Wine Institute