

Winegrapes and the Food and Drug Administration's Produce Safety Rule

California winegrape growers seek to exempt winegrapes from the Food and Drug Administration's (FDA) Produce Safety Rule on the basis that winegrapes are rarely consumed raw. Included in the final Produce Safety Rule, FDA established a list of exempt produce commodities identified as rarely consumed; winegrapes were not included on the list of commodities rarely consumed raw.

Background

The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011 with the intention of protecting public health by better ensuring the safety and security of the food supply. A key element of the FSMA was a requirement that FDA develop minimum science-based regulatory standards for fresh fruits and vegetables consumed raw. FDA published the final Produce Safety Rule on November 27, 2015, which establishes standards for the safe growing, harvesting, packing, and holding of produce on farms.

Certain raw produce commodities are excluded from the Produce Safety Rule, under § 112.2(a)(1), because these commodities are rarely consumed raw and the preparation (i.e., cooking) of these commodities by consumers or processing by a commercial processor sufficiently reduces or eliminates microbial hazards of public health significance that may be present. The final rule excluded from regulation thirty-three produce commodities, including asparagus, collards, figs and potatoes. Growers of these commodities are categorically exempt from the rule.

Alternatively, growers of produce commodities not listed as rarely consumed raw may qualify for a commercial processing exemption under the Produce Safety Rule, under § 112.2(b), provided such produce is processed in a manner that adequately reduces pathogens. FDA recognizes that while some commodities are often consumed raw, many growers produce these same commodities for processing. To obtain a processing exemption, growers of such produce are required to provide certain disclosure and documentation to the processor, annually obtain certain written assurances from the processor of the commodity, and maintain relevant records that must be made available to FDA upon request.

In the final rule, FDA made clear winegrapes are covered produce subject to the Produce Safety Rule. However, FDA acknowledged that, "Winemaking adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation). We are adding this to our list of examples of products of commercial processing in § 112.2(b)(1)." So, to obtain relief from the Produce Safety Rule winegrape growers must utilize the commercial processing exemption.

Commercial Processing Exemption

While the commercial processing exemption offers winegrape growers regulatory relief, compliance with the terms of the exemption entail significant notice and recordkeeping requirements, which contribute little to reducing public health risks and are burdensome for growers and wineries.

To qualify for the commercial processing exemption, beginning in 2018, growers of winegrapes must perform a two-step process: growers need to provide notice with each load of winegrapes shipped to a winery that the grapes are “not processed to adequately reduce the presence of microorganisms of public health significance.” In addition, with each load shipped, growers must also provide to the winery–

1. The name and location of the vineyard from which the grapes were harvested,
2. An adequate description of the covered produce, such as the specific variety of the grapes, and
3. The location of the growing area within the vineyard (i.e. the specific block where the grapes were grown).

The second step requires growers obtain from each winery written assurance that the grapes received from the grower were processed in a manner to adequately reduce the presence of microorganisms of public health significance. Just like the delivery documents the grower sends with each load of grapes, the annual assurance must include the name and location of the vineyard, an adequate description of the covered produce (i.e. specific variety), lot number (if available), and the location of the specific growing area (specific block or portion of the vineyard). Growers utilizing the commercial processing exemption will be required to retain for two years relevant notice and assurance records for all loads shipped.

If a grower sells winegrapes to an intermediary (broker, packing shed or crush facility) that in turn sells the grapes or unfermented grape juice to a third party, that intermediary is required to provide notice to the third party that the grapes have not been processed in a manner to adequately reduce the presence of microorganisms of public health significance and must obtain assurance from the third party that the grapes have been processed.

The processing exemption is burdensome and unsatisfactory for the following reasons –

- Notice requirements are very specific and failure to adhere to any part of the notice and assurance process may void the exemption for the grower;
- Growers already face tremendous recordkeeping burdens compelled by a myriad of federal, state and county regulations and additional recordkeeping is burdensome;
- Growers may sell to multiple different wineries or other buyers who take title to the winegrapes and growers will need to obtain assurance from each and every buyer of grapes shipped; and
- Winegrapes in California are rarely consumed raw.

Winegrapes Should Be Exempted From Produce Safety Rule for Reason of Being Rarely Consumed Raw

Winegrapes 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. In California, winegrapes are not grown or selected for raw consumption, but rather selected for properties that make good wine. Winemakers select specific grape varieties based on skin, color, and texture, among other things. Virtually all California winegrapes are grown, harvested, and then delivered for processing at a winery.

The California Association of Winegrape Growers (CAWG) and the Wine Institute submitted joint comments, dated November 15, 2013, on the proposed Produce Safety Rule, that argued winegrapes are rarely consumed raw and should be included in the exhaustive list of rarely consumed raw produce, § 112.2(a)(1). Attached is a copy of the November 15, 2013 comments. FDA rejected the request to include winegrapes as a commodity that is rarely consumed raw.

In its final rule, FDA stated, “Based on the data available to us, we do not agree that wine grapes meet the criteria for rarely consumed raw.” FDA’s rationale for rejecting the argument that winegrapes are rarely consumed raw is based on limited data and a failure to understand how the various distinct grape sectors operate.

FDA utilized the NHANES/WWEIA datasets to determine which foods are rarely consumed raw. NHANES/WWEIA refers to ‘What We Eat in America’ (WWEIA), a dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES). WWEIA is a partnership effort between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The FDA acknowledged that the NHANES/WWEIA data are imperfect, did not distinguish between varieties, and includes grapes used in the making of both wine and sherry, but the agency stated,

“...we consider the NHANES/WWEIA data to be the best data available for this purpose, and using this data it appears that “wine grapes” do not meet the criteria for rarely consumed raw. We do not have information on the specific grape cultivars or varieties that are solely and exclusively grown for use in winemaking that would allow us to establish a category covering only “wine grapes” and evaluate their eligibility using currently available dietary consumption data.” <https://www.federalregister.gov/d/2015-28159/p-498> (*Federal Register* 11/27/2015)

FDA’s reliance on NHANES/WWEIA means the agency’s determination as to whether winegrapes satisfy the meaning of a commodity rarely consumed raw rests entirely on consumer recall through an interview process. Generally, speaking, we don’t believe consumers, when asked, would know whether they are consuming a variety of grape specific to making wine, raisins or use as a fresh table grape. Moreover, it’s immaterial what the NHANES/WWEIA data may reveal, or not, regarding the potential consumption of winegrapes in fresh form, when other sources of data better document the potential of winegrapes to be consumed raw as table grapes or raisins.

FDA Should Consider Other Data in Determining Whether Winegrapes Are Consumed Raw

Instead of relying solely on consumer interview data to determine whether winegrapes are consumed raw, FDA should consider other data which answers the question whether or not winegrapes are actually shipped into the market for consumption as fresh table grapes or as raisins. If no winegrapes are actually produced, packed and shipped for consumption as table grapes or raisins, then the limitations of the NHANES/WWEIA data are irrelevant in determining whether winegrapes should be included on the list of produce commodities rarely consumed raw.

The California Table Grape Commission is a not-for-profit marketing and promotion commission, established under authority of Chapter 3 of Division 22 of the Agricultural Code of California, that has detailed data on California fresh table grape shipments. The California Table Grape Commission (hereafter referred to as the commission) has authority to levy and impose an assessment "...upon all fresh grapes shipped during each marketing season...." Furthermore, the authorizing statute requires, "Every shipper shall keep a complete and accurate record of all fresh grapes shipped by him and the producer thereof."

Tracking shipments of fresh table grapes is essential to the operation of the commission, which has significant authority to bring action to collect assessments, impose civil penalties or obtain injunctive relief to provide for accurate records and proper payment of assessments.

In short, the commission can be relied upon, as empowered under California state law, to accurately track and report commercial shipments of fresh table grapes by market channels. The commission can share with FDA data that identifies the county in which grapes were grown, the variety, volume shipped and the market channel (farmers' market, domestic retail, foreign export, etc.).

The commission reports for 2016 approximately 110 million boxes of California fresh table grape were shipped to market, of which only 7,264 boxes were of wine-type varietal grapes (French Colombard, Carignane and Grenache). These shipments were made by a single producer in San Luis Obispo County and were reported as farmers' market sales; it is highly likely these grapes were marketed and sold for use by home winemakers (CAWG is attempting to identify and contact the grower for more information on the marketing and sale of these grapes). Thus, grapes of a wine-type shipped to market as fresh table grapes accounted for only .00668% of all California shipments.

The Raisin Administrative Committee's (RAC) function is to administer the Raisin Marketing Order. The Raisin Marketing Order is authorized under the Agricultural Marketing Agreement Act of 1937 (The Act), which is administered by the U.S. Department of Agriculture. The RAC provides comprehensive reporting and documentation of the handling of raisins produced from grapes grown in California.

The RAC reports for 2016 that no winegrape varietals were shipped for processing and packing into raisins (*Marketing Policy & Industry Statistics, 2016 - 2017 Marketing Season*). The single most important varietal used for raisins is Thompson Seedless, which is reported as 'Natural Seedless.' The report demonstrates that commercial raisin grape varietals in production today are seedless.

Winegrapes are Physiologically Different than Grapes Produced for Raisin or Fresh Table Markets

The layperson may think 'grapes are grapes' and are readily interchangeable for use as fresh table grapes, raisins or for making wine or juice. This is not the case. In fact, to analogize, the variation between grape varieties is not unlike the variation between breeds of the domestic dog.

Domestic dogs are all of the same species, *Canis lupus familiaris*, but there is enormous variation between individual dog breeds. In theory, both the Siberian Husky and Dachshund could be hitched to a dog sled and raced over snow and ice, but in practical reality only one of these two breeds can serve

that purpose. The two breeds are readily distinguishable and serve different purposes. Likewise, all commercially produced varieties of grapes in California can be consumed raw or converted to raisin form, but the characteristics of specific grape species and varieties determine their commercial uses.

California 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 varieties 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 grown commercially for the United States market tend to have large seedless fruit with relatively thin skin. Winegrapes are smaller, 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: the higher sugar content of winegrapes is better suited to producing wine. Winegrapes are usually harvested at the time when their juice is approximately 23% to 28% sugar by weight, while table grapes are typically harvested when sugar content levels range from 15 to 20%.

A relative few varieties of grapes are grown for the raisin market – Thompson seedless accounts for the great majority of 86.9% of the total acreage planted to raisin type grapes. But, the most important feature of a raisin grape is that it is seedless. Ample availability of seedless grapes for the raisin market mean California raisin processors and packers do not utilize seeded grape varieties. The preference for seedless grapes is driven by the fact that additional costs are associated with mechanically deseeding raisins, thus seeded grapes are commercially uncompetitive in the raisin market. Leading grape varieties for the raisin market include Thompson seedless, Fiesta, Selma Pete and Zante Currant, which combined account for over 98% of all California raisin type acreage planted. (USDA National Agricultural Statistics Service *Grape Acreage Report 2016 Crop Year*, April 20, 2017)

With the possible exception of a single grower, California growers of winegrape varieties do not sell their grapes into the fresh market for consumption as raisin or table grapes. Once winegrapes are harvested for the purpose of shipping to a winery, the grapes are no longer fit for sale to a raisin grape processor and packer or as table grapes. Each market channel has distinct methods and requirements for harvesting and handling the grapes.

Table grapes demand exceptional care at harvest to ensure that grape clusters remain intact, the grapes suffer no or few visual blemishes, the product is sorted (in the field or at a packinghouse), packed into small, retail ready boxes and cooled.

Raisin grapes, by definition, are harvested in a manner that allows the raisin to dehydrate. Typically, dehydration of grapes for raisins is accomplished by laying down long rows of paper within the vineyard

row, parallel to the vines, where the harvested grape clusters are laid and allowed to dehydrate for 7 to 21 days (length of time varies by grape variety and weather). However, this system of dehydration is being replaced by 'dried on the vine' (DOV) varieties bred specifically for the raisin market that can be mechanically harvested.

In either instance, grapes harvested for wine are unfit for sale and shipment as fresh table grapes or raisin grapes; each of those market channels requires prior planning and preparation to ensure proper harvesting and handling of the grapes. Contrary to popular perception, the large majority (estimated at 80% – 85%) of California winegrapes are mechanically harvested. Mechanical harvesting of winegrapes often results in the berries being detached from the cluster (i.e., the rachis), superficial scarring of the skin occurs and there are broken berries, all of which renders the grapes unfit for sale as fresh table grapes or subsequent dehydration into raisins.

Hand harvesting of winegrapes into lugs and bins is reserved for more expensive winegrapes and typically occurs in those California counties where no raisin or table grapes are grown. While hand harvesting winegrapes may be more gentle on the winegrapes, growers who do hand harvest their crop nonetheless lack the requisite materials and processes to shift the harvested crop into fresh table grape or raisin market channels. In short, it would be both impractical and economically insensible for growers who hand harvest winegrapes destined for premium priced wines to shift their crop into market channels that would deliver lower economic returns.

Forty-two grape varieties account for the overwhelming volume of grapes crushed into wine.

Albarino	French Colombard*	Petit Verdot	Tannat
Alicante Bouchet	Gewurztraminer	Petite Sirah	Tempranillo
Arinarnoa	Grenache*	Pinot Gris	Teroldego
Barbera	Malbec	Pinot Noir	Touriga Nacional
Burger	Malvasia Bianca	Rubired	Triplet Blanc
Cabernet Franc	Mataro	Ruby Cabernet	Verdelho
Cabernet Sauvignon	Merlot	Sangiovese	Viognier
Carignane*	Mission	Sauvignon Blanc	White Riesling
Carnelian	Muscat Blanc	Semillon	Zinfandel
Chardonnay	Muscat of	Symphony	
Chenin Blanc	Alexandria	Syrah	

According to USDA NASS's *Grape Crush Report 2016 Crop*, these forty-two listed winegrape varieties constitute 99.4% of the total volume of winegrape varieties crushed in California and, when raisin and table grape varieties are included in the total volume of grapes crushed, these same winegrape varieties account for 94.8% of the total crush in California.

*The California Table Grape Commission reports in 2016 three winegrape varieties (Carignane, French Colombard and Grenache) accounted for 7,264 boxes (19-pounds apiece) of fresh table grape shipments, out of 110 million boxes of table grape shipments.

How Can FDA Distinguish Between Growers of Winegrapes and Other Grape Growers?

Unlike other commodities exempted from regulation under the Produce Safety Rule, such as asparagus, figs and potatoes, it may be difficult for untrained FDA officials and field personnel to easily distinguish between grape varieties grown for wine, raisins and the fresh table market. However, FDA can employ several methods to distinguish between vineyards producing for the wine, raisin and table grape markets.

Winegrape Varietals: The California Table Grape Commission can document for FDA, upon request, that commercially important varieties of winegrapes grown in California are not shipped into commerce for consumption as fresh fruit. However, FDA inspectors in the field can determine through several means which grape varieties are planted in their vineyards:

1. Inspect copies of growers' load tags/shipping documentation to wineries, which specifies grape varieties shipped, date shipped and the location of the vineyard and block from which the grapes originated (it is illegal under California law to falsify or misrepresent the variety of grapes sold to a winery);
2. Inspect copies of growers' purchase agreements with wineries which specify grape variety, vineyard location and sales price of grapes; and,
3. Require growers to attest to which grape varieties they are producing and whether the grapes under production are destined for processing; upon subsequent inspection and questioning, growers can provide some combination of the preceding to substantiate the veracity of the attestation.
4. Visual identification of leaves (and grape clusters if present) and compare to reference photographs on file at the National Grape Registry (managed by Foundation Plant Services, UC Davis);
5. Expert identification by University of California extension agents or trained viticulturalists;
6. Examine purchase receipts from nurseries for planted grapevines;

Seedless: Winegrape varietals produce a grape that is physically distinct from leading grape varietals used for the production of raisins or shipped as fresh table grapes. A key characteristic distinguishing winegrapes from other grapes is whether the grape is seeded or not. Grapes in California grown for raisins and the fresh table market are generally seedless. A notable exception is Red Globe, a variety that produces a very large red grape which does have small seeds. The California Table Grape Commission reports Red Globe grapes accounted for approximately 5.5% of total table grape shipments in 2016.

Different Production Systems

Generally, raisin, table and winegrape vineyards and canopies have distinctive appearances based on different trellis systems and pruning practices. Table grapes, for example, generally rely upon wider, gabled trellis systems which are intended to ensure even distribution of fruit. Perhaps most important, trellis systems used for raisin and table grape production do not lend themselves to harvest machines employed by winegrape growers. Machine harvesting of winegrapes is nearly universally employed in

southern San Joaquin Valley counties where significant overlap occurs between table, raisin and winegrape production.

If FDA desires, a more detailed discussion of distinctions between differing production systems associated with table, raisin and winegrapes can be developed.

County Distinctions: The vast majority of commercial production of grapes for the raisin and fresh table markets is found in a handful of California counties: Fresno, Kern, Kings, Merced, Madera, Riverside, San Bernardino, San Luis Obispo and Tulare counties account for 100% of shipments of commercial volumes of California table grapes. San Luis Obispo is primarily a winegrape producing county, however, one grower in that county shipped 7,264 boxes of table grapes.

When FDA considers where to deploy regulatory resources under the Produce Safety Rule, it makes sense to distinguish between counties and the grapes grown therein. For example, the best and highest use of grapes grown in Napa and Sonoma is for processing into wine, which is why the California Table Grape Commission and Raisin Administrative Committee report no grapes produced in the two counties were sold commercially for use as raisins or fresh table grapes. Combined, these two counties account for approximately 105,000 acres of winegrape acreage (USDA NASS Grape Acreage Report 2016). In comparison, Oregon and Washington have approximately 80,000 acres of winegrape vineyards.

There are 58 counties in California and FDA could categorically exempt from regulation all grapes in many of those counties. The following is a list of California winegrape producing counties where no table grapes were reported grown (according to the California Table Grape Commission).

Leading Winegrape Producing Counties with No Reported Table Grape Production

Alameda	Marin	Sacramento	Sonoma
Amador	Mariposa	San Benito	Stanislaus
Calaveras	Mendocino	San Diego	Sutter
Colusa	Monterey	San Joaquin	Tuolumne
El Dorado	Napa	Santa Barbara	Yolo
Lake	Nevada	Santa Cruz	
Los Angeles	Placer	Solano	

Failure to List Winegrapes as Rarely Consumed Raw is a Burden to Growers and Wineries, and a Waste of Scarce Regulatory Resources

Under the Produce Safety Rule, the processing exemption requires the grower to communicate to a winery that the winegrapes received have not been processed and, in turn, the winery must communicate to the grower that the grapes have been processed. This exchange of paperwork represents a statement of the obvious between the two involved parties. But, it is understood that in establishing this system FDA intended to create a means by which to document produce transactions and ensure raw commodities destined for processing are not diverted to fresh markets. However, for

reasons previously stated, winegrapes grown in California have only one purpose – conversion into wine (or brandy or other distilled spirit).

The U.S. Alcohol and Tobacco Tax and Trade Bureau reports there are 4,600 bonded wineries in California. There are 5,900 winegrape growers producing about four million tons of winegrapes on an estimated 602,000 vineyard acres. These 602,000 winegrape acres are recognized by the USDA National Agricultural Statistics Service as distinct from vineyards producing raisin and table grape varieties. If FDA fails to exempt winegrapes from the Produce Safety Rule on the basis of being rarely consumed raw, then the agency will expend significant time and effort ensuring that 10,500 distinct entities are engaged in the proper exchange of notice and assurance, and recordkeeping.

In 2016, a total of 4.03 million tons of winegrapes were crushed (USDA NASS *Grape Crush Report 2016 Crop*). A typical trailer load of winegrapes trucked to a crush facility (winery) will weigh 23 tons. Based on these numbers (4.03 million tons of winegrapes/23 tons) there were approximately 175,260 trailer loads of grapes harvested and trucked to California crush facilities in 2016. To obtain the processing exemption, each load must have an accompanying notice consistent with the requirements of the Produce Safety Rule. In turn, each winery must provide assurance to each grower that indicates all loads received were properly processed. And, records of these 175,260 transactions must be maintained for a period of up to two years.

A Lodi area grower with a 225 acre vineyard operation, assuming an average yield of 7.1 tons per acre, will ship 70 trailer loads of grapes during harvest. That Lodi grower may have two to four different winery customers, but the number could be greater. Sending notices, receiving assurances and keeping records for each and every load is a significant burden. Many growers, particularly in areas growing high value grapes, will have many more winery customers and a correspondingly greater burden to obtain the processing exemption.

In the final rule, FDA explicitly acknowledged that winemaking adequately reduces the presence of microorganisms of public health significance. It's reasonable to expect FDA will determine there is little to be gained in reducing public health risks by focusing efforts and expending scarce resources on ensuring growers of winegrapes and wineries are properly adhering to the terms of the processing exemption. So, while industry anticipates low levels of enforcement activity, absent a change in regulatory policy, the industry will continue to bear the burden of providing notice and assurance, and maintaining records. Failure to strictly adhere to the requirements of the processing exemption may result in significant regulatory consequences for industry operators. If, however, FDA decides to expend significant resources ensuring winegrape industry adherence to the terms of the processing exemption, then we fail to understand how such a position benefits public health.

Summary

California winegrape growers and wineries seek the inclusion of winegrapes on the list of commodities rarely consumed raw, under the Produce Safety Rule.

Winegrapes are very distinct from raisin and table grape varieties and distinct differences govern the production, harvest and handling of these varieties. With a single exception of one grower in San Luis Obispo County, FDA and the public can be assured that growers of winegrape varieties in California are not shipping commercial quantities of their produce into the raisin and table grape markets. One San Luis Obispo County grower is growing three winegrape varieties – Carignane, French Colombard and Grenache – for sale as fresh table grapes at farmers markets and his shipments account for only .00668% of all California table grape shipments. We believe most of these grapes from San Luis Obispo County are utilized by home winemakers.

As previously discussed, FDA has several ways to distinguish between growers of grape varieties destined for raisins, table grapes or processing into wine. However, the FDA should also consider the clear geographic realities that define grape production for the raisin, table and wine markets. Commercial grape growing in California for the raisin and table grape markets is limited to nine counties.

To obtain the processing exemption under the Produce Safety Rule, starting with the 2018 harvest, most California winegrape growers will be compelled to provide notice to wineries that the grapes shipped for processing into wine have not been processed to reduce microbial hazards of public health significance. In 2020, most wineries will be compelled to begin providing growers assurance that the grapes they received have in fact been processed into wine. Growers will need to maintain records of notice and assurance for a two year period.

The mandated paper exchange between 10,500 growers and wineries represents a significant burden. Likewise, the expenditure of FDA resources to enforce proper adherence to the terms of the processing exemption by winegrape growers will have no appreciable benefit in limiting foodborne illness.

FDA should provide the California winegrowing industry a more satisfactory exemption from the Produce Safety Rule by including winegrapes on the list of commodities rarely consumed raw.

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