

THE FOOD SAFETY MODERNIZATION ACT PRODUCE SAFETY RULE COMPLIANCE GUIDE

A legal resource for the Oregon Winegrowers Association



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Davis Wright Tremain LLP is a full service law firm providing services to the wine industry in the areas of mergers and acquisitions and other business transactions, land use and real estate, alcohol regulatory and licensing, intellectual property, employment, and litigation.

FOOD SAFETY MODERNIZATION ACT'S PRODUCE SAFETY RULE & WINEGROWERS

Although winegrowers fall under the Food Safety Modernization Act's ("FSMA") Produce Safety Rule ("PSR"), winegrowers are not required to comply with the PSR if certain processing and recordkeeping requirements are met. FDA has not yet issued guidance on the type of documentation that will suffice for this exemption. However, in addition to a summary of the regulatory requirements, this guide provides an example of a document that could be used to satisfy the exemption's requirements.

The PSR applies to the growing, harvesting, packing, and holding of "produce." Grapes are considered "covered produce" subject to the requirements of the PSR. However, covered produce is eligible for an exemption from the PSR's requirements if the covered produce undergoes commercial processing that "adequately reduces the presence of microorganisms of public health significance," such as turning grapes into wine. If covered produce is sold for further processing into wine, the covered produce must be accompanied by documents that disclose that the covered produce was "not processed to adequately reduce the presence of microorganisms of public health significance," and the covered produce grower/seller must obtain written assurances from its customer that the customer (or the customer's customer) will process the covered produce to adequately reduce the presence of microorganisms of public health significance. The covered produce grower/seller must also keep records of its compliance with those requirements. Termination of the assurance or failure to comply with the requirements means the covered produce grower/seller would have to comply with the PSR's requirements. The PSR's requirements are found in [21 C.F.R. pt. 112](#).

Following are additional details about the two requirements winegrowers must meet in order to take advantage of the PSR's exemption:

1. **Disclosure in Documents Accompanying the Grapes:** The winegrower must disclose to its customer in documents accompanying the wine grapes, in accordance with the practice of the trade, that the wine grapes have "not been processed to adequately reduce the presence of microorganisms of public health significance."
2. **Annual Written Assurances:** The winegrower must also get annual written assurances that the wine grapes will receive commercial processing that will adequately reduce the presence of microorganisms of public health significance from the entity in the distribution chain that will be turning the grapes into wine. This entity could be the winegrower's direct customer or another entity in the distribution chain. See below for an example agreement that the winegrower can use to get written assurances that the wine grapes will receive such commercial processing.

If the winegrower is the entity turning the wine grapes into wine, no disclosure documents or written assurances are required. However, in these cases, the winegrower should keep records showing that it grew the grapes used in its wine and that it did not sell any of its grapes to other entities (which would trigger the requirements discussed above).

To illustrate,

Hypothetical Scenario 1:

Winegrower and Wine Maker are same Business.
No need for disclosure documents or written assurances, as the Winegrower and the Wine Maker are the same entity which will apply the commercial processing required under the PSR.

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Hypothetical Scenario 2:

Winegrower (Business Entity #1)	Wine Maker (Business Entity #2)
Winegrower must include the disclosure language in documents accompanying the wine grapes when it sells the wine grapes to the Wine Maker. The Wine Maker must sign a document assuring the Winegrower that the Wine Maker will process the grapes in such a way as to adequately reduce the presence of microorganisms of public health significance.	

Hypothetical Scenario 3:

Winegrower (Business Entity #1)	3 rd Party (Business Entity #2)	Wine Maker (Business Entity #3)
Winegrower must include the disclosure language in documents accompanying the wine grapes when it sells the wine grapes to the 3 rd Party. The 3 rd Party must sign a document assuring the Winegrower that it will include the disclosure language in the documents accompanying the wine grapes and that it will only sell the grapes to another party that will provide assurances that the wine grapes will be processed in such a way as to adequately reduce the presence of microorganisms of public health significance.		
	The 3 rd Party must include the disclosure language in documents accompanying the wine grapes when it sells the wine grapes to the Wine Maker. The Wine Maker must sign a document assuring the 3 rd Party that it will process the grapes in such a way as to adequately reduce the presence of microorganisms of public health significance.	

Record-keeping Requirements:

The winegrower and any other sellers subject to the disclosure and written assurances requirements must comply with certain record-keeping requirements:

- Keep copies of the disclosures sent with each shipment of wine grapes.
- Keep copies of the written assurances received from customers; these written assurances must be completed each year.
- Records may be stored offsite as long as the records can be retrieved and provided on-site within 24 hours of a request for an official review. Electronic records are considered to be on-site if the records are accessible from a location on the farm/vineyard.
- Records must be kept for at least 2 years past the date the record was created.

Compliance Dates:

The compliance dates for the requirements discussed above depend on the average annual produce sales of the farm during the previous three-year period:

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- **Very small businesses**, those with more than \$25,000 but not more than \$250,000 in average annual produce sales during the previous three-year period, must comply with these requirements **by January 26, 2022**.
- **Small businesses**, those with more than \$250,000 but not more than \$500,000 in average annual produce sales during the previous three-year period, must comply with these requirements **by January 26, 2021**.
- **All other businesses** must comply with these requirements **by January 27, 2020**.

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[Note: The following is an example customer assurance that can be used by winegrowers and others in the distribution chain to satisfy the requirements of the Produce Safety Rule’s exemption for wine grapes that will be turned into wine.]

[on Grower / Seller Letterhead]

**FSMA Produce Safety Rule
Customer Assurance of Further Processing**

_____ (“Customer”) acknowledges that, as of the later date listed below (the “Effective Date”), the grapes listed on Exhibit A to this document (“Products”) that are provided by _____ (“Grower / Seller”) to Customer have not been processed to adequately reduce the presence of microorganisms of public health significance. In order to comply with the Food Safety Modernization Act (“FSMA”) and in consideration of the purchase, from time to time, of the Products, Customer makes the following assurance to Grower / Seller (the “Assurance”) (check the one that applies):

<input type="checkbox"/>	<p>If Customer performs commercial processing that adequately reduces the presence of microorganisms of public health significance, namely, manufacturing/processing the Products into wine or similar products (“Commercial Processing”), Customer assures Grower / Seller that it has established and is following appropriate procedures (identified in <u>Exhibit B</u>) to significantly reduce the presence of microorganisms of public health significance.</p>
<input type="checkbox"/>	<p>If Customer is relying on an entity in the distribution chain subsequent to the Customer (the “Entity”) to perform the Commercial Processing to the Products, Customer assures Grower / Seller that Customer will</p> <ol style="list-style-type: none"> (1) disclose to the Entity in documents accompanying the Products, in accordance with the practice of the trade, that the Products are “not processed to adequately reduce the presence of microorganisms of public health significance,” and (2) only sell to an Entity that agrees, in writing, to <ol style="list-style-type: none"> (a) perform the Commercial Processing procedures (identified in a written assurance) to adequately reduce the presence of microorganisms of public health significance, or (b) obtain similar written assurance from the Entity’s customer that the Entity’s customer will perform Commercial Processing on the Products and that the Entity will disclose to the Entity’s customer in documents accompany the Products, in accordance with the practice of the trade, that the Products are “not processed to adequately reduce the presence of microorganisms of public health significance.”

Customer acknowledges that it assumes legal responsibility to act consistently with this Assurance and to document its actions taken to satisfy this Assurance; Customer shall defend, indemnify, and hold Grower / Seller harmless from and against all claims of any kind that arise out of or relate to any breach of this Assurance. Neither party may terminate this Assurance except with 60 days’ prior written notice.

[signature page follows]



IN WITNESS WHEREOF, the parties have executed this Assurance as of the Effective Date.

Grower / Seller Name (Print)

Customer Name (Print)

Signature

Signature

Date

Date

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EXHIBIT A

Products

Grape Varietal	Location of Vineyard

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EXHIBIT B

Description of the Commercial Processing Procedures Customer is Following That Will Adequately Reduce the Presence of Microorganisms of Public Health Significance

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