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Maryland Produce Safety Program

Produce Safety Rule Exemptions and Compliance Dates Fact Sheet

The Maryland Produce Safety Program has adopted the U.S. Food and Drug Administration's (FDA) Produce Safety Rule through Maryland legislation that was effective July 1, 2019. The Maryland Department of Agriculture conducts outreach, education, registration, inspection and enforcement activities for the Produce Safety Rule. To make resources for compliance available to all Maryland farmers, MDA has partnered with the University of Maryland Plant Sciences, University of Maryland Extension and the University of Maryland Agricultural Law Education Initiative to provide outreach and education activities. MDA has implemented a registration program to determine which farms are exempt or partially exempt and to determine the compliance dates for farms that are required to comply with all or portions of the rule. All growers are required to submit the Produce Safety Rule Registration form (See Registration requirements section for more details). If the registration form indicates you may be eligible for an exemption, you need to file the correct form to request the exemption (see the section in this document that applies to your exemption for more details). Information on individual farms collected through this program will not be shared with any entities or persons outside of the Maryland Department of Agriculture (MDA) unless it is part of an active food borne illness outbreak investigation. All data collected concerning farms is shared with FDA as aggregate data only.

The exemptions and compliance dates for the Maryland Produce Safety Program are the same as those in the FDA Produce Safety Rule. The various exemptions in some cases totally exempt a farm from the requirements of the Produce Safety Rule and in other cases only exempt a farm from some portions of the rule. As the Produce Safety Rule is just one rule of several implementing provisions of the Food Safety Modernization Act (FSMA) and FSMA is part of the federal Food, Drug and Cosmetic Act, the Produce Safety Rule often references requirements/definitions from other federal rules. In addition to formal rules/regulations, FDA also issues guidance documents and policies on enforcement discretion that may change compliance requirements. Fully understanding these rules and determining whether you are required to comply with all or portions of the Produce Safety Rule or any of the other rules such as Preventive Controls for Human Food and Preventive Controls for Animal food can be difficult especially considering the diversity of crops and activities on many Maryland farms. Complete regulatory text of all FSMA final rules can be found at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#Rules> . Guidance documents and enforcement discretion documents can be found at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#Guidance> . It is important to remember that there are other Maryland and local government laws and regulations that may apply to your farm operation and any exemption you have from complying with all or portions of the Produce Safety Rule does not exempt you from complying with those regulations. If you have regulatory questions about any food you produce, please contact produce.safety@maryland.gov or value.added@maryland.gov .

In many cases understanding what the word means in the context of the rule makes a significant difference in fully understanding the compliance dates chart and the explanations of Registration

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Requirements and Exemptions. Words that have a specific definition in the Produce Safety Rule and/or other rules that are referenced in the Produce Safety Rule that impact the meaning of the compliance date and/or the exemption are in bold italics throughout this document and are included in the Definitions Section of this document.

Compliance Dates and Inspection Dates

***Note: Compliance dates and inspection start dates are subject to change based on revisions to the Produce Safety Rule and FDA enforcement discretion decisions**

	Compliance Date	Inspections Start
More than \$500,000 annual <i>produce</i> sales (Based on 3-year average)	January 26, 2018	March 2019
\$250,000 up to \$500,000 annual <i>produce</i> sales (Based on 3-year average)	January 28, 2019	March 2020
More than \$28,075 [†] up to \$250,000 annual <i>produce</i> sales (Based on 3-year average)	January 27, 2020	March 2021
Some Agricultural Water Quality Standards (112.44) >\$500,000 <i>Produce</i> Sales (Based on 3-year average) start testing	January 22, 2022	Next inspection after compliance date
Some Agricultural Water Quality Standards (112.44) \$250,000 up to \$500,000 <i>Produce</i> Sales (Based on 3-year average) start testing	January 26, 2023	Next inspection after compliance date
Some Agricultural Water Quality Standards (112.44) >\$28,075 [†] up to \$250,000 <i>Produce</i> Sales (Based on 3-year average) start testing	January 26, 2024	Next inspection after compliance date
Commercial Processing Exemption (all requirements except written assurances from customers)	January 27, 2020	Not determined yet
Commercial Processing Exemption – written assurances from customers	January 26, 2022	Not determined yet – requirements may change prior to 2022
Qualified Exempt records supporting eligibility retention	January 26, 2016	March 2021
Qualified Exempt modified requirements (Labeling)	January 1, 2020	March 2021

[†] On a rolling basis and **adjusted for inflation**; current value is based on adjusted inflation value for 2017, 2018 and 2019. FDA updates the adjusted inflation values annually by April 1.

Registration Requirements

Registration with MDA is required to establish compliance dates and eligibility for partial or full exemptions from compliance with the Produce Safety Rule. All farms that are growing *produce* are required to submit the MDA Produce Safety Rule Registration Form. This form establishes compliance dates and assists you with determining your eligibility for partial or total exemption from complying with the Produce Safety Rule. If you are fully covered by the Rule and have already registered with MDA you are not required to register again. If you grow *produce* and believe you are eligible for one of the exemptions, you are required to submit the applicable exemption request form. You are not required to

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request an exemption just because you are eligible. If you do not request the exemption you are eligible for, you will be inspected according to the compliance date based on **produce** sales. If you are receiving information from MDA on the Produce Safety Rule and you do not grow **produce**, you should still complete the registration form to be removed from the inventory we are maintaining for the Produce Safety Rule.

Exemptions Based on Crops

Non covered Produce

A farm that **only** grows **produce** that is on the exhaustive list of **non-covered produce** is not required to comply with any portions of the Produce Safety Rule. **Produce** in this category is still included in **food** sales and **produce** sales if the farm is growing, harvesting, packing, and/or holding any **covered produce**. Currently FDA is using enforcement discretion to include hops, wine grapes, pulse crops (some pulse crops are already on the list; dry peas and cowpea beans (black-eyed peas) are not on the non covered list) and almonds as **non covered produce** while FDA reconsiders if they should be added to the **non covered produce** list in the Rule. **Non covered produce** is still subject to the U.S. Food, Drug and Cosmetic Act and state laws prohibiting the sale and distribution of **adulterated** food.

All Produce Grown Receives Commercial Processing

Farms that **only** grow **produce** that receives commercial processing that adequately reduces the presence of microorganisms of public health significance are only exempt from the growing, harvesting and packing requirements of the Produce Safety Rule. These growers are required to disclose in documents accompanying the **produce**, in accordance with the practice of the trade, that the **food** is “not processed to adequately reduce the presence of microorganisms of public health significance”. FDA will not be enforcing the provisions in this rule requiring growers to obtain documentation of the commercial processing from their buyer(s) while it reconsiders options for the assurance requirements. Currently the compliance date for obtaining these written assurances from buyers has been extended until January 26, 2022 to allow FDA time to reconsider the options. Farms that grow **produce** that does not receive commercial processing and **produce** that receives commercial processing are required to include the **produce** that receives commercial processing in their total **produce** sales to determine compliance dates and in their total **food** sales to determine if they are eligible for the Qualified Exemption. Farms that **only** grow **produce** that receives commercial processing are required to submit the MDA Commercial Processing Partial Exemption to MDA to exclude them from the fully covered by the Produce Safety Rule inventory and notify MDA if their status changes.

All Produce Grown is used only for Personal Consumption on the Farm or Another Farm Under the Same Management

Produce that is grown on a **farm** that **only** grows **produce** for their own or their employees’ personal consumption on the **farm** or another **farm** under the same management is not considered **covered**

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produce. *Farms* that fall into this category are only required to submit the Personal Consumption exemption form to MDA one time to exclude them from the inventory of covered *farms* and notify MDA if their status changes in the future (i.e. they begin growing, harvesting, packing and/or holding *produce* for other than personal consumption).

Exemptions Based on Monetary Value of Sales

Produce Average Monetary Value of sales less than \$28,075.00[†] Exemption

The Produce Safety Rule does not consider a *farm* or *farm mixed-type facility* with an average annual monetary value of *produce* sold during the previous 3-year period of less than \$28,075[†] as a “covered” *farm*. When determining whether you qualify for this exemption it is important to note that the average monetary value is for *produce* not *covered produce*. If you grow potatoes (*non covered*) and tomatoes (*covered*), your average monetary value would be based on sales of both even though you are not required to grow, harvest, pack and/or hold the potatoes in compliance with the Rule. Farms in this category are required to file the MDA Produce Average Monetary Value of less than \$28,075.00[†] Registration Form one time, review their sales annually to determine if they still qualify for this exemption and notify MDA of any changes to their status. When reviewing annually, the *farm* or *farm mixed-type facility* should use the *adjusted for inflation* values for the immediately preceding three years.

[†] *On a rolling basis and adjusted for inflation; current value is based on adjusted inflation value for 2017, 2018 and 2019. FDA updates the adjusted inflation values annually by April 1.*

Qualified Exempt (*Food Sales of less than \$561,494[†] and more than 50% to Qualified End User*)

A farm is eligible for a Qualified Exemption if the average monetary value of all *food* sold during the previous three-year period was less than \$500,000[†] *adjusted for inflation* (currently \$561,494[†]) **and** the sales to *Qualified End Users* exceeded the sales to any other buyer. Records supporting eligibility are required to be maintained and are subject to inspection by MDA to verify eligibility. Records should not be submitted to MDA – any review of the records will be conducted on site and MDA will not maintain copies of these records. An annual review of the records supporting eligibility must be conducted and documented by the farm to verify they are still eligible for the exemption. It is important to note that this exemption is based on the monetary value of all *food* sales and a farm must meet both the total *food* sales and value of *food* sales to *qualified end users* specified in the Produce Safety Rule in order to be eligible for this exemption. A *farm* that operates under this exemption is required to comply with modified requirements. The primary modified requirement is that all *produce* grown while operating under this exemption must have the complete business address of the *farm* where it was grown on a label, poster, sign, placard, or documents delivered with the produce or if internet sales in an electronic notice. The complete business address of the *farm* includes the street address or post office box, city, state and zip code. For example, you sell your *produce* at a farmer’s market and you also purchase some produce from your neighbor to sell at the farmer’s market. Both of you are operating under the Qualified Exemption. You must prominently and conspicuously display on a label, poster, sign, or placard the complete business address of your *farm* for the produce you grew and the complete business address of your neighbor’s farm for the produce they grew. You are also required to comply with Subpart O of the Produce Safety Rule which specifies requirements for records and Subpart Q of the Produce Safety Rule

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which specifies prohibited acts which includes the sale of ***adulterated*** food. It is important to note the qualified exemption can be withdrawn by MDA and/or FDA if an active investigation of a foodborne illness outbreak is directly linked to your ***farm*** and/or if it is determined that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions on your ***farm***. It is also important to note that some buyers may have reservations about purchasing ***produce*** from a ***farm*** that is not fully covered by the Produce Safety Rule. You are not required to apply to MDA for the Qualified Exemption just because you are eligible – if you do not apply you will be considered fully covered by the Produce Safety Rule and inspected according to your ***produce*** sales compliance date. If you decide to operate under the Qualified Exemption, you must submit the Qualified Exempt Registration form to MDA annually to maintain your eligibility for the exemption. The worksheet that is part of the Qualified Exempt Registration form can be used as documentation of your annual review of your eligibility for this exemption if fully completed. The worksheet should never be submitted to MDA – it should be maintained as part of your records. The registration form that should be submitted to MDA is the second page of the Qualified Exempt registration form.

NOTE: Due to the COVID-19 related market disruptions and to support affected farm in selling food to all available buyers during the COVID-19 public health emergency FDA does not intend to enforce the criteria for sales to qualified end-users when determining eligibility for the qualified exemption as long as the farm met the criteria prior to COVID-19 for the duration of the public health emergency. MDA has adopted this same policy to facilitate the distribution of food. If your sales to qualified end users met the criteria in 2018 and 2019, your food sales for 2020 do not have to meet the more than 50% to qualified end user requirements (i.e. allows food sales to wholesalers and/or outside of the State of Maryland and/or outside of 275 mile radius from the farm).

[†] *On a rolling basis and adjusted for inflation; current value is based on adjusted inflation value for 2017, 2018 and 2019. FDA updates the adjusted for inflation values annually by April 1.*

Helpful Definitions

The following definitions are a summary of the text in the Produce Safety Rule and other applicable FDA rules intended to be helpful in determining if you are required to comply with all or portions of the rule. As they are summaries the following definitions may not cover all scenarios. For the complete regulatory text of the Produce Safety Rule definitions, see Title 21 CFR Part 112 §112.3 What definitions apply to this part.

Adjusted for inflation means the monetary value of produce sales to determine eligibility for the exempt or qualified exempt categories is adjusted for inflation each year. The inflation rate for the previous year is updated April 1 each year at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>. When calculating the three-year average monetary value of sales of produce for the exempt category or the three-year average monetary value of sales of food for the qualified exempt category you should use the three most recent years available. ***Adjusted for inflation*** does not apply when determining compliance dates.

Adulterated food per the Food, Drug and Cosmetic Act (partial relevant text from the FD&C §342.) means A food shall be deemed to be adulterated-

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(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered **adulterated** under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.¹

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

The following provisions in the Food, Drug and Cosmetic Act apply to adulterated food:

§331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

Adulterated food per the Produce Safety Rule means within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health

Covered Activity means growing, harvesting, packing, or holding **covered produce** on a farm. Certain processing activities are allowed if these activities are within the meaning of “farm” and the activities are not regulated by the Preventive Controls for Human Food Rule (Title 21 CFR Part 117).

Covered Produce means produce that is not listed as rarely consumed raw in the Produce Safety Rule. The rarely consumed raw list is exhaustive while the covered produce list in the rule is not exhaustive. Even if the produce you grow is not listed as covered, if it is not on the non covered produce rarely consumed raw list it is considered covered.

Covered Farm means an operation the meets the definition of farm and conducts a covered activity for covered produce.

Non Covered Produce (Rarely Consumed Raw) currently means Asparagus; beans, black; beans, great Northern; beans kidney, beans, lima; bean, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews, cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts. This list is

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exhaustive; however, FDA can add or remove produce from this list through enforcement discretion and/or changes to the rule. Currently FDA is using enforcement discretion to include wine grapes, **all** pulse crops, almonds and hops on the non covered rarely consumed raw list.

Farm means an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. There are operations that are included in the farm definition that in addition to these activities conduct other activities such a packing or holding raw agricultural commodities and or do some limited processing. If you do any other type of activity other than growing, harvesting and packing your own crops please read the full text of the rule to fully understand what activities are included in the farm definition. You should also check FDA’s website for guidance documents regarding enforcement discretion adopted based on the definition of a farm in other rules, the complexity of some operations, and the impact the complexity has on which rules apply to their business.

Farm mixed type facility means a farm as defined above that also engages in activities outside the farm definition that require the establishment to be registered per section 415 of the Federal Food, Drug, and Cosmetic Act. In general, the growing, harvesting, packing or holding of raw agricultural commodities is considered either a primary or secondary farm activity and does not require registration per section 415 of the Federal Food, Drug and Cosmetic Act.

Food means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such articles. If your sales include hay, grain, livestock, poultry, jellies, jams, or any other crops or products that would be used for food or drink for humans or animals, they must be included in determining any exemption based on food sales.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts, peanuts, tree nuts, and herbs. Produce does not include food grains such as barley, dent or flint corn, sorghum oats, rice, rye, wheat, oilseeds, etc. that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds. When the compliance date or exemption uses the word “produce” it means all produce – both covered and non covered by the Produce Safety Rule.

Qualified End User means consumers and/or restaurants and/or retailers in the same state as the farm or not more than 275 miles away from the farm.

Raw Agricultural Commodity means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. (FD&C 201(r))