

Transition from Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry

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For questions regarding this draft document contact the Office of Food Safety, Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700 or the FDA Produce Safety Network at <https://www.fda.gov/food/food-safety-modernization-act-fsma/produce-safety-network>.

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Transition from Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Guidance for Industry

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I. Introduction

This guidance is intended for farms subject to the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) (21 CFR Part 112). For certain farms, the Produce Safety Rule provides a qualified exemption; qualified exempt farms are subject to modified rule requirements. During the COVID-19 public health emergency as declared by the Secretary of the U.S. Department of Health and Human Services (HHS), FDA provided certain temporary flexibilities related to eligibility criteria for the qualified exemption. This document communicates FDA's current thinking on how, when the COVID-19 public health emergency expires, qualified exempt farms may transition away from those temporary policies and back to the qualified exemption eligibility criteria as established in the Produce Safety Rule.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be

viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

A. Qualified Exemption under the Produce Safety Rule

As set forth in 21 CFR 112.5(a), a farm is eligible for a qualified exemption and associated modified requirements in a calendar year if, during the three-year period preceding the applicable calendar year, the average annual monetary value of food the farm sold directly to qualified end-users exceeded the average annual monetary value of the food the farm sold to all other buyers during that period, and the average annual monetary value of all food the farm sold during the three-year period was less than \$500,000, adjusted for inflation.¹ “Qualified end-user” is defined in 21 CFR 112.3 as the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food or not more than 275 miles from such farm. The modified requirements with which qualified exempt farms must comply are described in 21 CFR 112.6 and include disclosing the name and complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation as described in 21 CFR 112.7 (e.g., records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption).

B. Temporary Qualified Exemption Policy During the COVID-19 Public Health Emergency

During the COVID-19 public health emergency the ability of farms to shift food sales to available buyers had the potential to help reduce food shortages and food waste and to help support both farms and the U.S. economy. In order to support affected farms in selling food to all available buyers while the country was experiencing acute impacts from COVID-19, in May 2020 FDA issued the guidance, “[Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)”² (COVID Qualified Exemption guidance). The COVID Qualified Exemption guidance communicated FDA’s intention to not enforce the criterion for direct sales to qualified end-users when determining eligibility for the qualified exemption under the Produce Safety Rule, for the duration of the public health emergency related to COVID-19. The purpose of the temporary policy was to provide flexibility to affected farms during the COVID-19 public health emergency.

Under the temporary policy, farms that were eligible in 2020 for the qualified exemption and associated modified requirements could continue to be considered eligible in subsequent years affected by the COVID-19 public health emergency even if they shifted food sales away from qualified end-users, provided that the farms continued to meet the requirement that the three-year

¹ See <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-during-covid-19-public-health-emergency-regarding-qualified-exemption-standards>

average annual monetary value of all food they sold is less than \$500,000, adjusted for inflation. We recommended that such farms retain documentation that the farm met all the criteria for the qualified exemption in 2020, and documentation that the average annual monetary value of all the food sold was less than \$500,000, adjusted for inflation, for any three-year period impacted by the public health emergency related to COVID-19.

Similarly, for farms that did not have three years of sales prior to 2020, but that met the relevant requirements during the years they were in operation prior to 2020, we stated that we did not intend to enforce the criterion regarding the portion of sales that are made directly to qualified end-users in 2020 (and any subsequent years that were affected by the COVID-19 public health emergency), provided the farms continued to meet the requirement regarding the average annual monetary value of all food they sold, adjusted for inflation. We recommended that such farms retain documentation that for the year(s) prior to 2020 that the farm was in operation, the average value of direct sales to qualified end-users exceeded that of food sold to all other buyers, and the average annual monetary value of all food sold was less than \$500,000, adjusted for inflation. We also recommended that for subsequent years, these newer farms retain documentation that the average annual monetary value of all food the farm sold during the preceding three-year periods (or the year(s) for which the farm was in operation if less than three years) was less than \$500,000 adjusted for inflation. We advised a similar approach for farms for which 2020 was their first year of operation.³

In the COVID Qualified Exemption guidance, we stated that we intended the policy to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of HHS on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)) (PHE). The most recent 90-day renewal was signed on February 9, 2023, and effective on February 11, 2023.⁴ On February 9, based on current COVID-19 trends, HHS announced that it is planning for the declaration to expire at the end of the day on May 11, 2023.⁵ In the COVID Qualified Exemption guidance, we stated that when the PHE expires, we intended to issue additional guidance regarding the eligibility criteria for the qualified exemption from the Produce Safety Rule. This document is that additional guidance. Finally, we stated in the COVID Qualified Exemption guidance that we intended to provide timely notice about the eventual expiration of the temporary policy. We provided such notice on March 13, 2023, in the Agency's *Federal Register* notice communicating our plans for specified currently in effect COVID-19-related guidance documents when the PHE declaration expires. In that notice, we indicated the COVID Qualified Exemption guidance would be revised to continue in effect for

³ For such farms, we recommended retaining documentation such as contracts with buyers that would provide a sufficient basis to establish that, absent the market disruption due to the COVID-19 pandemic, the average annual monetary value of the food sold by the farm to qualified end-users reasonably would have been anticipated to exceed the average annual monetary value of food sold to all other buyers; and, the monetary value of all food sold in 2020 was less than \$500,000, adjusted for inflation. For any three-year period impacted by the COVID-19 public health emergency, we also recommended such farms retain documentation that the average annual monetary value of all food sold was less than \$500,000, adjusted for inflation.

⁴ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

⁵ HHS, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap (February 9, 2023) available at <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023>

180 days after the PHE declaration expires, and then would no longer be in effect. (88 FR 15417) We are repeating such notice in section III.B. of this guidance.

III. Discussion

A. COVID-19 Impacts on the Market for Produce from Smaller Farms

Not long after COVID-19 appeared in the United States, impacts from the virus, including various public health orders and other mitigating efforts such as workplace shutdowns and cancellations of large gatherings, caused a massive disruption in the food sector. A vast number of restaurants and schools quickly closed or drastically curtailed their operations (e.g., some restaurants were open but only for carryout services). Many buyers that are qualified end-users suddenly stopped making their usual produce purchases. Although impacts related to COVID-19 continue to be felt across many sectors of the U.S. economy, there are no longer widespread public health orders closing schools or prohibiting dining at restaurants. As a general matter, entities such as restaurants and schools that are qualified end-users affected by past public health orders, are again open and purchasing produce.

B. Timeline for Expiration of COVID Qualified Exemption Guidance

In the COVID Qualified Exemption guidance, we noted that State and local governments across the United States had instituted public health orders resulting in the temporary closure or limited operational status of many restaurants, retail food establishments, and institutional food service establishments (including schools). These closures and limitations had a significant impact on the supply chain for food by significantly reducing the demand for food normally sold to these establishments.

To FDA's awareness, in the United States there are no longer many, if any, COVID-19 public health orders resulting in the temporary closure or limited operational status of restaurants, retail food establishments, and institutional food service establishments such as schools. Accordingly, because such orders are no longer impacting produce sales to such entities, and consistent with our statements in the COVID Qualified Exemption guidance and the Agency's March 13, 2023, *Federal Register* notice communicating our plans for specified currently in effect COVID-19-related guidance documents when the PHE declaration expires, the COVID Qualified Exemption guidance will continue in effect for 180 days after the PHE declaration expires (88 FR 15417). The PHE declaration is expected to expire on May 11, 2023, meaning the COVID Qualified Exemption guidance is intended to remain in effect until Nov. 7, 2023. Providing 180 days after the PHE declaration expires will allow time for affected farms to learn that the PHE declaration has expired and adjust their activities and recordkeeping accordingly.

C. Plan to Transition Back to the Qualified Exemption Criteria Established in the Produce Safety Rule

Upon the expiration of the COVID Qualified Exemption guidance, qualified exempt farms will be expected to satisfy both prongs of the qualified exemption as described in the Produce Safety Rule: during the three-year period preceding the applicable calendar year, the average annual

monetary value of food the farm sold directly to qualified end-users must exceed the average annual monetary value of the food the farm sold to all other buyers during that period, AND the average annual monetary value of all food the farm sold during the three-year period must have been less than \$500,000, adjusted for inflation. See 21 CFR 112.5(a). During the time period covered by the COVID Qualified Exemption guidance, some farms have not had direct sales to qualified end-users exceed sales to all other buyers. In this section we describe our recommended approach for such farms to transition back to averaging sales to qualified end-users over relevant three-year periods.

FDA is aware that not all qualified exempt farms experienced the same level of market disruption during the PHE. That is, some qualified exempt farms did not suddenly lose their qualified end-user buyers, and so those farms have continued their sales and associated recordkeeping without interruption. Assuming they satisfy the qualified exempt criteria, such farms readily will be able to establish qualified exempt status even for three-year periods impacted by the PHE.

Farms that shifted sales away from qualified end-users during years affected by the PHE may not meet the criterion that the average monetary value of direct sales to qualified end-users exceed the average monetary value of sales of food to all other buyers. Such farms must nevertheless have documentation that the average annual monetary value of all food sold during the relevant three-year periods was less than \$500,000, adjusted for inflation.

In the preamble to the final Produce Safety Rule, we acknowledged that there may be circumstances where a farm may not have three calendar years of records to support its eligibility for the qualified exemption. We stated that, “[u]nder such circumstances, it would be reasonable for the farm to make the calculation based on records it has (*i.e.*, for one or two preceding calendar years), and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances” (80 FR 74354 at 74413 (Nov. 27, 2015)).

We intend to apply that policy in this circumstance. Accordingly, in anticipation of farms seeking to comply with the provision in the Produce Safety Rule that qualified exempt status requires that a farm’s direct sales to qualified end-users must exceed its food sales to all other buyers, FDA will essentially restart the clock on the three years that get averaged for the criterion related to direct sales to qualified end-users. That means that farms that have not been selling directly to qualified end-users during the PHE may begin counting anew to reach three years of direct sales to average.

FDA will consider the first calendar year after expiration of the PHE to be Year 1. Specifically, since the PHE is expected to expire on May 11, 2023, Year 1 would begin January 1, 2024. During 2024, farms that had been following the recommendations described in the COVID Qualified Exemption guidance to determine eligibility for qualified exempt status (regarding sales to qualified end-users) may continue to do so, but such farms also should begin collecting data on the monetary value of food the farm sold directly to qualified end-users (as well as the monetary value of food the farm sold to all other buyers).

2025 would be Year 2. In 2025, farms that had been following the recommendations described in the COVID Qualified Exemption guidance to determine eligibility for qualified exempt status may satisfy the criterion regarding direct sales to qualified end-users if the monetary value of food the farm sold directly to qualified end-users in 2024 exceeded the average monetary value of food the farm sold to all other buyers in 2024. Stated differently, in 2025, no averaging is necessary to satisfy the criterion regarding direct sales to qualified end-users; the farm may simply consider its sales from 2024 to determine whether the qualified end-user criterion is satisfied.

2026 would be Year 3. In 2026, farms that had been following the recommendations described in the COVID Qualified Exemption guidance to determine eligibility for qualified exempt status may establish sufficient sales to qualified end-users if the average monetary value of direct food sales to qualified end-users in 2024 and 2025 exceeded the average monetary value of food the farm sold to all other buyers in 2024 and 2025. If the qualified end-user criterion is not satisfied, then the farm would no longer have qualified exempt status and, unless another exemption applies, would be expected to comply with the full requirements of the Produce Safety Rule.

In 2027, farms should have all the data needed to determine if the criterion regarding direct sales to qualified end-users has been met; they should be able to calculate a three-year average using sales data from 2024-2026. Stated differently, farms that had been following the recommendations described in the COVID Qualified Exemption guidance to determine eligibility for qualified exempt status may establish sufficient sales to qualified end-users if the average monetary value of direct food sales to qualified end-users in 2024-2026 exceeded the average monetary value of food the farm sold to all other buyers in 2024-2026.

This process of phasing back in FDA's expectations regarding compliance with the qualified end-user criterion does not impact the total food sales criterion. For the duration of the PHE, qualified exempt status has been reserved for farms for which the average annual monetary value of all food sold during the preceding three-year period was less than \$500,000, adjusted for inflation. During the transition period described in this guidance, the annual monetary value of all food sold by the farm must continue to be averaged over the preceding three-year period (21 CFR 112.5(a)(2)).

A farm that began operations during the PHE is covered by the qualified end-user transition policy and thus may be eligible for qualified exempt status in accordance with this guidance. That is, such a farm may establish sufficient sales to qualified end-users if the monetary value of food the farm sold directly to qualified end-users in 2024 exceeded the average monetary value of food the farm sold to all other buyers in 2024, and so on. In terms of the total food sales criterion, the farm would use its sales data based on the records it has; that is, the farm would consider just the year(s) in which it has been in operation.

We recognize that, for some farms, market channels were not as seriously disrupted during the period in which the COVID Qualified Exemption guidance was in effect. Some farms have sold more directly to qualified end-users than all other buyers throughout the pandemic period and have retained the relevant documentation. Other farms may have been able to regain sufficient direct sales to qualified end-users and, therefore, start transitioning away from the COVID

Qualified Exemption guidance earlier than the expiration of the PHE. Farms that became able to meet the qualified end-user criterion for qualified exempt status, and that collected relevant data during the time that the COVID Qualified Exemption guidance was in effect, may voluntarily consider that data in their calculations.