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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

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Guidance for Industry

May 2020

This guidance is intended to remain in effect until November 7, 2023.
For further information, refer to
88 FR 15417, March 13, 2023.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with statutory requirement and the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1386 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, the FDA webpage titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents, and the FDA Webpage titled "FSMA Rules and Guidance for Industry," *available at* https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#guidance. You may also send an e-mail request to Samir.Assar@fda.hhs.gov to receive an additional copy of the guidance. Please include the docket number FDA-2020-D-1386 and complete title of the guidance in the request.

Questions

For questions about this document, contact Samir Assar, Samir.Assar@fda.hhs.gov, 240-402-1636.

Table of Contents

I. Introduction 4
II. Background 5
A. Coronavirus 5
B. Qualified Exemption under the Produce Safety Rule 6
III. Discussion 6

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

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Guidance for Industry

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to announce flexibility in the eligibility criteria for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) (21 CFR Part 112) due to disruptions to the supply chain for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and renewed for 90 days on April 21, 2020, effective April 26, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). When the public health emergency concludes, FDA intends to issue additional guidance regarding the eligibility criteria for the qualified exemption from the Produce Safety Rule, which depends on the calculation of a three-year average as described below.

Given this public health emergency, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with statutory requirement and the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's 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 Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Coronavirus

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

State and local governments across the United States have 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 have had a significant impact on the supply chain for food by significantly reducing the demand for food normally sold to these establishments. These changes in the supply chain have impacted the ability of some farms to sell food to typical buyers and, consequently, may impact some farms' eligibility for a particular exemption under the Produce Safety Rule.[3]

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[1] Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

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[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[3] The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR Part 117) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507) regulations established criteria for a food facility to be a qualified facility. If you believe your status as a qualified facility under either part 117 or part 507 will be impacted by market disruptions related to COVID-19, please contact us as described in the preface of this guidance.

B. 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 previous 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.[4] "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.

FDA recognizes that the ability of farms to shift food sales to available buyers during the COVID-19 public health emergency has 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 during the COVID-19 public health emergency, under the circumstances described in section III FDA does not intend to enforce the criteria for 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.

III. Discussion

In order to provide flexibility to affected farms during the COVID-19 public health emergency, under the circumstances described below FDA does not intend to enforce the requirement in 21 CFR 112.5(a)(1) that a majority of sales be to qualified end-users for a farm to be eligible for the qualified exemption under the Produce Safety Rule. This policy will apply to any calendar year during which the COVID-19 public health emergency is ongoing and will remain in effect until the public health emergency is terminated. FDA intends to provide timely notice about the eventual withdrawal of this policy. At that time, FDA intends to issue additional guidance, which will take into account comments received on and our experience with the implementation of this guidance, regarding how the three-year averages should be calculated moving forward.

[4] In the preamble to the final rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," the Agency described how a new farm can establish eligibility for a qualified exemption if it does not yet have three years of records. When a farm has not yet begun operations, the preamble states that, "it would be reasonable for the farm to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the farm's number of employees." The preamble goes on to state that, "After the farm has records for one or two preceding calendar years, 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).) In section III, we provide examples of how the temporary policy announced in this guidance will apply to farms in these situations.

As described below, for farms that met the criteria for the qualified exemption in 2020 based on sales that were made in 2017-2019, FDA does not intend to enforce the criteria regarding the portion of sales that are made to qualified end-users in 2020 (and any subsequent years that are affected by the COVID-19 public health emergency). This means that farms that are currently eligible for the qualified exemption and associated modified requirements will still be considered eligible even if they shift food sales away from qualified end-users, provided that they continue to meet the requirement that the average annual monetary value of all food they sell is less than $500,000, adjusted for inflation. 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, FDA does not intend to enforce the criteria regarding the portion of sales that are made to qualified end-users in 2020 (and any subsequent years that are affected by the COVID-19 public health emergency), provided the farms continue to meet the requirement regarding the average annual monetary value of all food they sell.

This guidance does not affect the status of farms who continue to sell a majority of their food to qualified end-users despite COVID-19 market disruptions. Any farm that is able to meet the requirements of 21 CFR 112.5 using contemporaneous sales data (e.g., using sales data from 2020 as part of their eligibility calculation for 2021) will be eligible for the qualified exemption, even if they are not within the scope of the enforcement discretion policy described below.

All farms are responsible for ensuring that the food they produce is not adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA strongly encourages farms to use good agricultural practices (see, e.g., FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables).

How do I determine eligibility for the qualified exemption in 2021 if I met the criteria for the qualified exemption in 2020?

For farms that were eligible for the qualified exemption in 2020, eligibility for qualified exemption status for 2021, and until the end of the public health emergency, may be determined based on:

> (1) Documentation that the farm met all of the criteria for the qualified exemption in 2020, based on records from 2017, 2018, and 2019; and
>
> (2) Documentation that the average annual monetary value of all food the farm sold during the preceding three-year period (e.g., 2018, 2019, and 2020 for determining status in 2021) was less than $500,000, adjusted for inflation. FSMA inflation adjusted cut off values can be found at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

For example:

Farm A had previously determined that they were eligible for the qualified exemption for 2020, based on sales data from 2017, 2018, and 2019. Furthermore, the average annual monetary value of all food sold by Farm A in 2018, 2019, and 2020 was less than $500,000, adjusted for inflation.

FDA does not intend to enforce the criteria regarding sales by Farm A to qualified end-users in 2020. FDA therefore intends to treat Farm A as eligible for the qualified exemption in 2021, regardless of the monetary value of sales to qualified end-users in 2020.

Farm B did not meet the criteria for the qualified exemption in 2020 because the average monetary value of food sold directly to qualified end-users **did not** exceed the average monetary value of food sold to all other buyers in 2017, 2018, and 2019. The average annual monetary value of all food sold by Farm B in 2018, 2019, and 2020 was less than $500,000, adjusted for inflation. The temporary policy described in this guidance does not apply to Farm B.

How do I determine eligibility for the qualified exemption if I did not have three years of sales prior to 2020?

If the farm has not been in operation long enough to have annual values of sales for the three-year period prior to 2020, eligibility for qualified exemption status for 2021, and until the end of the public health emergency, may be determined based on:

> (1) Documentation that for the year(s) the farm was in operation prior to 2020, the average annual monetary value of food sold directly to qualified end-users exceeded the average annual monetary value of food sold to all other buyers, and the average annual monetary value of all food the farm sold was less than $500,000, adjusted for inflation; and
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> (2) Documentation that the average annual monetary value of all food the farm sold during the preceding three years (or the year(s) for which the farm was in operation if less than 3 years) was less than $500,000, adjusted for inflation. FSMA inflation adjusted cut off values can be found at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

For example:

Farm C began operations in 2018. The average monetary value of food sold directly to qualified end users in 2018 and 2019 exceeded the average monetary value of food sold to all other buyers, and the average annual monetary value of all food the farm sold in 2018 and 2019 was less than $500,000, adjusted for inflation. Furthermore, the average annual monetary value of food sold by Farm C in 2018, 2019, and 2020 is less than $500,000, adjusted for inflation. FDA does not intend to enforce the criteria regarding sales by Farm C to qualified end-users in 2020. FDA therefore intends to treat Farm C as eligible for the qualified exemption in 2021, regardless of the monetary value of sales to qualified end-users in 2020.

Farm D began operations in 2018 and the average monetary value of food sold directly to qualified end users in 2018 and 2019 **did not** exceed the average monetary value of food sold to all other buyers. The average annual monetary value of food sold by Farm D in 2018, 2019, and 2020 is less than $500,000, adjusted for inflation. The temporary policy described in this guidance does not apply to Farm D.

How do I determine eligibility for the qualified exemption if I began sales in 2020?

If a farm was newly operational and began sales in 2020, eligibility for qualified exemption status for 2021, and until the end of the public helath emergency, may be determined based on:

> (1) Documentation (e.g. contracts with buyers) that provides a sufficient basis to establish that, had there not been market disruption due to the COVID-19 pandemic, the average monetary value of food sold directly to qualified end-users in 2020 was reasonably 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; and
>
> (2) Documentation that the average annual monetary value of all food the farm sold during the preceding three years (or the year(s) for which the farm was in operation if less than 3 years) was less than $500,000, adjusted for inflation. FSMA inflation adjusted cut off values can be found at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

For example:

Farm E began selling food in 2020 and had contracts that demonstrate that the average monetary value of food sold directly to qualified end-users was reasonably anticipated to exceed the average annual monetary value of food sold to all other buyers. Due to market disruptions, in 2020 the monetary value of food sold directly to qualified end-users by Farm E did not exceed the monetary value of food sold to all other buyers. The monetary value of food sold in 2020 was less than $500,000. FDA does not intend to enforce the criteria regarding sales by Farm E to qualified end-users in 2020. FDA therefore intends to treat Farm E as eligible for the qualified exemption in 2021, even though the monetary value of food sold directly to qualified end-users by Farm E did not exceed the monetary value of food sold to all other buyers, due to market disruptions.