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# **Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID- 19 Public Health Emergency**

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## **Guidance for Egg Producers**

**April 2020**

**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 we) 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) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for FDA 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-1139 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," 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>. You may also send an e-mail request to [andrew.yeung@fda.hhs.gov](mailto:andrew.yeung@fda.hhs.gov) to receive an additional copy of the guidance. Please include the complete title of the guidance in the request.

## Questions

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# **Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency**

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## **Guidance for Egg Producers**

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

### **I. Introduction**

The Food and Drug Administration (FDA or we) 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.

We encourage all shell egg producers to continue to comply with applicable requirements of 21 CFR part 118 (the Egg Safety Rule). However, due to the increased consumer demand for eggs in the table egg market (e.g., sold directly to consumers in retail establishments), we are providing temporary flexibility to allow producers who currently only sell eggs to facilities for further processing (e.g., into “egg products”) to sell to the table egg market, provided certain circumstances are present.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including

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any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act (42 U.S.C. 247d(a)(2)).<sup>1</sup>

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, 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 FD&C Act and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the FDA’s good guidance practices.

In general, 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 our guidance means that something is suggested or recommended, but not required.

## **II. Background**

There is currently a pandemic of respiratory disease caused by a novel coronavirus. The virus has been named “severe acute respiratory syndrome coronavirus 2” (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.<sup>2</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>3</sup>

According to the egg industry, the COVID-19 pandemic has created a market imbalance. Although there is not currently an egg shortage, there is increased consumer demand for shell eggs in the table egg market. At the same time, there is reduced demand for eggs that are further processed into egg products to be used by restaurants and similar establishments. The egg industry has expressed concern that, absent additional flexibility to redirect eggs to the table egg market from poultry houses currently producing eggs for further processing, producers may have difficulty meeting the increased consumer demand for eggs in the table egg market.

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<sup>1</sup> Generally speaking, section 319(a)(2) of the PHS Act authorizes the Secretary of Health and Human Services to take various actions if the Secretary determines that there is a public health emergency. The provision expressly mentions “significant outbreaks of infectious diseases” as an example of a public health emergency.

<sup>2</sup> Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

<sup>3</sup> 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/>.

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The Egg Safety Rule includes requirements for producers who sell shell eggs to the table egg market. The requirements are intended to address the risk of *Salmonella* Enteritidis (SE) because SE is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. The Egg Safety Rule requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and to prevent SE from growing during storage and transportation (21 CFR 118.4). The Egg Safety Rule also requires shell egg producers to maintain records documenting compliance with the rule and to register with FDA (21 CFR 118.10 and 21 CFR 118.11, respectively). If all of the eggs at a farm go to further processing that will achieve at least a 5-log destruction of SE (21 CFR 118.1(a)(2)), only the refrigeration and registration requirements apply. However, if any of the eggs go to the table egg market, then all of the requirements of the Egg Safety Rule apply to all of the poultry houses on the farm (21 CFR 118.1(a)(1)).

Under the Egg Safety Rule, producers selling to the table egg market must test the poultry house environment when laying hens in the house are between 40-45 weeks of age (21 CFR 118.5). The rule requires testing during this time period because it is when SE is most likely to be detected, if present, in the environment. A positive environmental test signals a higher probability of SE-positive eggs originating from that production environment and triggers a requirement for egg testing unless the eggs are then sent for further processing.

## **III. Discussion**

To help address the increased demand for shell eggs in the table egg market, we are providing temporary flexibility so producers who currently sell eggs only for further processing (and are therefore not subject to most of the requirements of the Egg Safety Rule) may sell eggs to the table egg market when certain conditions are present at individual poultry houses. We believe these conditions will address food safety concerns that could arise when poultry houses shift from producing eggs for further processing to producing eggs for the table egg market.

FDA does not intend to object if shell eggs from a poultry house consisting solely of laying hens up to 45 weeks of age are sold to the table egg market provided the following conditions are present:

#### For Poultry Houses Providing Eggs to the Table Egg Market:

- A producer complies and has been in compliance with all requirements of the Egg Safety Rule for the poultry house for the life of the flock, including SE monitored pullets, biosecurity, rodent and pest control, cleaning and disinfection, environmental and egg testing, refrigeration, and recordkeeping.
- Before sending any eggs to the table egg market, a producer simultaneously conducts environmental and egg testing (as described in 21 CFR 118.7 and 118.8) for the poultry house. Note that environmental testing would still occur when the laying hens are 40-45 weeks of age and subsequently if molting is induced.
- No environmental tests or egg tests are positive for SE in the poultry house.

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- A producer processes eggs from the poultry house separately from eggs on the farm that are not going to the table egg market.
- A producer implements and maintains a written plan (e.g., use of dedicated equipment, change of personnel protective equipment between houses) to prevent cross-contamination between poultry houses whose eggs are going to the table egg market and any other poultry houses on the farm.

#### For Poultry Houses Not Providing Eggs to the Table Egg Market:

- Before sending any eggs to the table egg market, a producer complies with all requirements of the Egg Safety Rule for poultry houses that are not sending eggs to the table egg market (e.g., biosecurity, rodent and pest control, cleaning and disinfection, refrigeration, and recordkeeping), except for testing and SE monitored pullets.

This policy does not apply to poultry houses with laying hens over 45 weeks of age at the time this guidance is issued. Egg producers whose poultry houses have laying hens over 45 weeks of age that have been sending the eggs for further processing may continue to do so.