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MEMORANDUM

From: Elizabeth Barr Fawell
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Date: April 7, 2020

Re: COVID-19 Update: FDA Announces Temporary Policy for Shell Egg Producers and Updates COVID-19 Guidance

The U.S. Food and Drug Administration (FDA) recently released guidance regarding compliance with the shell Egg Safety Rule during the COVID-19 pandemic to facilitate distribution of eggs to retail. The agency also updated its COVID-19 questions and answers guidance with additional information regarding this development, as well as its guidance providing flexibility for packaging and labeling shell eggs sold at retail, and its temporary policy on food supplier verification onsite audit requirements. ^{1/} We discuss these developments below.

Temporary Policy for Shell Egg Producers

FDA issued a new guidance document that provides egg producers who currently only sell eggs to egg breaking facilities for further processing to sell to the table egg market (e.g., sold directly to consumers in retail establishments) in order to facilitate the distribution of eggs during the COVID-19 pandemic. ^{2/} This guidance provides a basis for egg producers who currently sell eggs to breakers for further processing (and thus are not subject to most of the requirements of the Egg Safety Rule) to instead sell those eggs to the table egg market, provided the producer can implement certain controls at the individual poultry houses. The guidance is effective for as long as the Department of Health and Human Service's COVID-19 emergency declaration remains in effect.

The Egg Safety Rule requires shell egg producers to implement measures to prevent *Salmonella* Enteritidis (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). Under current regulations, 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

^{1/} *Food Safety and the Coronavirus Disease 2019 (COVID-19)* (April 7, 2020), <https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>.

^{2/} *FDA Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID19 Public Health Emergency* (April 2020), <https://www.fda.gov/media/136732/download>.

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 guidance, 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 met:

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.
- 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.

FDA's Updated COVID-19 Guidance

FDA updated its questions and answers guidance on COVID-19 to include its temporary guidance and flexibility on three distinct issues:

1. Temporary policy regarding enforcement of the Egg Safety Rule for producers of shell eggs;
2. Temporary guidance providing flexibility regarding certain packaging and labeling requirements for shell eggs sold in retail establishments; and
3. Temporary guidance for receiving facilities and FSVP importers regarding enforcement discretion for requirements to conduct onsite audits.

This memorandum discusses the first issue, above. Hogan Lovells provided discussion and commentary on #2 and #3 in separate memoranda. 3/, 4/

3/ HL Memo, FDA Issues Temporary Policy Regarding Labeling of Shell Eggs Sold by Retail Establishments (April 3, 2020), <https://www.hlfoodlaw.com/2020/04/fda-issues-temporary-policy-regarding-labeling-of-shell-eggs-sold-by-retail-establishments/>.

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We will continue to monitor FDA's response to COVID-19. Should you have any questions or if we can be of assistance with your COVID-19 response strategy, please contact us.

^{4/} *HL Memo, COVID-19 Update: FDA and USDA Issue Guidance for Industry and Inspectors* (March 18, 2020), <https://www.hffoodlaw.com/wp-content/uploads/sites/357/2020/03/HL-Memo-COVID-19-Update-FDA-and-USDA-Issue-Guidance-for-Industry-and-Inspectors.pdf>.