

section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the EPIA or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(f) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(g) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement allowing refrigeration of unpasteurized shell eggs

at retail establishments at any temperature greater than 7.2 °C (45 °F).

[65 FR 76112, Dec. 5, 2000]

PART 118—PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS

Sec.

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AUTHORITY: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

SOURCE: 74 FR 33095, July 9, 2009, unless otherwise noted.

§ 118.1 Persons covered by the requirements in this part.

(a) If you are a shell egg producer with 3,000 or more laying hens at a particular farm that does not sell all of your eggs directly to consumers and that produces shell eggs for the table market, you are covered by some or all of the requirements in this part, as follows:

(1) If any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3, you must comply with all of the requirements of this part for egg production on that farm.

(2) If all of your eggs that are produced at the particular farm receive a treatment as defined in § 118.3, you must comply only with the refrigeration requirements in § 118.4(e) for production of eggs on that farm and with the registration requirements in § 118.11.

(b) If you transport or hold shell eggs for shell egg processing or egg products facilities, you must comply with the refrigeration requirements in §118.4(e). This section applies only to eggs from farms with 3,000 or more laying hens.

§ 118.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321) are applicable to such terms when used in this part, except where they are redefined in this part. The following definitions also apply:

Biosecurity means a program, including the limiting of visitors on the farm and in poultry houses, maintaining personnel and equipment practices that will protect against cross contamination from one poultry house to another, preventing stray poultry, wild birds, cats, and other animals from entering poultry houses, and not allowing employees to keep birds at home, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

Egg products facility means a USDA-inspected egg products plant where liquid, frozen, and/or dried egg products are produced.

Farm means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program.

Flock means all laying hens within one poultry house.

Group means all laying hens of the same age within one poultry house.

Induced molting means molting that is artificially initiated.

Laying cycle means the period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production and the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

Molting means a life stage during which hens stop laying eggs and shed their feathers.

Pest means any objectionable animal including, but not limited to, rodents, flies, and larvae.

Positive flock means a flock that has had an egg test that was positive for SE. A flock is considered positive until that flock meets the egg testing requirements in §118.6(c) to return to table egg production.

Positive poultry house means a poultry house from which there has been an environmental test that was positive for SE at any time during the life of a group in the poultry house until that house is cleaned and disinfected according to §118.4(d).

Poultry house means a building, other structure, or separate section within a structure used to house poultry. For structures comprising more than one section containing poultry, each section that is separated from the other sections is considered a separate house.

Producer means a person who owns and/or operates a poultry house containing laying hens which produce shell eggs for human consumption.

Shell egg (or egg) means the egg of the domesticated chicken.

Shell egg processing facility means a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market.

Treatment (or treated) means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

§ 118.4 Salmonella Enteritidis (SE) prevention measures.

You must follow the SE prevention measures set forth in this section. In addition, you must have and implement a written SE prevention plan that is specific to each farm where you produce eggs and that includes, at a minimum, the following SE prevention measures:

(a) *Pullets*. You must procure pullets that are SE monitored or raise pullets under SE monitored conditions. "SE monitored" means the pullets are raised under SE control conditions that prevent SE, including:

(1) *Procurement of chicks*. Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for "U.S. S. Enteritidis Clean" status (9 CFR 145.23(d)) or equivalent standard;