

## Food and Drug Administration, HHS

## § 118.1

because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in

accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

[80 FR 56145, Sept. 17, 2015]

## 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.

EDITORIAL NOTE: Nomenclature changes to part 118 appear at 81 FR 49896, July 29, 2016.

### § 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.

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(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