## Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation: Guidance for Industry

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

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#### Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation: Guidance for Industry<sup>1</sup>

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 responsible for this guidance as listed on the title page.

#### 1. Introduction

This document provides guidance to egg producers and other persons who are covered by FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030 (July 9, 2009) (codified at 21 CFR part 118)). The guidance document revises our previous guidance (regarding questions FDA has received on the final rule since its publication) by removing text pertaining to Competitive Exclusion Products, providing citations for regulatory requirements, and making a few editorial changes.

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 FDA guidances means that something is suggested or recommended, but not required.

#### 2. Background

FDA regulations at 21 CFR part 118 require shell egg producers and certain other persons to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation. The rule also requires shell egg producers to maintain records concerning their compliance with the rule and to register with FDA. FDA took this action because SE is among the leading

<sup>&</sup>lt;sup>1</sup> This guidance has been prepared by the Division of Dairy, Egg and Meat Products in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. The final rule will reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE.

This guidance document contains questions and answers relating to the requirements contained in 21 CFR Part 118, "Production, Storage, and Transportation of Shell Eggs," including (1) compliance dates; (2) coverage; (3) definitions; (4) SE prevention measures; (5) sampling and testing for SE; (6) registration; and (7) enforcement and compliance.

#### **3.** Questions and Answers

#### A. Compliance Dates for the Egg Final Rule

## 1. Is the compliance date determined by the number of layers on a farm, the number of layers in a poultry house, or the number of layers one producer owns, even if those layers are spread out over many farms?

As stated in the preamble to the final rule, the compliance date for the rule is July 9, 2010; except that, for producers with fewer than 50,000 but at least 3,000 laying hens, the compliance date is July 9, 2012. The compliance date for persons who must comply with only the refrigeration requirements is July 9, 2010 (74 FR 33030, 33034). The compliance date is determined by the number of layers a producer has at a particular farm. The rule defines a "farm" as "all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program" (21 CFR § 118.3). If you are a producer and you own and/or operate many farms, only those farms with 50,000 or more layers must be in compliance with the egg rule by July 9, 2010. If you also own and/or operate some farms with at least 3,000 but fewer than 50,000 layers, you have until July 9, 2012, to bring those farms into compliance with the egg rule.

# 2. Must all layers on my farm be in compliance with all provisions of the egg rule on my applicable compliance date (July 9, 2010, or July 9, 2012) if layers in one house are 30 weeks of age on my compliance date and layers in another house are 10 weeks post-molt?

No. On your applicable compliance date (see response to question A-1), you must be in compliance with only those requirements of the egg rule that have not yet passed for layers in each house. For example, if layers in one house are 30 weeks old, you do not need to comply with the pullet requirements for those layers, but you must comply with all other applicable requirements. Similarly, if layers in another house are more than six weeks post-molt, you do not need to comply with the pullet requirements for those layers. You also do not need to comply with any of the environmental or egg testing requirements for those layers, unless they are molted again.

#### **B.** Coverage of the Egg Rule

# **1.** If I am a shell egg producer with 3,000 or more laying hens at a particular farm, must I follow *all* of the requirements of the egg rule if I send eggs from four of my houses to treatment and eggs from my other four houses (on the same farm) to shell egg processing?

Yes. Under § 118.1(a)(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 the egg rule for all eggs produced on that farm.

# 2. If I am a shell egg producer with 3,000 or more laying hens at a particular farm, must I follow *all* of the requirements of the egg rule if I usually send all of the eggs from my farm to treatment and only occasionally send surplus eggs (from the same farm) to shell egg processing?

Yes. Under § 118.1(a)(1), if any of your eggs that are produced at a particular farm do not receive a treatment, you must comply with all of the requirements of the egg rule for all eggs produced on that farm.

## **3.** Am I covered by the egg rule if I am an owner of broiler breeder flocks (breeding hens that supply hatching eggs) and I occasionally send surplus eggs to either the table egg market or to an egg products facility for breaking?

Yes. Under § 118.1(a), you are covered by some or all of the requirements of the egg rule if you own 3,000 or more layers at a particular farm and do not sell all your eggs directly to consumers. Under § 118.1(a)(2), if all of your surplus eggs receive a treatment (as defined in § 118.3), you must comply only with the refrigeration requirements in § 118.4(e) and with the registration requirements in §118.11. Under § 118.1(a)(1), if any of your surplus eggs do not receive a treatment, you must comply with all of the requirements of the rule for that farm.

## 4. Am I covered by the egg rule if I have fewer than 3,000 layers on my farm, but I am a member of an egg cooperative that is made up of several farms, and the total number of layers at all farms within the cooperative is greater than 3,000?

No. Producers with fewer than 3,000 layers *at a particular farm* are exempt from the egg rule. See the response to question A-1, above.

#### **C. Definitions**

• Farm (21 CFR 118.3)

In § 118.3, FDA defines "farm" as "all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program." Can I separate my existing farm into several smaller farms, each with fewer than 3,000 layers and each with its own biosecurity program, so that each new (smaller) farm will be exempt from the rule?

No. We are not aware of any circumstances where it would be appropriate for poultry houses located in close proximity to one another to have different biosecurity programs.

#### D. SE Prevention Measures (21 CFR 118.4)

#### • SE Prevention Plan (21 CFR 118.4)

## **1.** What additional preventive measures can I implement during egg production to reduce the potential contamination of eggs with SE?

In addition to the SE prevention measures required by the egg rule, there are several other measures that producers can incorporate into their SE prevention plans. If producers have identified a vaccination program that is effective for their particular farms, they should consider including SE vaccination. Other intervention measures might include treatment of feed and/or water, e.g., FDA permits ionizing radiation for the treatment of poultry feed and poultry feed ingredients (21 CFR 579.40).

#### 2. What SE vaccines are available for layers?

There are a number of different SE vaccines available, both killed (bacterins) and live attenuated, and numerous vaccination programs that use a combination of one or both types. Individual producers who choose to use a vaccine should determine which program is most effective for the particular set of circumstances that exist at their farm.

#### 3. How effective are SE vaccines?

Vaccines can be a very effective component of an SE prevention program. However, the efficacy of a vaccination program depends on various parameters, some of which include the vaccination program used, effectiveness of administration by the vaccination crew, age of the birds when the vaccine is administered, and the environmental load of SE in pullet or layer houses.

## 4. Can vaccines be used in lieu of any of the SE preventive measures required by the egg rule?

No. As was discussed in the preamble to the final rule (74 FR 33030 at 33035), FDA believes that data on the efficacy of vaccines are not sufficient to allow substitution of vaccination for any of the SE prevention measures required in the egg rule. Vaccination against SE is most effective when it is one part of a larger SE prevention plan which includes SE-monitored pullets, effective biosecurity measures, effective rodent and fly control, thorough cleaning and disinfection procedures, and a monitoring program for SE in the environment and eggs. If individual producers have

identified a vaccination program that is effective for their particular farms, FDA would encourage the use of the program as an additional SE prevention measure.

#### 5. How can I treat feed for my layers as an additional SE prevention measure?

Feed can be treated with heat, a combination of heat and pressure, the chemical formaldehyde (see 21 CFR 573.460(b)), and/or irradiation (see 21 CFR 579.40) to reduce contamination with SE. Producers should determine if feed treatment is an appropriate addition to their SE prevention plan. If feed treatment is incorporated, it is the producer's responsibility to determine the appropriate type of treatment and equipment requirements necessary for treatment of feed.

#### 6. How does treating feed help minimize SE contamination of eggs?

Treating feed helps reduce the environmental load of SE within the pullet or layer house and is an added measure that may help prevent the introduction of SE into the rodent and fly populations, which are the predominant vectors for its spread across layer farms.

### 7. How can I treat water used for my layers as an additional SE prevention measure?

There are several chemical treatments available to reduce or eliminate SE in water. A producer may consider water treatment particularly when a non-municipal water source is used, such as well water. It is up to individual producers to determine if water treatment should be part of their SE prevention plans. Producers considering water treatment should consult the appropriate local, state and federal agencies before treating any water source to ensure the specific treatment being considered is approved.

#### • Cleaning and Disinfection (21 CFR 118.4(a)(3))

## Under certain circumstances, the egg rule requires the removal of all visible manure. What can I do with manure I remove from my poultry houses during the winter in cold climates when I cannot apply it to fields?

The egg rule requires removal of manure regardless of whether it can be applied to fields. FDA notes that other possible options in some circumstances include composting and storage in manure barns.

#### • Refrigeration (21 CFR 118.4(e))

## **1.** How will I determine when the "36-hour clock" for refrigeration starts when it is impossible to determine when each individual egg is laid?

Under § 118.4(e), you must hold and transport eggs at or below 45°F ambient temperature beginning 36 hours after time of lay. FDA considers that the "36-hour

clock" for refrigeration begins at the end of the egg collection shift. For example, if you collect eggs from 6:00 a.m. until 5:00 p.m., the "36-hour clock" will begin at 5:00 p.m. on Tuesday for all eggs laid between 5:00 p.m. on Monday and 5:00 p.m. on Tuesday. Thus, those eggs will have to be refrigerated no later than 5:00 a.m. on Thursday.

### 2. Once eggs are at an official egg products facility, must they be refrigerated at 45 degrees F ambient temperature until they are broken?

Once eggs are at an official egg products facility, they are under the jurisdiction of the U.S. Department of Agriculture, which will determine the proper procedures to be followed. However, pursuant to § 118.4(e), they must be refrigerated prior to arriving at the official egg products facility if they are more than 36 hours old.

## 3. If I am not a shell egg producer who is covered under § 118.1(a), but instead I run a hard-cooking or in-shell pasteurization facility, must I comply with the refrigeration requirements of § 118.4(e)?

No. The refrigeration requirements of § 118.4(e) apply to certain shell egg producers and to persons who transport or hold shell eggs for shell egg processing or egg products facilities (§ 118.1(a) and (b)). You state that you are not a producer covered under § 118.1(a). Further, hard-cooking facilities and in-shell pasteurization facilities are neither shell egg processing facilities (facilities that process (e.g., wash, grade, pack) shell eggs for the table egg market) nor egg products facilities (USDA-inspected egg products plants where liquid, frozen, and/or dried egg products are produced). Therefore, you do not have to comply with the refrigeration requirements in § 118.4(e).

#### 4. If I am a shell egg producer with 3,000 or more laying hens at a particular farm, I do not sell all of my eggs directly to consumers, and I produce shell eggs for the table market, must I refrigerate eggs that I am going to send directly from my farm to a hard-cooking operation or an in-shell pasteurization facility?

Yes, beginning 36 hours after time of lay, you must refrigerate them as set forth in § 118.4(e). Hard-cooking and in-shell pasteurization methods that achieve at least a 5-log destruction of SE for shell eggs, or that are carried out in accordance with the Egg Products Inspection Act, meet the definition of "treatment" in § 118.3. Under § 118.1(a)(2), if you have 3,000 or more layers at a particular farm, you do not sell all your eggs directly to consumers, and you produce shell eggs for the table market, you must comply with the refrigeration requirements in § 118.4(e), even if all of your eggs receive a treatment as defined in § 118.3.

# 5. How can I prevent thermal checks (hairline cracks in the shell caused by too great of a difference between the temperature of the wash water and the temperature of the eggs being washed) when I wash eggs that have been refrigerated?

The equilibration step, a process allowed for in § 118.4(e) to bring the internal temperature of refrigerated eggs up to room temperature just prior to washing, is

designed to prevent thermal checks.

6. If I refrigerate eggs destined for a shell egg processing facility within 36 hours of time of lay, must they be refrigerated a minimum amount of time before I can remove them from refrigeration and store them at room temperature for up to 36 hours to temper them (i.e., perform the equilibrium step, as discussed in question D-5)?

No. There is no minimum amount of time eggs destined for shell egg processing must be refrigerated before they may be tempered. However, the reason FDA is allowing these eggs to be tempered prior to washing is to reduce the risk of thermal checks (see question D-5 above). If the eggs have not been refrigerated long enough to reduce their internal temperature to the point where there is a risk of thermal checks, then there is no need to temper those eggs.

7. If I am a shell egg processor and I refrigerate eggs that are not processed for the ultimate consumer within 36 hours of time of lay, the egg rule allows me to remove eggs from refrigeration and store them at room temperature for up to 36 hours just prior to processing to temper them. Is the 36 hours (for tempering) cumulative, e.g., may I remove them from refrigeration for several hours in anticipation of processing, then return them to refrigeration if they are not processed, then remove them again in anticipation of processing and again return them to refrigeration if they are not processed, as long as the total time they are removed from refrigeration does not exceed 36 hours?

No. Section 118.4(e) states "If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then you may then hold them at room temperature for no more than 36 hours *just prior to processing* to allow an equilibration step to temper the eggs" [emphasis added]. The reason FDA allows eggs to be tempered prior to washing is to reduce the risk of thermal checks (see question D-5 under the Refrigeration bullet above). Therefore, the tempering process is only allowed *just prior to processing*.

8. If eggs are washed and/or graded and then loose-packed and transferred to a second location to be placed in containers (overwrapped trays, sleeves, boxes, etc.) for sale to the ultimate consumer, must the eggs be refrigerated during

### transport to the second location and while being held and repacked at the second location, under § 118.4(e)?

Yes (beginning 36 hours after time of lay), if the eggs originate from farms with 3,000 or more laying hens. Section 118.1(b) states (in part), "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)." "Shell egg processing facility" is defined in § 118.3 as "a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market." In the above situation, the location to which the washed and/or graded eggs are transferred to be placed in containers (overwrapped trays, sleeves, boxes, etc.) is considered a shell egg processing facility under the rule. The refrigeration requirements in § 118.4(e) state, "You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay." The only exception to these refrigeration requirements is the equilibration allowance in § 118.4(e) that allows the eggs to be held at room temperature for no more than 36 hours just prior to processing to temper them (see response to question D-7 above).

### 9. Must I refrigerate surplus eggs from broiler breeder flocks (breeding hens that supply hatching eggs) that are destined for an official egg products facility?

Yes, unless they reach the official egg products facility within 36 hours of time of lay, per § 118.4(e). Under § 118.1(a), your surplus eggs are covered by some or all of the requirements of the egg rule if you have 3,000 or more layers at a particular farm and do not sell all your eggs directly to consumers. Pursuant to § 118.1(a)(2), even if all of your surplus eggs receive a treatment, such as processing into egg products at an official egg products facility, you still must comply with the refrigeration requirements in § 118.4(e) for those eggs.

#### E. Environmental Testing for SE (21 CFR 118.5)

## 1. When does FDA consider "the end of any molting process" (§ 118.5) to have occurred?

FDA considers that the molting process has ended when the layers have reached 50 percent of production. Although there are other possible indicators, FDA considers that this standard is the most objective, easy to apply indicator. Further, FDA notes that many of the State egg quality assurance programs use this standard.

## 2. If an environmental test comes back positive for SE, and I choose to begin egg testing instead of diverting eggs to treatment for the life of the flock, as set forth at § 118.5(a)(2)(ii), must I hold eggs until the first egg test results come back?

No. As was discussed in the preamble to the final rule (74 FR 33030 at 33042-43), producers in this situation are not required to hold eggs until test results are received.

### **3.** Is a positive environmental test result cause for a voluntary recall or market withdrawal?

An egg producer should assess the implications of a positive environment test result for any product in the marketplace to determine if a voluntary recall or market withdrawal is appropriate. Not all SE positive environmental test results lead to SE contaminated eggs, and so FDA does not expect that most findings of positive environmental test results will result in recalls. Some factors egg producers should consider when making a decision whether to withdraw product from the marketplace include the extent of the positive findings (for example, several positives throughout the farm, or one positive remote from the eggs), whether the farm has had positive environmental test results previously, and whether it is likely that impacted eggs remain on the market.

#### F. Egg Testing for SE (21 CFR 118.6)

#### 1. Is a positive egg test result cause for a voluntary recall or market withdrawal?

FDA considers eggs containing SE to be adulterated. An egg producer obtaining a positive egg test result should take appropriate action to determine if a voluntary recall or market withdrawal is the appropriate response to a positive finding of SE in an egg sample. FDA expects that most findings of positive egg test results will result in recalls in situations where eggs produced by the flock on or after the day the eggs were sampled have been placed in the table egg market.

### 2. If I initiate a voluntary recall or market withdrawal based on a positive egg test result, which eggs should be subject to the recall/withdrawal?

An egg producer who determines that a voluntary recall or market withdrawal is necessary in light of a positive finding of SE in an egg sample (see response to question F-1) should take appropriate action to determine what the scope of that recall or market withdrawal should be. If an egg test result is positive, all eggs produced by that flock on or after the day those eggs were sampled would be considered SE-positive by FDA. Eggs that were produced before the day on which the positive sample was taken would not automatically be considered SE-positive by FDA. For example, for a producer conducting a series of four egg tests following an environmental positive test result as set forth in § 118.6(c), if the first egg test were negative and the second egg test were positive, absent other factors, FDA generally would only consider the eggs produced by the flock on or after the day on which the second sample was taken to be SE-positive.

## 3. Would all my eggs produced between the time I receive a positive environmental test result and the time I receive a positive egg test result for SE always be considered SE-positive by FDA?

No. All eggs produced between the time a positive environmental test result is received and the time a positive egg test result is received would not automatically be considered SE-positive by FDA. Only those eggs produced on or after the day eggs are sampled would automatically be considered SE-positive by FDA (when the egg sample leads to a positive egg test result). However, under some circumstances, FDA

may consider the conditions under which the eggs were produced to be such that the earlier produced eggs may be rendered injurious to health. As an example, if the firm had a positive environmental test and had a major rodent infestation, FDA may consider the eggs produced between the time of the positive environmental test and the positive egg test to be adulterated because of the conditions under which the eggs were produced.

#### 4. What can I do with my eggs after I receive a positive egg test result?

Under § 118.6(d), eggs from positive flocks must be diverted to treatment. Treatment is defined in § 118.3 to refer to 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 (21 U.S.C. 1031 et seq.). As was discussed above at question E-2, there is no obligation to hold eggs until the results of an egg test are received. Therefore, the obligation to begin diverting eggs to treatment does not begin until a positive egg test result is received. *See* 74 FR 33030, 33043. However, as was discussed above at questions F-1 through F-3, if an egg test result is positive, all eggs produced by that flock on or after the day those eggs were sampled would be considered SE-positive by FDA, and a recall or market withdrawal of those eggs would likely be appropriate.

#### G. Sampling Methodology for SE (21 CFR 118.7)

#### Whom may I designate to collect environmental and egg samples at my farm?

You may designate any individual who is capable of following the sampling requirements in §118.7.

#### H. Testing Methodology for SE (21 CFR 118.8)

## **1.** How can I determine whether the test methods I use for environmental and egg samples are equivalent in accuracy, precision, and sensitivity to the testing methods specified in the egg rule for detecting SE?

Under § 118.8(a), testing to detect SE in environmental samples must be conducted by the method entitled "Environmental Sampling and detection of *Salmonella* in Poultry Houses," April 2008, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Under § 118.8(b), testing to detect SE in egg samples must be conducted according to Chapter 5 of FDA's Bacteriological Analytical Manual (BAM), December 2007 Edition, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Alternative methods used to analyze environmental or egg samples for SE do not require a formal determination of equivalency or prior approval by FDA. If you have information that you believe demonstrates that a method is equivalent to a method specified in the egg rule and want to obtain FDA's view regarding the method, you may contact FDA's Microbial Methods Development Branch (MMDB). Methods that have undergone a validation process through the Association of Official Analytical Chemists (AOAC International) Research Institute

(RI) or the AOAC International Official Methods of Analysis (OMA) Program and that have been certified by that body as being equivalent to the FDA methods specified in the egg rule are not automatically considered equivalent by FDA. To obtain FDA's view regarding whether such a method is equivalent to a method specified in the egg rule, you may contact MMDB, as set forth above. MMDB can be reached by phone at 240-402-2408, or by mail at: MMDB, Division of Microbiology, Office of Regulatory Science, CFSAN, HFS-711, 5001 Campus Drive, College Park, MD 20740. All methods ultimately determined by FDA to be equivalent to the methods cited in the rule will be listed on FDA's website here: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinfor mation/eggs/ucm228796.htm.

### 2. Is FDA evaluating any alternative test methods for SE, specifically any rapid test methods?

Yes. As of the date of this guidance, FDA is evaluating a rapid method for detection of SE in eggs. FDA encourages the industry to evaluate rapid methods as well, using the protocol described in the response to question H-1, above.

#### 3. Can I use any laboratory for testing my environmental and egg samples?

You may use any laboratory that is capable of properly carrying out the testing methods specified in the egg rule.

4. Do laboratories need to register with FDA or be acknowledged or authorized by FDA as a compliant tester for environmental and/or egg samples for SE under this regulation?

No.

#### I. Registration Requirements (21 CFR 118.11)

**1.** If I buy eggs from a producer and then sell them to a processor, am I required to register with FDA?

No. Only shell egg producers covered under § 118.1(a) must register with FDA.

## 2. Must I register my farm with FDA if I send all of my surplus eggs from broiler breeder operations (as defined at question B-3) to an official egg products facility?

Yes, you must comply with the registration requirements in § 118.11. Under § 118.1(a), you are covered by some or all of the requirements of the egg rule if you have 3,000 or more layers at a particular farm and do not sell all your eggs directly to consumers. As set forth in § 118.1(a)(2), even if all of your surplus eggs receive a treatment, such as processing into egg products at an official egg products facility, you still must comply with the registration requirements in § 118.11.

#### 3. Who must register contract flocks?

The registration requirements of § 118.11 apply to "[s]hell egg producers covered under § 118.1(a)." "Producer" is defined in § 118.3 as "a person who owns and/or operates a poultry house containing laying hens which produce shell eggs for human consumption." It is the producer who must comply with the registration requirements, regardless of who owns the flock.

#### J. Enforcement and Compliance (21 CFR 118.12)

#### 1. How will FDA determine that eggs are in compliance with the rule?

FDA will inspect both domestic and foreign egg producers as necessary to ensure that eggs distributed in the United States are produced in compliance with the rule.

#### 2. What biosecurity measures will FDA inspectors follow when inspecting a farm?

FDA's Investigations Operations Manual, the primary source regarding FDA policy and procedures for field investigators and inspectors, discusses biosecurity measures for FDA inspectors in Chapter 5.2.10, "Routine Biosecurity Procedures for Visits to Facilities Housing or Transporting Domestic or Wild Animals" (available at: <a href="http://www.fda.gov/ICECI/Inspections/IOM/ucm122530.htm#5.2.10">http://www.fda.gov/ICECI/Inspections/IOM/ucm122530.htm#5.2.10</a>). FDA inspectors will follow these procedures.

### **3.** In those States that contract with FDA to enforce the egg rule, how will FDA ensure that individuals doing the inspections have received proper training?

Inspectors from States that contract with FDA to enforce the egg rule will first be trained by FDA using the same training module used to train FDA field staff. This will ensure consistency among inspectors and inspections.

#### K. Other

FDA held two public meetings to discuss the egg rule. Where can I obtain copies of the transcripts from these meetings and the presentations that were given?

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm195536.htm.