

SECTION 3: SHELL EGGS ELIGIBLE FOR GRADING

I. Eggs of Current Production

Eggs of current production, means shell eggs that are no more than 21 days old (date of the final gather from layer house) are eligible for grading in accordance with the U.S. Standards, Grades and Weight Classes for Shell Eggs, AMS 56.

For example: Completion of the gathering of eggs at 4:00 p.m. on Monday, August 23, 2012, will be identified with the production date 08-23-2012 representing the first day of the 21 days.

II. Eggs Identified as Wholesome

Eggs identified as wholesome are defined as shell eggs that have not been contaminated or adulterated. Any eggs on the premises of an official plant that are contaminated or adulterated must be properly segregated, identified, and controlled by plant management. This includes eggs identified through a condition inspection for quality (sensory/organoleptic examination) such as the odor of smoke or residual chemical odor, mold, and the following:

- A. Eggs tested positive for the presence of Salmonella Enteritidis (identified as adulterated).
- B. Eggs that have been recalled by the packer as a result of contamination of the product.

III. Eggs Eligible for Identification with the USDA Grademark

The applicant requesting service is responsible for presenting only eggs that are wholesome and unadulterated for grading in accordance with minimum quality standards for identification with the USDA grademark. In signing the Application for Service, Form PY-32, (Exhibit I), or a State-Trust State's Application for Service, with the attached Wholesomeness Statement, plant management for a shell egg processing facility agrees to notify the USDA grader of any contaminated or adulterated (chemical, physical, or biological agents) shell eggs in the plant and assure proper identification, segregation, and inventory control of such product. This includes eggs originating from a layer flock that tests positive for the presence of Salmonella Enteritidis (SE). Additionally, plant management must inform USDA of any company recalls, eggs subject to a market withdrawal, or any recalled eggs received at the plant and procedures for control of such eggs.

The USDA grader and Federal-State supervisor will review the detailed description and implementation of the identification, segregation, and the inventory control for eggs detained by the company. When the company's detention procedures are determined inadequate for control of such product, the USDA grader will retain the product following procedures outlined in Section 8, item VI. B, C.

When conducting shell egg grading service at a non-official plant, the applicant must sign the Wholesomeness Certification worksheet (Exhibit II), for each day's certification activity or grading

certificate covering the lot certified. The Wholesomeness Certification worksheet will be attached to the grader's file copy of the Shell Egg Grading Certificate, Form PY-210S, issued.

A. Monitoring the Handling of Eggs Originating from Egg-Laying Flocks in an Environment Testing Positive for the Presence of Salmonella Enteritidis (SE) or Eggs from a Layer Flock Testing SE-Positive

The Food and Drug Administration's (FDA) regulations for the Prevention of Salmonella Enteritidis in Shell Eggs during Production, Storage, and Transportation requires shell egg producers to generate food safety information that may impact an egg processor's eligibility to use the USDA grademark. The FDA has identified fresh shell eggs that test positive for SE as adulterated, requiring treatment to destroy the microorganism.

The FDA regulations require egg producers to monitor the layer house environment. When these monitoring procedures require testing of eggs for the presence of SE, the producer/processor is responsible for notifying the USDA grader of the date of collection of the eggs for testing, identity of the house(s) involved, and the date test results are received. The processor may package eggs from the layer house(s) being tested, but any product identified with the USDA grademark must be controlled until the facility presents negative test results.

The FDA regulations require egg producers to test the layer house environment for the presence of SE. When an environmental sample result is positive for SE, the producer/processor must:

1. Inform the USDA grader of the identity and location of the layer house flock(s) and the date laboratory results were received.
2. If plant management acknowledges the receipt of eggs from a layer house flock with a SE-positive environment, the USDA grader is to request the following information:
 - a. If management will elect to test the eggs for the presence of SE in accordance with FDA regulations to determine if production from the identified layer house flock(s) can continue to be marketed to the table egg market?
 - b. If management is not going to test the eggs, will the eggs be diverted for treatment to destroy SE for the remainder of the production cycle of the layers?
 - c. Will any eggs from the identified layer flock(s), enter the official processing plant? If plant management confirms that the eggs will be stored in the plant, a copy of the company's segregation plan shall be reviewed with and remain accessible by the USDA grader to aid in monitoring the segregation process.
 - d. If management elects to depopulate the layer flock(s) and proceed with the cleaning and disinfecting of the layer house, what is the estimated date of depopulation?

Upon obtaining the above information, the USDA grader will notify (by telephone) the immediate supervisor and provide relevant information reported by plant management regarding the identified layer flock(s), (approximate number of layers, identity, and location), and plant management's decision on handling the affected eggs.

B. Diversion

When eggs from a layer house(s) have been determined positive for the presence of SE, are diverted for the remainder of the flock's production cycle, the pallet, case, or other shipping container must be legibly and conspicuously labeled with the following statement:

"Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of Salmonella Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6 (f)."

If plant management elects to divert eggs from a layer house with SE-positive environment, the USDA grader(s) must monitor and verify the plant's segregation plan assures that, when required, the eggs designated for diversion are not commingled with eggs eligible for packing and distribution, in commerce.

C. Company Notification of Egg Testing

A company may elect to test eggs from the identified flock(s) in accordance with FDA regulations. When the USDA grader receives notification of a negative-egg test result from an identified flock(s):

1. Confirm through company records the date in which the negative-egg test results were received.
2. Release for distribution into commerce all of the detained eggs identified with the USDA grademark back to the time and date of collection of egg samples to be tested.

Note: Eggs packed in containers that are not identified with the USDA grademark packaged during the period while awaiting egg test results may be distributed in commerce in accordance with the referenced FDA regulations. If egg test results are SE-positive, the egg packer must issue a market recall of eggs packaged and distributed subsequent to the collection of the samples for egg testing.

A company may elect to continue testing eggs from the identified flock(s) in accordance with FDA regulations by conducting a total of 4 consecutive tests taken not more than 2 weeks apart. When the company elects to continue the testing of eggs, the grader will request the following information and follow the guidance below:

3. Company management will provide notification to the USDA grader of the date of collection of eggs for each consecutive test.
4. The USDA grader will follow the procedures outlined above, in C.1 and C.2 until four consecutive, negative-egg test results are achieved

5. When additional testing of the identified flock (s) is conducted in accordance with the requirements stated in the FDA regulations or in accordance with a State SE monitoring program, company management must notify the USDA grader of the sample collection date for control of eggs as outlined above.

D. Positive-Egg Test Results

Eggs testing SE-positive must be diverted for treatment (breaking for pasteurization, hard cooking, or other FDA-approved process). Additionally, in accordance with the regulations,

1. All eggs testing SE-positive must be labeled as stated below in accordance with FDA regulations.

“Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of Salmonella Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6 (f).”

2. All eggs from a layer flock(s) with an SE-positive test result entering an official shell egg facility must be labeled and controlled as stated in the company’s procedures to assure the adulterated eggs are not commingled with other eggs determined eligible to be identified with the USDA grademark. When the company elects to conclude the production cycle and depopulate the identified layer flock(s), the USDA grader must be notified and the information recorded on the company’s control records.

Additional guidance may be provided by the Federal-State supervisor to address detailed control procedures at each official facility testing eggs originating from a layer house with an SE-positive environment as provided in the referenced FDA regulations.

IV. COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION (FDA) REPRESENTATIVES OR OTHER GOVERNMENT AGENCIES

The Food and Drug Administration (FDA) maintains jurisdiction for the production and processing of shell eggs in accordance with good manufacturing practices to assure that the product is safe for human consumption. Therefore, FDA officials may visit shell egg plants to observe operations and collect market survey samples for a variety of analysis.

When an FDA representative visits a plant the grader shall cooperate, to the extent possible without neglecting required grading and certification duties. If the FDA representative is introduced, exchange official identification and contact information. If the grader is invited to accompany the FDA representative during a tour of the egg processing facility, the grader will determine if it is feasible. The grader shall inform the FDA representative of availability to review observations or any deficiency to be included in a report relative to sanitary conditions and processing of shell eggs. The grader will not be present during FDA discussions with plant management.

The grader will immediately (same day) instruct the Federal-State supervisor of the visit from the FDA representative(s), providing all relative contact information and comments regarding the egg processing plant. Visits to an in-line egg production facility focusing solely on the egg production

must also be reported. This information will be forwarded to the National Office by the Regional Office as soon as practical.

A. Plant Management's Responsibility

Plant management at an official shell egg plant is responsible for notifying the USDA grader whenever contaminated or adulterated shell eggs are present in the official shell egg plant. Any shell eggs identified as contaminated or adulterated must be properly labeled and controlled by plant management. This includes shell eggs originating from a layer house with a positive environment for Salmonella Enteritidis (SE) or eggs testing positive for the presence of SE. Failure to control, detain and/or notify the grader of the presence of contaminated or adulterated shell eggs in the official plant will constitute a violation of the regulations.

B. Procedures to Follow When Product Is Suspected of Being Adulterated, Through Contaminated or Evident Tampering

Graders shall be alert for any possible product contamination, either accidental or intentional. Although processors may have extensive preventative and security measures in place, graders may encounter product that may be suspected of or found to be contaminated. Contamination may be from various sources such as:

- **Chemical Agents** - Agents usually delivered as airborne droplets, liquids, aerosols, or solids. Additionally, these agents can include toxic industrial chemicals such as pesticides, rodenticides, and heavy metals.
- **Biological Agents** – Agents that are generally in the form of bacteria, toxins, viruses, and parasites and are usually delivered through liquids, aerosols, or solids.
- **Physical Agents** - Materials that could cause adverse health effects if consumed- Examples include bones or hard-like materials, glass fragments, and metal pieces or filings.

After review by applicable parties, the Federal-State supervisor will provide the grader guidance in determining what further action is to be taken.

C. Memorandum of Understanding (MOU) Between the Food and Drug Administration (FDA) and the Agricultural Marketing Service (AMS)

In accordance with the MOU between the agencies, AMS graders and Shell Egg Surveillance Inspectors will report the observation of the violation of the Federal Food Drug and Cosmetic Act (FFDCA) that reflect a high risk or probable contamination while conducting grading or inspection activities. When graders encounter evident instances of adulteration or contamination, the affected product shall be retained to prevent further distribution in marketing channels. Upon review of the information provided additional guidance for contacting the FDA District Office and further guidance for the grader will be provided to the Federal-State supervisor. The detailed information and observations regarding such an incident will be reported immediately to the Federal-State supervisor and plant management. The Federal-State supervisor will complete the Interagency Referral Report (Exhibit III) and submit the report through the Regional Office to the National Office for electronic transmission to FDA.

D. Reporting Tampering or Intentional Contamination

When graders encounter probable instances of contamination or evident tampering, the identified shell eggs will be retained. The grader will contact the Federal-State supervisor to provide detailed information pertaining to the incident. The Federal-State supervisor will report the information through the Regional Office to the National Office Staff. Upon receipt of information relative to final disposition of the retained product the information will be forwarded to the National Office. In instances of tampering or intentional contamination, the Federal-State supervisor is to notify FDA and the Office of Inspector General (OIG) by calling their local district offices or their 24-hour emergency numbers:

FDA: 1-866-300-4374 or (301) 796-8240

OIG: (202) 447-7257

V. Refrigeration of Shell Eggs From Production to Processing in Accordance with FDA Regulations

The FDA Regulations for the Prevention of Salmonella Enteritidis in Shell Eggs during Production, Storage, and Transportation establish the ambient refrigeration requirements for egg producers with 3,000 or more layers. The following is a list of principal points defined in these regulations.

A. Eggs Washed and Packaged for the Ultimate Consumer or Further Processed

1. Nest run eggs that are not processed within 36 hours from the time of lay (date and time of final gathering) must be refrigerated at 45°Fahrenheit or less during storage and transport.
2. The ambient refrigeration requirements in item 1 apply to:
 - a. Surplus or culled eggs originating from breeder flocks or hatcheries.
 - b. Restricted eggs segregated at a grading station for further processing at an official egg products plant.
 - c. Loose packed, graded eggs held for reprocessing and repackaging into containers for sale to the ultimate consumer or diverted/traded as breaking stock.
3. Refrigerated nest run eggs may be equilibrated up to 36 hours at room temperature prior to washing and grading to reduce the risk of thermal cracks. Only nest run eggs may be equilibrated at room temperature prior to processing.

Note: The equilibration time is not a cumulative period. For example: When nest run eggs are removed from refrigerated storage to an unrefrigerated area (processing room) awaiting processing, but then returned to a refrigerated storage area 10 hours later, the equilibration period is terminated for the lot of nest run eggs.

When the equilibration period for a lot of eggs has been terminated, that lot cannot be brought out to the processing room for the equilibration process again. The lot must be immediately placed on the line for processing/reprocessing or for packaging only. Product brought out into the processing room is limited to a pallet at a time and must be actively transferred to the grading machine.

If product is brought out for placement on the grading machine for processing/reprocessing or packaging, and is not actively transferred to the grading machine, it is no longer eligible to be processed/reprocessed or packaged into USDA grademarked product. At this point, if the company/facility elects to process/reprocess or package the pallet of eggs into non-USDA grademarked product, the grader is to allow them to do so; however, the grader shall notify their immediate supervisor, who shall complete the FDA, Interagency Referral Report (Exhibit III).

It is recommended that the USDA grader review these requirements with plant management to assure that the eggs remain eligible for grading.

The resident grader is not required to specifically monitor the egg processing plant's conformance with these FDA regulatory refrigeration requirements. However, if nonconformance is evident, contact the Federal-State supervisor. The Federal-State supervisor will provide guidance regarding refrigeration nonconformance and the eligibility of the eggs to be identified with the USDA grademark at the official plant. Additionally, the Federal-State supervisor will complete the FDA, Interagency Referral Report for submission to the National Office.

VI. Avian Disease Restrictions

In the event of the detection of a highly pathogenic avian disease in egg-laying flocks in the United States, State and Federal veterinary service officials may establish restrictions to control potential transmission and eradicate such disease.

If detection is confirmed, officials with the Animal and Plant Health Inspection Service (APHIS), USDA, will identify the geographical area involved and define any restrictions regarding the movement and use of eggs originating from the identified layer flock(s). APHIS officials will notify the National Office with detailed information and instructions that will be distributed to all impacted shell egg graders.

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OMB APPROVED - NO. 0581-0127

U.S. DEPARTMENT OF AGRICULTURE
 AGRICULTURAL MARKETING SERVICE
 POULTRY PROGRAMS

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APPLICATION FOR SERVICE

In accordance with the applicable provisions of the regulation issued by the Agricultural Marketing Service, U.S. Department of Agriculture, application is hereby made for the furnishing of the service(s) checked below to be performed at the plant specified:

"X"	VOLUNTARY SERVICE REQUESTED	TYPE OF SERVICE	REGULATIONS APPLICABLE TO SERVICE REQUESTED
	SHELL EGG GRADING SERVICE	<input type="checkbox"/> Resident <input type="checkbox"/> Non-Resident <input type="checkbox"/> Temporary	Grading of Shell Eggs (7 CFR Part 56)
	POULTRY OR RABBIT GRADING SERVICE	<input type="checkbox"/> Resident <input type="checkbox"/> Non-Resident <input type="checkbox"/> Temporary	Voluntary Grading of Poultry Products and Rabbit Products (7 CFR Part 70)

NAME, ADDRESS, TELEPHONE NUMBER, AND FAX NUMBER OF PLANT (Street and No., City, State, and ZIP Code)

PLANT NUMBER

CERTIFICATION: I agree to comply with the terms and conditions of the regulations applicable to the service(s) requested (including but not limited to such instructions governing such service as may be issued, from time to time, by the Agricultural Marketing Service). I also agree to notify the Agricultural Marketing Service of any contaminated or adulterated (chemical, physical, or biological agents) shell eggs in the processing plant and to assure identification and segregation of such product. This notification includes shell eggs that have tested positive for *Salmonella Enteritidis* (SE) or shell eggs from houses determined positive for the presence of SE, or any shell eggs that have been recalled or subject to any recall. I also agree to provide the AMS grader detailed information pertaining to the method of identification and segregation required of any shell eggs that have been determined to be contaminated, or adulterated, including eggs from an identified layer flock that tests positive for the presence of SE. I hereby acknowledge receipt of a copy of Public Law 84-272 (7 U.S.C. 1622(h)) and the regulations under which this application is made.

NAME (As shown on your income tax return)

ADDRESS OF APPLICANT (Street and No., city, State, and ZIP Code)

NAME OF APPLICANT (If different from above)

E-MAIL ADDRESS:

EMPLOYER IDENTIFICATION NUMBER (EIN) _____ (is a 9 digit number assigned to sole proprietorships, corporations, partnerships, estates, trusts, and other entities for filing and reporting purposes).

DATE

SIGNATURE OF APPLICANT

APPLICATION GRANTED
 (FOR USE BY USDA, Agricultural Marketing Service)

DATE	TITLE	BY (Signature)

*No member of or delegate to Congress, or Resident Commissioner, shall be admitted to any benefit that may arise from this service unless derived through service rendered a corporation for its general benefit.



United States
Department of
Agriculture

Agricultural
Marketing
Service

Room 3935-S, STOP 0258
1400 Independence Avenue
Washington, DC 20250-0258

Wholesomeness Certification

- Resident Service**
- Temporary Service**
- Fee Grading Service**

In accordance with the applicable provisions of the Regulations Governing the Voluntary Grading of Shell Eggs (7 CFR 56) issued by the Agricultural Marketing Service (AMS), U.S. Department of Agriculture, I agree to notify the AMS grader of any contaminated or adulterated (chemical, physical, or biological agents) or potentially contaminated or adulterated shell eggs in the processing plant and to assure required identification and segregation of such product. This notification includes shell eggs that have tested positive for Salmonella enteritidis (SE), shell eggs from houses determined positive for the presence of SE, or any shell eggs that have been recalled or subject to any recall. I also agree to provide the AMS grader detailed information pertaining to the method of identification and segregation required of any shell eggs that have been determined to be contaminated, or adulterated, including eggs from an identified layer flock that tests positive for the presence of SE. Further, I certify that, to the best of my knowledge, none of the contaminants or adulterants described above exist in the shell eggs presented for USDA certification.

Company Name and Address (Official Plant #)

Signature and Title of Company Representative

Date

Report of Alleged Violation of the Federal Food Drug and Cosmetic Act – Shell Eggs

1. Name and Address of Establishment: (City, State, Zip Code)	2. Name of Reporting Employee:	5. Date of Alleged Violation:
		6. Date Report Completed:
	3. Title of Reporting Employee:	7. Establishment Identification Number: AMS Plant Number: EPIA Registrant Number: State Identification Number:
	4. Name of Reporting Employee's Agency:	

DESCRIPTION OF ALLEGED VIOLATION

8. Facility Description: (i.e. Farm, warehouse, processing facility, manufacturing facility, etc.)

9. Violation Observation: (i.e. Who, What, Where, When, How, Significance, etc.)

10. List of Products Potentially Affected:

11. Description of Specific Location within a Facility Where Violation Occurred: (i.e. Dry Storage Room, Processing Line, Loading Dock, etc.)

12. Action Taken by Reporting Agency, if Applicable/Authorized: (i.e. USDA Retain Tag Numbers Used, Notification of Plant Management, etc.)

13. Additional Comments:

