§ 56.77

of testing for potability and iron content shall be determined by the Administrator. When the water source is changed, new tests are required.

- (8) Waste water from the egg washing operation shall be piped directly to drains.
- (9) The washing, rinsing, and drying operations shall be continuous and shall be completed as rapidly as possible to maximize conservation of the egg's quality and to prevent sweating of eggs. Eggs shall not be allowed to stand or soak in water. Immersion-type washers shall not be used.
- (10) Prewetting shell eggs prior to washing may be accomplished by spraying a continuous flow of water over the eggs in a manner which permits the water to drain away or other methods which may be approved by the Administrator. The temperature of the water shall be the same as prescribed in this section.
- (11) Washed eggs shall be spray-rinsed with water having a temperature equal to, or warmer than, the temperature of the wash water. The spray-rinse water shall contain a sanitizer that has been determined acceptable for the intended use by the national supervisor and of not less than 100 p/m nor more than 200 p/m of available chlorine or its equivalent. Alternate procedures, in lieu of a sanitizer rinse, may be approved by the national supervisor.
- (12) Test kits shall be provided and used to determine the strength of the sanitizing solution.
- (13) During non-processing periods, eggs shall be removed from the washing and rinsing area of the egg washer and from the scanning area whenever there is a buildup of heat that may diminish the quality of the egg.
- (14) Washed eggs shall be reasonably dry before packaging and packing.
- (15) Steam, vapors, or odors originating from the washing and rinsing operation shall be continuously and directly exhausted to the outside of the building.
- (g) Requirements for eggs officially identified with a grademark. (1) Shell eggs that are officially identified with a grademark shall be placed under refrigeration at an ambient temperature no greater than 45 °F (7.2 °C) promptly after packaging.

- (2) Eggs that are to be officially identified with the grademark shall be packed only in new or good used packing material and new packaging materials that are clean, free of mold, mustiness and off odors, and must be of sufficient strength and durability to adequately protect the eggs during normal distribution. When packed in other than fiber packing material, the containers must be of sound construction and maintained in a reasonably clean manner.
- (h) Use of approved chemicals and compounds. (1) All egg washing and equipment cleaning compounds, defoamers, destainers, sanitizers, inks, oils, lubricants, or any other compound that comes into contact with the shell eggs shall be approved by the national supervisor for their specified use and handled in accordance with the manufacturer's instructions.
- (2) All pesticides, insecticides, and rodenticides shall be approved for their specified use and handled in accordance with the manufacturer's instructions.

[69 FR 76376, Dec. 21, 2004]

§ 56.77 Health and hygiene of personnel.

- (a) No person known to be affected by a communicable or infectious disease shall be permitted to come in contact with the product.
- (b) Plant personnel coming into contact with the product shall wear clean clothing.

[32 FR 8232, June 8, 1967. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

Subpart B [Reserved]

PART 57—INSPECTION OF EGGS (EGG PRODUCTS INSPECTION ACT)

Subpart A—Provisions Governing the Inspection of Eggs

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Subpart B—Administrative Provisions Governing Proceedings Under the Egg Products Inspection Act

SCOPE AND APPLICABILITY OF ADMINISTRATIVE PROVISIONS

57.1000 Administrative proceedings.

AUTHORITY: 21 U.S.C. 1031-1056.

Source: 63 FR 69968, Dec. 17, 1998, unless otherwise noted.

EDITORIAL NOTE: 1. At 63 FR 69969, Dec. 17, 1998, part 57 was added by duplicating portions of part 59. At 63 FR 72353, Dec. 31, 1998, part 59 was redesignated as part 590 of 9 CFR.

2. Nomenclature changes to part 57 appear at 63 FR 69971, Dec. 17, 1998.

Subpart A—Provisions Governing the Inspection of Eggs

GENERAL

§ 57.1 Definitions.

For the purpose of the regulations in this part, words in the singular shall be deemed to import the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

Acceptable means suitable for the purpose intended by the Agricultural Marketing Service.

Act means the applicable provisions of the Egg Products Inspection Act, as amended, (Pub. L. 91–597, 84 Stat. 1620 et seq.).

Administrator means the Administrator of AMS of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in the Administrator's stead.

Adulterated means any egg under one or more of the following circumstances:

- (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
- (b)(1) If it bears or contains any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity; a food additive; or a color additive) which may in the judgment of the Secretary, make such article unfit for human food;
- (2) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;
- (3) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

- (4) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, that an article which is not otherwise deemed adulterated under paragraph (b)(2), (3), or (4) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;
- (c) If it consists, in whole or in part, of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;
- (d) If it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health:
- (e) If it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;
- (f) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health:
- (g) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act; or
- (h) If any valuable constituent has been, in whole or in part, omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Agricultural Marketing Service or AMS mean the Agricultural Marketing Service of the Department.

Applicant means any interested party who requests any inspection service.

Capable of use as human food means any egg, unless it is denatured, or otherwise identified, as required by these regulations to deter its use as human food

Chief of the Grading Branch means Chief of the Grading Branch, Poultry Programs, AMS.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind, species, or method of processing.

Commerce means interstate, foreign, or intrastate commerce.

Condition means any characteristic affecting a products merchantability including, but not being limited to, the following: The state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food of any product; or the processing, handling, or packaging which affects such product.

Container or Package mean for shell eggs, any carton, basket, case, cart, pallet, or other receptacle.

- (a) Immediate container means any package or other container in which shell eggs are packed for household or other ultimate consumers.
- (b) Shipping container means any container used in packing an immediate container

Department means the United States Department of Agriculture.

Egg means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea. Some of the terms applicable to shell eggs are as follows:

- (a) *Check* means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.
- (b) Clean and sound shell egg means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.
- (c) *Dirty egg* or *Dirties* means an egg(s) that has an unbroken shell with adhering dirt, or foreign material.
- (d) *Incubator reject* means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.
- (e) *Inedible* means eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

- (f) Leaker means an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.
- (g) Loss means an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat or blood spot, a large quantity of blood, or other foreign material.
- (h) Restricted egg means any check, dirty egg, incubator reject, inedible, leaker, or loss.

Egg handler means any person, excluding the household consumer, who engages in any business in commerce that involves buying or selling any eggs or processing any egg products, or otherwise using any eggs in the preparation of human food.

Federal Food, Drug, and Cosmetic Act means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Inedible egg products means dried, frozen, or liquid inedible egg products that are unfit for human consumption.

Inspection means the application of such inspection methods and techniques as are deemed necessary by the responsible Secretary to carry out the provisions of the Egg Products Inspection Act and the regulations under this part.

Interested party means any person financially interested in a transaction involving any surveillance inspection service.

Label means a display of any printed, graphic, or other method of identification upon the shipping container, if any, or upon the immediate container, including but not limited to, an individual consumer package of eggs, or accompanying such product.

National supervisor means:

- (a) The officer-in-charge of the surveillance inspection service; and
- (b) Other employee of the Department designated by the national super-

Nest-run eggs means eggs that have been packed as they come from the production facilities without having been washed, sized and/or candled for

quality, with the exception that some checks, dirties, or other obvious undergrades may have been removed.

Office of inspection means the office of any inspector.

Official certificate means any certificate prescribed by regulations of the Administrator for issuance by an inspector or other person performing official functions under this part.

Official device means any device prescribed or authorized by the Secretary for use in applying any official mark.

Official egg products processing plant means one or more buildings or parts thereof comprising a single plant in which the plant facilities and methods of operation therein have been approved by the Administrator of the Food Safety Inspection Service as suitable and adequate for the continuous inspection of egg products and in which inspection service is carried on.

Official standards means the official U.S. standards of quality, grades, and weight classes for shell eggs maintained by and available from Poultry Programs, AMS.

Person means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

Pesticide chemical, Food additive, Color additive, and Raw agricultural commodity mean the same for purposes of this part as under the Federal Food, Drug, and Cosmetic Act.

Plant means any place of business where eggs are processed.

Quality means the inherent properties of any product which determine its relative degree of excellence.

Regional director means any employee of the Department in charge of the surveillance inspection service in a designated geographical area.

Regulations means the provisions in this entire part and such U.S. Standards, Grades, and Weight Classes for Shell Eggs as may be in effect at the time grading is performed.

Regulatory inspector or Inspector means any Federal employee or the employee of a cooperating agency to whom a license has been issued by the Secretary to make such inspections as required in §57.28 of these regulations.

Regulatory officer or staff officer means staff assistants to regional directors who assist the regional director in administering the surveillance inspection service.

Sampling means the act of taking samples of any product for inspection.

Secretary means the Secretary of Agriculture or any other officer or employee of the Department to whom the authority to act in the Secretary's stead has been delegated.

Service means the personnel who are actively engaged in the administration, application, and direction of the surveillance inspection service pursuant to the regulations in this part.

Shell egg packer means any person engaged in the sorting of eggs into their various qualities.

- (a) *Producer-packer* means any person engaged in the sorting of eggs from their own production into their various qualities, either mechanically or by other means.
- (b) Grading station means any person engaged in the sorting of eggs from their own production and sources other than their own production into their various qualities, either mechanically or by other means.

State means any State of the United States of America, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia.

State supervisor or Federal-State supervisor means any authorized and delegated individual who is in charge of the surveillance inspection program in a state.

Surveillance inspection service means the official service within the Department having the responsibility for carrying out the provisions of the Egg Products Inspection Act under this part.

Ultimate consumer means any household consumer, restaurant, institution, or any other party who has purchased or received shell eggs for consumption.

Unclassified eggs means eggs that have been washed or are unwashed and show evidence of segregating or sizing.

United States Standards, Grades, and Weight Classes for Shell Eggs (AMS 56) means the official U.S. standards, grades, and weight classes for shell eggs that are maintained by and available from Poultry Programs, AMS.

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Washed ungraded eggs means eggs which have been washed and that are either sized or unsized, but not segregated for quality.

[69 FR 57164, Sept. 24, 2004, as amended at 71 FR 12614, Mar. 13, 2006]

§ 57.10 Administration.

The Administrator shall perform, for and under the supervision of the Secretary such duties as the Secretary may require in the enforcement or administration of the provisions of the act and the regulations in this part. The Administrator is authorized to waive for limited periods any particular provisions of the regulations in this part to permit experimentation so that new procedures, equipment, grading, inspection, and processing techniques may be tested to facilitate definite improvements and at the same time to determine full compliance with the spirit and intent of the regulations in this part. The AMS and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

[69 FR 57166, Sept. 24, 2004]

§ 57.13 Federal and State cooperation.

The Secretary shall, whenever determined necessary to effectuate the purposes of the Act, authorize the Administrator to cooperate with appropriate State and other governmental agencies in carrying out any provisions of the Egg Products Inspection Act and this part. In carrying out the provisions of the Act and the regulations in this part, the Secretary may conduct such examinations, investigations, and inspections as the Secretary determines practicable through any officer or employee of any such agency commissioned by the Secretary for such purpose. The Secretary shall reimburse the States and other agencies for the services rendered by them stated in the cooperative agreements signed by the Administrator and the duly authorized agent of the State or other agency.

[69 FR 57166, Sept. 24, 2004]

§ 57.17 Nondiscrimination.

The conduct of all services and the licensing of inspectors under these regulations shall be accomplished without discrimination as to race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

[69 FR 57166, Sept. 24, 2004]

§57.18 OMB control number.

The information collection requirements in this part have been approved by the Office of Management and Budget and assigned OMB control number 0581–0113.

[63 FR 69970, Dec. 17, 1998]

SCOPE OF INSPECTION

§ 57.20 Inspection in accordance with methods prescribed or approved.

Inspection of eggs shall be rendered pursuant to these regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

[63 FR 69968, 69970, Dec. 17, 1998]

§ 57.22 Basis of service.

This part provides for inspection services pursuant to the Egg Products Inspection Act, as amended. Eggs shall be inspected in accordance with such standards, methods, and instructions as may be issued or approved by the Administrator. Inspection services shall be subject to supervision at all times by the applicable Federal-State supervisor, staff officer, regulatory officer, regional director, and national supervisor.

[69 FR 57166, Sept. 24, 2004]

§ 57.28 Inspections.

(a) Periodic inspections shall be made of business premises, facilities, inventories, operations, transport vehicles, and records of egg handlers, and the records of all persons engaged in the business of transporting, shipping, or receiving any eggs. In the case of shell egg packers packing eggs for the ultimate consumer, such inspections shall be made a minimum of once each calendar quarter. Hatcheries are to be inspected a minimum of once each fiscal year.

(2) [Reserved]

(b) Inspections shall be made of imported eggs as required in this part.

 $[63~{\rm FR}~69968,~69970,~{\rm Dec.}~17,~1998,~{\rm as}~{\rm amended}$ at $69~{\rm FR}~57166,~{\rm Sept.}~24,~2004]$

RELATION TO OTHER AUTHORITIES

§ 57.35 Eggs in commerce.

- (a)(1) For eggs that moved or are moving in interstate or foreign commerce, no State or local jurisdiction:
- (i) May require the use of standards of quality, condition, grade, or weight classes which are in addition to or different than the official standards; or
- (ii) Other than states in noncontiguous areas of the United States, may require labeling to show the State or other geographical area of production or origin.
- (2) This shall not preclude a State from requiring the name, address, and license number of the person processing or packaging eggs to be shown on each container.
- (b) Any State or local jurisdiction may exercise jurisdiction for the purpose of preventing the distribution of eggs for human food purposes that are in violation of this part or any other Federal acts or State or local laws consistent therewith.

[69 FR 57166, Sept. 24, 2004]

EGGS NOT INTENDED FOR HUMAN FOOD

§ 57.45 Prohibition on eggs not intended for use as human food.

- (a) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation in commerce, any eggs that are not intended for use as human food, unless they are denatured or decharacterized, unless shipped under seal as authorized in §57.720(a) and identified as required by the regulations in this part.
- (b) No person shall import or export shell eggs classified as loss, inedible, or incubator rejects unless they are denatured or decharacterized and identified as required by the regulations in this part.

[63 FR 69968, 69970, Dec. 17, 1998, as amended at 69 FR 57166, Sept. 24, 2004]

§ 57.100 Specific exemptions.

The following are exempt to the extent prescribed as to the provisions for control of restricted eggs in section 8(a)(1) and (2) of the Act: Provided, That as to paragraphs (c) through (f) of this section, the exemptions do not apply to restricted eggs when prohibited by State or local law: And provided further, That the sale of "hard-cooked shell eggs'' or "peeled hard-cooked shell eggs" prepared from checks is subject to the conditions for exemption in paragraphs (c), (d), and (f) of this section: And provided further, That the conditions for exemption and provisions of these regulations are met:

EXEMPTIONS

- (a) The sale, transportation, possession, or use of eggs that contain no more restricted eggs than are allowed by the tolerances in the official standards for U.S. Consumer Grade B shell eggs;
 - (b) [Reserved]
- (c) The sale at the site of production, on a door-to-door retail route, or at an established place of business away from the site of production, by a poultry producer of eggs from his own flock's production directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees, and the transportation, possession, and use of such eggs: *Provided*, That each such sale of restricted eggs shall be limited to no more than 30 dozen eggs; *And provided further*,
- (1) That eggs sold directly to consumers at an established place of business away from the site of production be moved directly from the producer to such place of business;
- (2) That such business away from the site of production be owned and managed by the producer; and
- (3) That such eggs which are sold on a door-to-door route or at an established place of business away from the site of production shall contain no more loss and/or leakers than allowed in the official standards for U.S. Consumer Grade B shell eggs.
- (d) The sale of eggs by any producer with an annual egg production from a flock of 3,000 hens or less and the record requirements of §57.200;

- (e) The processing and sale of egg products by any producer from eggs of the producer's own flock when sold directly to a household consumer exclusively for use by such consumer and members of the consumer's household and the consumer's nonpaying guests and employees:
- (f) The sale of eggs by shell egg packers on the premises where the grading station is located, directly to household consumers for use by such consumer and members of the consumer's household and the consumer's nonpaying guests and employees, and the transportation, possession, and use of such eggs. Each such sale of "restricted eggs" shall be limited to no more than 30 dozen eggs:
- (g) The processing in nonofficial plants, including but not limited to bakeries, restaurants, and other food processors, without continuous inspection, of certain categories of food products which contain eggs or egg products as an ingredient, and the sale and possession of such products: *Provided*, That such products are manufactured from inspected egg products processed in accordance with this part or from eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs;
- (h) The purchase, sale, possession, or transportation of shell eggs containing more restricted eggs than allowed in the tolerances for U.S. Consumer Grade B shell eggs: *Provided*, That such eggs are handled in accordance with §§ 57.200 and 57.700 through 57.860 to assure that only eggs fit for human food are used for such purpose. This exemption applies to the following:
- (1) Egg producers, assemblers, whole-salers, and grading operations;
 - (2) Hatcheries;
 - (3) Transporters:
- (4) Laboratories, pharmaceutical companies; and
- (5) Processors of products not intended for use as human food.

 $[63~{\rm FR}~69968,~69971,~{\rm Dec.}~17,~1998,~{\rm as}~{\rm amended}$ at $69~{\rm FR}~57166,~{\rm Sept.}~24,~2004]$

§ 57.105 Suspension or termination of exemptions.

(a) The Administrator may modify or revoke any regulation of this part,

granting exemptions whenever he determines such action appropriate to effectuate the purposes of the Act.

(b) Failure to comply with the condition of the exemptions contained in §57.100 shall subject such person to the penalties provided for in the Act and in this part.

[63 FR 69968, Dec. 17, 1998, as amended at 69 FR 57166, Sept. 24, 2004]

PERFORMANCE OF SERVICES

§ 57.110 Licensed inspectors.

- (a) Any person who is a Federal employee or the employee of a cooperating agency who possesses proper qualifications as determined by an examination for competency, and who is to perform surveillance inspection services, may be licensed by the Secretary as an inspector.
- (b) All licenses issued by the Secretary shall be countersigned by the Administrator or by any other designated official of the service.

[69 FR 67166, Sept. 24, 2004]

§57.112 Suspension of license or authority; revocation.

Pending final action by the Secretary, any person authorized to countersign a license to perform surveillance inspection services may, whenever such action is necessary to assure that any inspection service is properly performed, suspend or revoke any license to perform inspection services issued pursuant to this part by giving notice of such action to the respective licensee, accompanied by a statement of the reasons. Within 7 days after the receipt of the suspension or revocation notice and statement of reasons, the licensee may file an appeal in writing to the Secretary, supported by any argument or evidence that the licensee may wish to offer as to why the license should not be suspended or revoked. After the expiration of the 7-day period and consideration of such argument and evidence, the Secretary will take appropriate action regarding the suspension or revocation. When no appeal is filed within the prescribed 7 days, the license is revoked or suspended.

[69 FR 57166, Sept. 24, 2004]

§57.114

§ 57.114 Surrender of license.

Each license that is canceled, suspended, revoked, or expired shall immediately be surrendered by the licensee to the office of inspection serving the area in which the licensee is located.

[69 FR 57167, Sept. 24, 2004]

§57.119 Political activity.

Federal inspectors may participate in certain political activities, including management and participation in political campaigns as allowed by Federal regulation and AMS directives. Inspectors are subject to these rules while they are on leave with or without pay, including furlough; however the rules do not apply to cooperative employees not under Federal supervision and intermittent employees on the days they perform no service. Willfull violations of the political activity rules constitute grounds for removal from the service.

[69 FR 57167, Sept. 24, 2004]

§ 57.120 Financial interest of inspectors.

An inspector shall not inspect any product in which the inspector is financially interested.

[69 FR 57167, Sept. 24, 2004]

§ 57.130 Identification.

Each inspector shall have in their possession at all times, and present while on duty upon request, the means of identification furnished by the Department.

[69 FR 57167, Sept. 24, 2004]

§ 57.132 Access to plants.

Access shall not be refused to any representative of the Secretary to any plant, place of business, or transport vehicle subject to inspection under the provisions of this part upon presentation of identification furnished by the Department.

 $[63\ FR\ 69968,\ Dec.\ 17,\ 1998,\ as\ amended\ at\ 69\ FR\ 57166,\ Sept.\ 24,\ 2004]$

§57.134 Accessibility of product.

Each product for which inspection service is required shall be so placed as

to disclose fully its class, quality, quantity, and condition as the circumstances may warrant.

[63 FR 69968, Dec. 17, 1998, as amended at 69 FR 57167, Sept. 24, 2004]

RECORDS AND RELATED REQUIREMENTS FOR EGG HANDLERS AND RELATED IN-DUSTRIES

§ 57.200 Records and related requirements.

(a) Persons engaged in the business of transporting, shipping, or receiving any eggs in commerce, or holding such articles so received, and all egg handlers, including hatcheries, shall maintain for 2 years records showing the receipt, delivery, sale, movement, and disposition of all eggs handled by them, and upon the request of an authorized representative of the Secretary, shall permit the representative, at reasonable times, to have access to and to copy all such records.

(b) All egg handlers shall maintain production records as approved by the Administrator. The records (bills of sale, inventories, receipts) shall show the name and address of the shipper and receiver, the date of the transaction, the quality of the eggs (graded eggs, nest-run eggs, dirties, checks, leakers, loss, inedible eggs), and the quantity of the eggs (amount). Producers who ship all of their production as nest-run eggs without segregation need only to maintain records indicating the amount of shell eggs shipped, date of shipment, and the receivers' name and address.

[69 FR 57167, Sept. 24, 2004]

§ 57.220 Information and assistance to be furnished to inspectors.

When surveillance inspection service is performed at any plant, the plant operator shall furnish the inspector such information and assistance as may be required for the performance of inspection functions, preparing certificates, reports, and for other official duties.

 $[63\ FR\ 69968,\ Dec.\ 17,\ 1998,\ as\ amended\ at\ 69\ FR\ 57167,\ Sept.\ 24,\ 2004]$

Agricultural Marketing Service, USDA

ADMINISTRATIVE DETENTION

§ 57.240 Detaining product.

Whenever any eggs subject to the Act are found by any authorized representative of the Secretary upon any premises, and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of the Act or the regulations in this part, or that they are in any other way in violation of the Act, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations in this part, such articles may be detained by such representative for a period not to exceed 20 days, as more fully provided in section 19 of the Act. A detention tag or other similar device shall be used to identify detained product, and the custodian or owner shall be given a written notice of such detention. Only authorized representatives of the Secretary shall affix or remove detention identification. The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of the Act, the regulations in this part, or other

[63 FR 69968, 69971, Dec. 17, 1998]

APPEAL OF AN INSPECTION

§57.300 Who may request an appeal inspection.

An appeal inspection may be requested by any interested party who is dissatisfied with the determination by an inspector of the class, quality, quantity, or condition of any product.

[69 FR 57167, Sept. 24, 2004]

§ 57.310 Where to file an appeal.

Any interested party that is not satisfied with the determination of the class, quality, quantity, or condition of product which was inspected may request an appeal inspection by filing such request with the Regional Director in the region where the product is

located or with the Chief of the Grading Branch.

[63 FR 69971, Dec. 17, 1998, as amended at 69 FR 57167, Sept. 24, 2004]

§ 57.320 How to file an appeal.

The request for an appeal inspection may be made orally or in writing. If made orally, written confirmation may be required. The applicant shall clearly state the identity of the product, the decision that is questioned, and the reason(s) for requesting the appeal service.

[69 FR 57167, Sept. 24, 2004]

§ 57.330 When an application for an appeal inspection may be refused.

When it appears to the official with whom an appeal request is filed that the reasons given in the request are frivolous or not substantial, or that the condition of the product has undergone a material change since the original inspection, or that the original lot has changed in some manner, or the Act or the regulations in this part have not been complied with, the applicant's request for the appeal inspection may be refused. In such case, the applicant shall be promptly notified of the reason(s) for such refusal.

 $[63\ FR\ 69968,\ Dec.\ 17,\ 1998,\ as\ amended\ at\ 69\ FR\ 57167,\ Sept.\ 24,\ 2004]$

§ 57.340 Who shall perform the appeal.

The assignment of the inspector(s) who will make the appeal inspection under §57.310 shall be made by the Regional Director or the Chief of the Grading Branch.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57167, Sept. 24, 2004]

§ 57.350 Procedures for selecting appeal samples.

(a) Products shall not have been moved from the place where the inspection being appealed was performed and must have been maintained under adequate refrigeration when applicable.

(b) The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. When the original samples are not available or have been altered, such as removing the undergrades, the sample size shall

be double the number of samples required in 7 CFR 56.4.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57167, Sept. 24, 2004]

§ 57.360 Appeal inspection certificates.

Immediately after an appeal inspection is completed, an appeal certificate shall be issued to show that the original inspection was sustained or was not sustained.

[63 FR 69968, Dec. 17, 1998, as amended at 69 FR 57167, Sept. 24, 2004]

§57.370 Cost of appeals.

The costs of an appeal inspection shall be borne by the appellant on a fee basis at rates set forth in 7 CFR 56.46, plus any travel and additional expenses. If the appeal inspection or review of an inspector's decision discloses that a material error was made in the original determination, no fee or expense will be charged.

[69 FR 57157, Sept. 24, 2004]

RETENTION

§ 57.426 Retention.

Retention tags or other devices and methods as may be approved by the Administrator shall be used for the identification and control of products which are not in compliance with the regulations or are held for further examination. No product, shall be released for use until it has been made acceptable. Such identification shall not be removed by anyone other than an inspector.

[63 FR 69968, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

REGISTRATION OF SHELL EGG HANDLERS

§57.690 Person required to register.

Egg handlers, except for producer-packers with an annual egg production from a flock of 3,000 hens or less, who grade and pack eggs for the ultimate consumer, and hatcheries, are required to register with the Department by furnishing their name, place of business, and such other information requested on the registration form available from the Department. Completed forms shall be sent to the addressee indicated on the form. Persons above who are estab-

lishing a business will be required to register before they start operations.

[69 FR 571688, Sept. 24, 2004]

INSPECTION AND DISPOSITION OF RESTRICTED EGGS

§ 57.700 Prohibition on disposition of restricted eggs.

- (a) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation in any business in commerce any restricted eggs, except as authorized in §§57.100 and 57.720.
- (b) No egg handler shall possess any restricted eggs, except as authorized in §§ 57.100 and 57.720.
- (c) No egg handler shall use any restricted eggs in the preparation of human food, except as provided in §§ 57.100 and 57.720.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69970, Dec. 17, 1998]

§57.720 Disposition of restricted eggs.

- (a) Eggs classified as checks, dirties, incubator rejects, inedibles, leakers, or loss shall be disposed of by one of the following methods at point and time of segregation:
- (1) By shipping directly or indirectly to an official egg products processing plant for segregation and processing, if a check or dirty and if labeled in accordance with §57.800. Inedible and loss eggs shall not be intermingled in the same container with checks and dirties.
- (2) By destruction and identification in a manner approved by the Administrator.
- (i) Loss and inedible eggs shall be crushed and shall be placed in a container containing a sufficient amount denaturant approved decharacterant, such as FD&C brown, blue, black, or green colors, meat and fish by-products, grain and milling byproducts, or any other substance, as approved by the Administrator, that will accomplish the purposes of this section. The approved denaturant or decharacterant substance shall be dispersed through the product in amounts sufficient to give the product a distinctive appearance or odor.

- (ii) The denatured and decharacterized product shall be labeled as required in §§ 57.840 and 57.860.
- (3) By processing for industrial use or for animal food. Such product shall be denatured or decharacterized in accordance with §57.720(a)(2) and identified as provided in §§57.840 and 57.860, or handled in accordance with other procedures approved by the Administrator. Notwithstanding the foregoing, product which was produced under official supervision and transported for industrial use or animal food need not be denatured or decharacterized if it is shipped under Government seal and received by an inspector or grader as defined in this part.
- (4) By coloring the shells of loss and inedible eggs with a sufficient amount of FD&C color to give a distinct appearance, or applying a substance that penetrate the shell decharacterize the egg meat. Except that, lots of eggs containing significant percentages of blood spots or meat spots, but no other types of loss or inedible eggs may be shipped directly to official egg products processing plants, provided they are conspicuously labeled with the name and address of the shipper and the wording "Spots-For Processing Only In Official Egg Products Processing Plants.'
- (b) Eggs which are packed for the ultimate consumer and which have been found to exceed the tolerance for restricted eggs permitted in the official standards for U.S. Consumer Grade B shall be identified as required in §§ 57.800 and 57.860 and shall be shipped directly or indirectly:
- (1) To an official egg products processing plant for proper segregation and processing; or
- (2) Be regraded so that they comply with the official standards: or
 - (3) Used as other than human food.
- (c) Records shall be maintained as provided in §57.200 to assure proper disposition.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971; 37 FR 6659, Apr. 1, 1972; 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995. Redesignated at 63 FR 69970, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

IDENTIFICATION OF RESTRICTED EGGS OR EGG PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

§ 57.800 Identification of restricted eggs.

The shipping container of restricted eggs shall be determined to be satisfactorily identified if such container bears the packer's name and address, the quality of the eggs in the container (e.g., dirties, checks, inedibles, or loss), or the statement "Restricted Eggs-For Processing Only In An Official USDA Egg Products Processing Plant,' for checks or dirties, or "Restricted Eggs-Not To Be Used As Human Food," for inedibles, loss, and incubator rejects, or "Unclassified Eggs-To Be Regraded" for graded eggs which contain more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. The size of the letters of the identification wording shall be as required in §57.860. When eggs are packed in immediate containers, e.g., cartons, sleeve packs, overwrapped 2½- or 3-dozen packs, etc., for sale to household consumers under the exemptions provided for in section 57.100 (c), or (f), they shall be deemed to be satisfactorily identified in accordance with the requirements of this part if such immediate containers bear the packer's name and address and the quality of the eggs. Alternatively, a point of sale sign may be displayed showing the above information.

[63 FR 69968, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.801 Nest run or washed ungraded eggs.

Nest run or washed ungraded eggs are exempt from the labeling provisions in §57.800. However, when such eggs are packed and sold to consumers, they may not exceed the tolerance for restricted eggs permitted in the official standards for U.S. Consumer Grade B shell eggs.

[60 FR 49171, Sept. 21, 1995. Redesignated at 63 FR 69970, Dec. 17, 1998]

§ 57.840 Identification of inedible, unwholesome, or adulterated egg products.

All inedible, unwholesome, or adulterated egg products shall be identified

with the name and address of the processor, the words "Inedible Egg Products—Not To Be Used as Human Food."

§ 57.860 Identification wording.

The letters of the identification wording shall be legible and conspicuous.

IMPORTS

§ 57.900 Requirements for importation of restricted eggs into the United States.

- (a) Restricted eggs may be imported into the United States from any foreign country only in accordance with these regulations. The importation of any egg in violation of the regulations of this part is prohibited. The importation of any egg in violation of the regulations of this part is prohibited.
- (b) All such imported articles shall upon entry into the United States be deemed and treated as domestic articles and be subject to the other provisions of the Act, these regulations, and other Federal or State requirements.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.905 Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B.

(a) No containers of restricted egg(s) other than checks or dirties shall be imported into the United States. The shipping containers of such eggs shall be identified with the name, address, and country of origin of the exporter, and the date of pack and quality of the eggs (e.g., checks, or dirties) preceded by the word "Imported" or the statement "Imported Restricted Eggs-For Processing Only In An Official USDA Processing Plant," or "Restricted Eggs—Not To Be Used As Human Food." Such identification shall be legible and conspicuous. Alternatively, for properly sealed and certified shipments of shell eggs imported for breaking at an official egg products processing plant, the shipping containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

(b) Eggs which are imported for use as human food and upon entry are found to contain more restricted eggs than permitted in the official standards for U.S. Consumer Grade B, shall be refused entry and returned to the importing country or be conspicuously and legibly identified as "Imported Restricted Eggs" and be sent directly under official seal: (1) To a place where they may be regraded to comply with the official U.S. standards for consumer grades; (2) to an official USDA egg products processing plant; or (3) to be used as other than human food.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.915 Foreign inspection certification required.

- (a) [Reserved]
- (b) Except as otherwise provided in §57.960, each consignment of shell eggs shall be accompanied by a foreign inspection certificate, that, unless otherwise approved by the Administrator contains the following information:
- (1) Name of Country exporting product;
 - (2) City and date where issued;
 - (3) Quality or description of eggs;
- (4) Number of cases and total quantity;
- (5) Identification marks on containers;
 - (6) Name and address of exporter;
 - (7) Name and address of importer;
- (8) A certification that the quality or description of the shell eggs, including date of pack, is true and accurate;
- (9) A certification that shell eggs which have been packed into containers destined for the ultimate consumer have, at all times after packing, been stored and transported under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C); and
- (10) Name (including signature) and title of person authorized to issue inspection certificates for shell eggs exported to the United States.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.920 Importer to make application for inspection of imported eggs.

Each person importing any eggs as defined in these regulations, unless exempted by §57.960 shall make application for inspection upon LPS Form 222-Import Request. The application may be submitted to the address located on LPS Form 222, filed through electronic QAD.importrequesteggs@ams.usda.gov, orby accessing the U.S. Customs and Border Protection's International Trade Data System. Application shall be made as far in advance as possible prior to the arrival of the product. Each application shall state the approximate date of product arrival in the United States, the name of the ship or other carrier, the country from which the product was shipped, the destination,

[81 FR 1482, Jan. 13, 2016]

States.

§ 57.925 Inspection of imported eggs.

the quantity and class of product, and

the point of first arrival in the United

(a) Except as provided in §57.960, eggs offered for importation from any foreign country shall be subject to inspection in accordance with established inspection procedures, including the examination of the labeling information on the containers, by an inspector before the product shall be admitted into the United States. Importers will be advised of the point where inspection will be made, and in case of small shipments (less than carload lots), the importer may be required to move the product to the location of the nearest inspector.

(b) Inspectors may take samples, without cost to the United States, of any product offered for importation that is subject to quality determination, except that samples shall not be taken of any products offered for importation under §57.960, unless there is reason for suspecting the presence therein of a substance in violation of that section.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.930 Imported eggs; retention in customs custody; delivery under bond; movement prior to inspection; sealing; handling; facilities, and assistance.

- (a) No eggs required by this part to be inspected shall be released from customs custody prior to required inspections, but such product may be delivered to the consignee, or his agent, prior to inspection if the consignee shall furnish a bond, in the form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through customs.
- (b) Notwithstanding paragraph (a) of this section, no product required by this part to be inspected shall be moved prior to inspection from the port of arrival where first unloaded, and if arriving by water from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this part as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this part.
- (c) Means of conveyance or packages in which any product is moved in accordance with this part, prior to inspection, from the port or wharf where first unloaded in the United States, shall be sealed with special import seals of the Department or otherwise identified as provided herein, unless already sealed with customs or consular seals in accordance with the customs regulations. Such special seals shall be affixed by an inspector or, if there is no inspector at such port, by a customs officer. In lieu of sealing packages, the carrier or importer may furnish and attach to each package of product a warning notice on bright yellow paper, not less than 5×8 inches in size, containing the following legend in black type of a conspicuous size:

(Name of Truck Line or Carrier)

NOTICE

This package of ____ must be delivered intact to an inspector of the Poultry Programs, U.S. Department of Agriculture.

WARNING

Failure to comply with these instructions will result in penalty action being taken against the holder of the customs entry bond

- If the product is found to be acceptable upon inspection, the product may be released to the consignee, or his agent, and this warning notice defaced.
- (d) No person shall affix, break, alter, deface, mutilate, remove, or destroy any special import seal of the Department, except customs officers or inspectors, or as provided in paragraph (f) of this section.
- (e) No product shall be removed from any means of conveyance or package sealed with a special import seal of the Department, except under the supervision of an inspector or a customs officer, or as provided in paragraph (f) of this section.
- (f) In case of a wreck or similar extraordinary emergency, the special import seal of the Department on a car, truck, or other means of conveyance may be broken by the carrier and, if necessary, the articles may be reloaded into another means of conveyance for transportation to destination. In all such cases, the carrier shall immediately report the facts to the Chief of the Grading Branch.
- (g) The consignee or his agent shall provide such facilities and assistance as the inspector may require for the inspection and handling and marking of products offered for importation.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.935 Means of conveyance and equipment used in handling eggs to be maintained in sanitary condition.

Compartments of boats, railroad cars, and other means of conveyance transporting any product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling such product offered for importation, shall be maintained in a sanitary condition.

§ 57.945 Foreign eggs offered for importation; reporting of findings to customs; handling of products refused entry.

- (a) Inspectors shall report their findings to the collector of customs at the port where products are offered for entry, and shall request the collector to refuse entry to eggs that are marked or designated "U.S. Refused Entry" or otherwise are not in compliance with the regulations in this part. Unless such products are exported by the consignee within a time specified by the collector of customs (usually 30 days), the consignee shall cause the destruction of such products for human food purposes under the supervision of an inspector. If products are destroyed for human food purposes under the supervision of an inspector, he shall give prompt notice thereof to the District Director of Customs.
- (b) Consignees shall, at their own expense, return immediately to the collector of customs, in means of conveyance or packages sealed by the Department, any eggs received by them under this part which in any respect do not comply with this part.
- (c) Except as provided in §57.930(a), no person shall remove or cause to be removed from any place designated as the place of inspection, any eggs that the regulations require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this part.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.950 Labeling of containers of eggs for importation.

- (a) Immediate containers of product offered for importation shall bear a label, printed in English, showing:
 - (1) The name of product;
- (2) The name of the country of origin of the product, and for consumer packaged products, preceded by the words "Product of," which statement shall appear immediately under the name of the product;
- (3) The quality or description of shell eggs, including date of pack;
- (4) For shell eggs, the words, "Keep Refrigerated," or words of similar meaning;
- (5) [Reserved]

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- (6) The name and place of business of manufacturer, packer, or distributor, qualified by a phrase which reveals the connection that such person has with the product;
- (7) An accurate statement of the quantity;
- (b) For properly sealed and certified shipments of shell eggs imported for breaking at an official egg products processing plant, the immediate containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.
- (c) The labels shall not be false or misleading in any respect.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.955 Labeling of shipping containers of eggs for importation.

- (a) Shipping containers of foreign product offered for importation shall bear a label, printed in English, showing:
- (1) The common or usual name of the product;
 - (2) The name of the country of origin;
 - (3)-(4) [Reserved]
- (5) The quality or description of the eggs, except as required in $\S 57.905$;
- (6) The words "Keep refrigerated" or words of similar meaning.
- (b) Labeling on shipping containers examined at the time of inspection in the United States, if found to be false or misleading, shall be cause for the product to be refused entry.
- (c) For properly sealed and certified shipments of shell eggs imported for breaking at an official egg products plant, the shipping containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.
- (d) In the case of products which are not in compliance solely because of misbranding, such products may be brought into compliance with the regulations only under the supervision of an authorized representative of the Administrator.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§57.960 Small importations for consignee's personal use, display, or laboratory analysis.

Any eggs that are offered for importation, exclusively for the consignee's personal use, display, or laboratory analysis, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food; and which is not adulterated and does not contain any substance not permitted by the Act or regulations, may be admitted into the United States without a foreign inspection certificate. Such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part: Provided, That the Department may, with respect to any specific importation, require that the consignee certify that such product is exclusively for the consignee's personal use, display, or laboratory analysis and not for sale or distribution. The amount of such product imported shall not exceed 30-dozen shell eggs, unless otherwise authorized by the Administrator.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.965 Returned U.S. inspected and marked products; not importations.

Products that have been inspected by the Department and so marked, and which are returned from foreign countries are not importations within the meaning of this part. Such returned shipments shall be reported to the Administrator by letter.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

§ 57.970 Charges for storage, cartage, and labor with respect to products imported contrary to the Act.

All charges for storage, cartage, and labor with respect to any product that is imported contrary to this part shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such product and any other product thereafter imported under the Act by or for such owner or consignee.

[63 FR 69968, 69971, Dec. 17, 1998, as amended at 69 FR 57168, Sept. 24, 2004]

Subpart B—Administrative Provisions Governing Proceedings Under the Egg Products Inspection Act

SOURCE: 64 FR 40738, July 28, 1999, unless otherwise noted.

SCOPE AND APPLICABILITY OF ADMINISTRATIVE PROVISIONS

§ 57.1000 Administrative proceedings.

- (a) The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicating administrative proceedings under section 12(c) of the Egg Products Inspection Act (21 U.S.C. 1041).
- (b) In addition to the proceedings set forth in paragraph (a) of this section, the Administrator, at any time prior to the issuance of a complaint seeking a civil penalty under the Act may enter into a stipulation with any person, in accordance with the following prescribed conditions:
- (1) The Administrator gives notice of an apparent violation of the Act or the regulations issued thereunder by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;
- (2) Such person expressly waives hearing and agrees to a specified order including an agreement to pay a specified civil penalty within a designated time: and
- (3) The Administrator agrees to accept the specified civil penalty in settlement of the particular matter involved if it is paid within the designated time.
- (4) If the specified penalty is not paid within the time designated in such stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty that may be assessed after the institution of a formal administrative proceeding pursuant to the Uniform Rules of Practice, Subpart H, Part 1, Title 7, Code of Federal Regulations.

[64 FR 40738, July 28, 1999, as amended at 69 FR 57168, Sept. 24, 2004]

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

Subpart A—Provisions Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products

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- 58.22 When appeal inspection or grading may be requested.
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- 58.27 Order in which appeal inspections or gradings are performed.
- 58.28 Who shall make appeal inspections or gradings.
- ¹Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug and Cosmetic Act.