PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

Authority: 7 U.S.C. 138f, 1633; 21 U.S.C. 451-472; 7 CFR 2.7, 2.18, 2.53.

Source: 37 FR 9706, May 16, 1972, unless otherwise noted.

Subpart A—Definitions

§ 381.1 Definitions.

(a) For the purposes of the regulations in this part, unless otherwise required by the context, the singular form shall also import the plural and the masculine form shall also import the feminine, and vice versa.

(b) For the purposes of such regulations, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Acceptable. "Acceptable" means suitable for the purpose intended and acceptable to the Administrator.

Act. "Act" means the Poultry Products Inspection Act (71 Stat. 441, as amended by the Wholesome Poultry Products Act, 82 Stat. 791; 21 U.S.C. 451 *et seq.*).

Adulterated. "Adulterated" applies to any poultry product under one or more of the following circumstances:

(i) 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;

(ii)

(*a*) If it bears or contains (by reason of administration of any substance to the live poultry or otherwise) 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 Administrator, make such article unfit for human food;

(*b*) If it is, in whole or 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;

(*c*) 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;

(*d*) 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 paragraphs (b)(4)(ii) (*b*), (*c*), or (*d*) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by the regulations in this part in official establishments;

(iii) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(iv) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(v) If it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(vi) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(vii) 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

(viii) 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.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from carcasses or parts or products of the carcass of poultry, except that the term animal food as used herein does not include

(i) processed dry animal food or

(ii) livestock or poultry feeds manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate).

Animal food manufacturer. "Animal Food Manufacturer" means any person engaged in the business of manufacturing or processing animal food.

Applicant. "Applicant" means any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. "Biological Residue" means any substance, including metabolites, remaining in poultry at the time of slaughter or in any of its tissues after slaughter, as the result of treatment or exposure of the live poultry to a pesticide, organic compound, metallic or other inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other agent that leaves a residue.

(a) The name and place of business of the manufacturer, packer, or distributor; and

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in § 381.121(a) with respect to the quantity of contents;

(vi) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(vii) If it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by the regulations in subpart P of this part unless:

(a) It conforms to such definition and standard, and

(b) Its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(viii) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary,[2] and falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(ix) If it is not subject to the provisions of paragraph (b)(vii) of this section, unless its label bears:

(a) The common or usual name of the food, if any there be, and

(b) In case it is fabricated from two or more ingredients, the common or usual name of each ingredient, except as otherwise provided in § 381.118(c);

(x) If it purports to be or is represented for special dietary uses, unless the label bears such information concerning its vitamin, mineral, and other dietary properties as is required by § 381.124;

(xi) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided in § 381.119, or

(xii) If it fails to bear, directly thereon or on its containers, when required by § 381.123, the official inspection legend and the official establishment number of the establishment where the product was processed; and unrestricted by any of the foregoing; such other information as the Administrator may require in the regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compounds. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of poultry or poultry products, excluding labeling and packaging materials as covered in subpart N of this part.

Official certificate. This term means any certificate prescribed in subpart M of this part relating to poultry or poultry products.

Official device. This term means any label or other device prescribed in subpart M of this part for use in applying any official mark.

Official establishment. "Official establishment" means any establishment as determined by the Administrator at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained pursuant to the regulations.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this definition where inspections are authorized to be conducted as prescribed in § 381.199.

Official inspection legend. This term means the official inspection mark prescribed in § 381.96 or the official poultry identification mark prescribed in § 381.97, showing that an article was inspected for wholesomeness and passed in accordance with the Act.

Official mark. This term means any symbol prescribed in subpart M of this part to identify the status of any article or poultry under the Act.

U.S. Detained. This term is applicable to poultry, poultry products, and other articles which are held in official custody in accordance with section 19 of the Act and § 381.210, pending disposal as provided in said section 19.

U.S. Refused Entry. This term means that the slaughtered poultry or other poultry product so identified was presented for inspection for entry into the United States and was found not to comply with the requirements of the Act.

U.S. Rejected. This term means that the equipment or facility so identified is prohibited from being used in the processing of any poultry or poultry product until such equipment or facility is found by an inspector to be sanitary and otherwise eligible for use under the regulations.

U.S. Retained. This term means that the poultry or carcass, or part or product of a carcass, of poultry so identified is held at an official establishment by the inspection service for further determination as to its disposal.

(c) For the purposes of the standard for cooked, smoked sausage (§ 319.180 of this chapter), the term "poultry byproduct" means the skin, fat, gizzard, heart, or liver, or any combination thereof, of any poultry.

[37 FR 9706; May 16, 1972, as amended at 39 FR 4568, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 48 FR 6091, Feb. 10, 1983; 49 FR 2236, Jan. 19, 1984; 49 FR 3643, Jan. 30, 1984; 49 FR 47478, Dec. 5, 1984; 51 FR 37709, Oct. 24, 1986; 64 FR 745, Jan. 6, 1999; 64 FR 56416, Oct. 20, 1999; 66 FR 1770, Jan. 9, 2001; 66 FR 22905, May 7, 2001; 67 FR 13258, Mar. 22, 2002; 69 FR 255, Jan. 5, 2004; 79 FR 56233, Sept. 19, 2014]

FOOTNOTES - 381.1

[2] No such standards are currently in effect. However, § 381.129 prohibits the use of false or misleading containers.

Subpart B—Administration; Application of Inspection and Other Requirements

§ 381.3 Administration.

(a) [Reserved]

(b) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided,* That such waivers of the provisions of the regulations are not in conflict with the purposes or provisions of the Act.

(c) Pursuant to section 6 of the Act, the Administrator believes that, in establishments processing poultry products at which inspection under the Act and regulations is required, the frequency with which and the manner in which poultry products made from poultry previously slaughtered and eviscerated in official establishments are reinspected by Inspection Service employees should be based on considerations relevant to effective regulation of poultry products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be deemed necessary pursuant to section 6 of the Act, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Inspection Service employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(d) The determinations referred to in paragraph (c) of this section shall be made by the Inspection Service and shall reflect evaluations of the performance and the characteristics of such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person operating such establishment or by anyone responsibly connected with the business operating such establishment, as "responsibly connected" is defined in section 18(a) of the Act,

(ii) The competence of the person operating such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

§ 381.5 Publications.

Publications under the Act and the regulations shall be made in the FEDERAL REGISTER and in such other media as the Administrator may designate.

§ 381.6 Establishments requiring inspection.

Inspection under the regulations is required at:

(a) Every establishment, except as provided in § 381.10 (a) and (b) or § 381.11, in which any poultry is slaughtered for transportation or sale in commerce, or in which any poultry products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food;

(b) Every establishment, except as provided in § 381.10 (a) and (b), (c), or (d), or § 381.11, within any State or organized territory which is designated pursuant to section 5(c) of the Act, at which any poultry is slaughtered or any poultry products are processed, for use as human food solely for distribution within such jurisdiction; and

(c) Except as provided in § 381.10 (a) and (b), or (c), or § 381.11, every establishment designated by the Administrator pursuant to section 5(c) of the Act as one producing adulterated poultry products which would clearly endanger the public health.

[37 FR 9706, May 16, 1972, as amended at 90 FR 27226, June 26, 2025]

§ 381.7 Coverage of all poultry and poultry products processed in official establishments.

All poultry and poultry products processed in an official establishment shall be inspected, handled, processed, marked, and labeled as required by the regulations.

Subpart C—Exemptions

§ 381.10 Exemptions for specified operations.

(a) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products shall not apply to:

(1) Any retail dealer with respect to poultry products sold in commerce directly to consumers in an individual retail store, if the only processing operation performed by such retail dealer is the cutting up of poultry products on the premises where such sales to consumers are made: *Provided,* That such operation is conducted under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further,* That the poultry products sold in commerce are derived from poultry inspected and passed under the Act and such poultry products are not adulterated or misbranded at the time of sale (except that the official inspection legend shall not be used). (For the purposes of this subparagraph, a retail dealer is any person who sells poultry products directly to consumers as defined in paragraph (d)(2)(vi) of this section and whose sales of poultry products to household consumers constitute, in terms of dollar value, at least 75 percent of his total sales of poultry products.)

(2) The slaughter of poultry, and the processing of poultry products, by any person in any territory not organized with a legislative body, solely for distribution within such territory: *Provided,* That such poultry is sound and healthy and is slaughtered under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further,* That the poultry products are not adulterated or misbranded when so distributed (except that the official inspection legend shall not be used).

(3) The slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his nonpaying guests and employees: *Provided,* That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food, and the shipping containers of such poultry products bear the producer's name and address and the statement "Exempted—P.L. 90-492."

(4) The custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and the employees: *Provided,* That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food: *And provided further,* That in lieu of complying with all the adulteration and misbranding provisions of the

(1) Such producer slaughters not more than 1,000 poultry during the calendar year for which this exemption is being determined;

(2) Such poultry producer does not engage in buying or selling poultry products other than those produced from poultry raised on his own farm; and

(3) None of such poultry moves in "commerce" (as defined in § 381.1).

(d)

(1) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar-retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For the purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants include any processing of poultry products except canning of poultry products and except slaughtering of poultry unless such slaughtering is conducted at a retail store with respect to live poultry purchased by the consumer at the retail store and processed by the retail store operator in accordance with the consumer's instructions.

(ii) A normal retail quantity is any quantity of a poultry product purchased by a household consumer from a retail supplier that in the aggregate does not exceed 75 pounds. A normal retail quantity sold by a retail supplier to other than a household consumer is any quantity that in the aggregate does not exceed 150 pounds.

(iii) A retail store is any place of business where:

(*a*) The sales of poultry products are made to consumers only;

(*b*) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.[1]

(*c*) Only federally or State inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*d*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(e) The processing of poultry products for sale is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(iv) ***Restaurants.***

(*a*) A restaurant is any establishment where:

(*1*) Poultry products are processed only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(*2*) Only federally inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*3*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*4*) The processing of poultry products is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(*b*) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

of Agriculture, Washington, DC 20250 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) ***Manual cleaning and sanitizing.***

(A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(*1*) Sinks shall be cleaned prior to use.

(*2*) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(*3*) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(*4*) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (*1*) through (*4*) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(*1*) Immersion for at least $^{1}/_{2}$ minute in clean, hot water at a temperature of at least 170 °F; or

(*2*) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(*3*) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(*4*) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(*5*) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(*6*) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(*4*) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(*1*) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(*2*) A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and

(*3*) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(2) Single-tank, stationary-rack, single-temperature machine:

Wash temperature	165 °F
Final rinse temperature	165 °F

(3) Single-tank, conveyor machine:

Wash temperature	160 °F
Final rinse temperature	180 °F

(4) Multitank, conveyor machine:

Wash temperature	150 °F
Pumped rinse temperature	160 °F
Final rinse temperature	180 °F

(5) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature	140 °F
Final rinse temperature	180 °F

(l) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) ***Steam.*** Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term "private nonprofit institution" means "a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office."

(5) The Administrator may withdraw or modify the exemption set forth in § 381.10(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(6) The adulteration and misbranding provisions of the Act and the regulations apply to articles which are exempted from inspection under § 381.10(e).

[37 FR 9706, May 16, 1972, as amended at 38 FR 16991, June 28, 1973; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 16, 1981; 48 FR 2959, Jan. 24, 1983; 51 FR 29909, Aug. 21, 1986; 53 FR 24679, June 30, 1988; 57 FR 34184, Aug. 3, 1992; 90 FR 27227, June 26, 2025]

The following articles contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry. Therefore said articles are exempted from the definition of "poultry product" and the requirements of the Act and the regulations applicable to poultry products, if they comply with the conditions specified in this section.

(a) Any human food product (in a consumer package) not provided for in paragraph (c) of this section, if:

(1) It contains less than 2 percent cooked poultry meat (deboned white or dark poultry meat, or both) and/or "Mechanically Separated (Kind of Poultry)" as defined in § 381.173;

(2) It contains less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat (as meat is limited in paragraph (a)(1) of this section) or "Mechanically Separated (Kind of Poultry)" as defined in § 381.173, in any combination;

(3) The poultry ingredients used in the product were prepared under inspection as defined in § 381.1, or were inspected under a foreign inspection system approved under § 381.196(b) and imported in compliance with the Act and the regulations;

(4) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(5) The product is not represented as a poultry product. The aforesaid percentages of ingredients shall be computed on the basis of the moist, deboned, cooked poultry in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) Any human food product (in an institutional pack), not provided for in paragraph (c) of this section, if:

(1) It is prepared for sale only to institutional users, such as hotels, restaurants, and boardinghouses, for use as a soup base or flavoring;

(2) It contains less than 15 percent cooked poultry meat (deboned white or dark poultry meat or both) and/or "Mechanically Separated (Kind of Poultry)" as defined in § 381.173, computed on the basis of the moist deboned, cooked poultry meat and/or "Mechanically Separated (Kind of Poultry)" in such product; and

(3) It complies with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(c) Bouillon cubes, poultry broths, gravies, sauces, seasonings, and flavorings if:

(1) They contain poultry meat and/or "Mechanically Separated (Kind of Poultry)" as defined in § 381.173 or poultry fat only in condimental quantities;

(2) They comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects; and

(3) In the case of poultry broth, it will not be used in the processing of any poultry product in any official establishment.

(d) Fat capsules and sandwiches containing poultry products if they comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(e) Products of the types specified in this section except those specified in paragraphs (c) and (d) of this section will be deemed to be represented as poultry products if the kind name of the poultry (chicken, turkey, etc.) is used in the product name of the product without appropriate qualification. For example, a consumer-packaged noodle soup product containing less than 2 percent chicken meat on a ready-to-serve basis may not be labeled "Chicken Noodle Soup" but, when appropriate, could be labeled as "Chicken Flavored Noodle Soup." Products exempted under this section are subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55982, Nov. 3, 1995]

Subpart D—Application for Inspection; Grant or Refusal of Inspection

§ 381.16 How application shall be made.

The operator of each establishment of the kind required by § 381.6 to have inspection shall make application to the Administrator for inspection service. In cases of change of name, ownership, or location, a new application shall be made.

§ 381.17 Filing of application.

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an official establishment or an official import inspection establishment, must have developed written Sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, in accordance with §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

[61 FR 38866, July 25, 1996, as amended at 77 FR 26936, May 8, 2012; 79 FR 56233, Sept. 19, 2014]

Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

§ 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§ 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§ 381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.

§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

Subpart F—Assignment and Authorities of Program Employees; Appeals

§§ 381.30-381.31 [Reserved]

§ 381.32 Access to establishments.

[See § 300.6 of this chapter regarding access to establishments and other places of business.]

[69 FR 255, Jan. 5, 2004]

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe.

feet; the platform shall be designed with a 42-inch high rail on the back side and with $^{1}/_{2}$-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

(ix) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to prechill and postchill reinspection stations:

(i) Floor space shall consist of a minimum of 3 feet along each conveyor line and after each chiller to allow carcasses to be removed for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 2 feet wide, 2 feet deep, and 3 feet high designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85 on the table surface shall be provided.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy access of persons working at the stations.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(d) Facilities for the New Line Speed (NELS) inspection system. The following requirements for lines operating under the NELS inspection system are in addition to the normal requirements to obtain a grant of inspection and to the requirements for NELS in § 381.76 (b) and (c).

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (d)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 6 feet along the conveyor line for the establishment employee presenting the birds, 4 feet for the inspector, and 4 feet for the establishment helper. A total of at least 42 feet along the conveyor line shall be supplied for three inspection stations.

(iii) Selectors or "kickouts" shall be installed so the three inspection stations will receive birds on 18-inch centers with no intervening birds to impede inspection. The selector must move the bird to the end of the trough for the presenter, inspector, and establishment helper. The selectors must be smooth, steady, and consistent in moving

(iii) The inspector's station shall have an easily and rapidly adjustable platform with a minimum width of 2 feet which covers the entire length of the station (4 feet). The platform must adjust vertically a minimum of 14 inches, and must have a 42-inch rail on the back side and $^1/_2$-inch foot bumpers on the sides and the front to allow safe working conditions.

(iv) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(v) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be wide enough to prevent trimmings, drippage, and debris from accumulation on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to prevent contamination of carcasses by splash.

(vi) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index value of 85[1] where the birds are inspected to facilitate inspection is required. The minimum lighting requirement for inspection stations in § 381.52(b) shall not apply.

(vii) On-line handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85[1] at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

(f) ***Facilities for post-mortem inspection under the New Poultry Inspection System.*** The following facilities requirements apply to establishments operating under the New Poultry Inspection System and are in addition to the requirements for obtaining a grant of inspection.

(1) The following provisions apply to the online carcass inspection station:

(i) On each production line, at a point before the chiller and after the establishment has completed all sorting, trimming, and reprocessing activities necessary to comply with § 381.76(b)(6)(ii), at least 4 feet of floor space along the conveyor line must be provided for one online carcass inspection station.

(ii) The conveyor line must be level for the entire length of the online carcass inspection station. The vertical distance from the bottom of the shackles to the top of the platform (paragraph (f)(1)(iii) of this section) must not be less than 60 inches.

(iii) Each online carcass inspection station must have a platform that is slip-resistant and can be safely accessed by the inspector. The platform must be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform must be a minimum length of 4 feet and have a minimum width of 2 feet. The platform must be designed with a 42-inch high rail on the back side and with $^1/_2$-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

FOOTNOTES - 381.36

[1] This requirement may be met by deluxe cool white type of fluorescent lighting.
[1] This requirement may be met by deluxe cool white fluorescent lighting.

§ 381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as $5^{1}/_{2}$ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of § 381.38: *Provided,* That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday. The 8-hour day excludes the lunch period but shall include activities deemed necessary by the Agency to fully carry out an inspection program, including the time for FSIS inspection program personnel to put on required gear, pick up required forms and walk to a work station; and the time for FSIS inspection program personnel to return from a work station, drop off required forms, and remove required gear; and to conduct duties scheduled by FSIS, including administrative duties. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in § 381.145(h) of this subchapter.

(d)

(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided, however,* Minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided,* That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

[40 FR 45800, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986; 76 FR 33980, June 10, 2011; 77 FR 59294, Sept. 27, 2012]

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(c) When thawing frozen ready-to-cook poultry in water, the establishment must use methods that prevent adulteration of, or net weight gain by, the poultry.

(d) The water used in washing the poultry must be permitted to drain freely from the body cavity.

(e) Detached ova may be collected for human food and handled only in accordance with 9 CFR 590.44 and may leave the establishment only to be moved to an official egg product processing plant for processing. Ova from condemned carcasses must be condemned and treated as required in § 381.95.

(f) ***Procedures for controlling visible fecal contamination.*** Official poultry slaughter establishments must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

(g) ***Procedures for controlling contamination throughout the slaughter and dressing operation.*** Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in paragraphs (g)(1) and (2) of this section to monitor their ability to maintain process control.

(1) ***Sampling locations.*** Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process.

(i) Very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million.

(ii) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

(2) ***Sampling frequency.***

(i) Establishments, except for very low volume establishments as defined in paragraph (g)(1)(ii) of this section, must, at a minimum, collect and analyze samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) ***Chickens.*** Once per 22,000 carcasses, but a minimum of once during each week of operation.

(B) ***Turkeys, ducks, geese, guineas, and squabs.*** Once per 3,000 carcasses, but at a minimum once each week of operation.

(ii) Very low volume establishments as defined in paragraph (g)(1)(ii) of this section must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a very low volume establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan.

(iii) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (h) of this section.

(h) ***Recordkeeping requirements.*** Official poultry slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

[66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001, as amended at 79 FR 49634, Aug. 21, 2014]

§ 381.66 Temperatures and chilling and freezing procedures.

(4) Warm packaged ready-to-cook poultry which is to be chilled by immediate entry into a freezer within the official establishment shall within 2 hours from time of slaughter be placed in a plate freezer or a freezer with a functioning circulating air system where a temperature of −10 °F. or lower is maintained.

(5) Frozen poultry shall be held under conditions which will maintain the product in a solidly frozen state with temperature maintained as constant as possible under good commercial practice.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4568, 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 49 FR 9411, Mar. 13, 1984; 60 FR 44412, Aug. 25, 1995; 63 FR 48960, Sept. 11, 1998; 66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001; 66 FR 22905, May 7, 2001; 79 FR 49634, Aug. 21, 2014]

§ 381.67 Young chicken and squab slaughter inspection rate maximums under traditional inspection procedure.

The maximum number of birds to be inspected by each inspector per minute under the traditional inspection procedure for the different young chicken and squab slaughter line configurations are specified in the following table. These maximum rates will not be exceeded. The inspector in charge will be responsible for reducing production line rates where in the inspector's judgment the prescribed inspection procedure cannot be adequately performed within the time available, either because the birds are not presented by the official establishment in such a manner that the carcasses, including both internal and external surfaces and all organs, are readily accessible for inspection, or because the health conditions of a particular flock dictate a need for a more extended inspection procedure. The standards in 381.170(a) of this part specify which classes of birds constitute young chickens and squabs. Section 381.76(b) specifies when either the traditional inspection procedure or the modified traditional inspection procedure can or must be used.

Maximum Production Line Rates—Chickens and Squabs-Traditional Inspection Procedures

Line configuration [1]	Number of inspection stations	Birds per inspector per minute
6-1	1	25
12-1	2	23
12-2	2	21
18-1	3	19
18-2	3	19
18-3	3	18
24-1	4	16 1/2
24-2	4	16
24-4	4	15 1/2

[1] Birds are suspended on the slaughter line at 6-inch intervals. The first number indicates the interval in inches between the birds that each inspector examines. The second number indicates how many of the birds presented, the inspector is to inspect, i.e., "1" means inspect every bird. "4" means inspect every fourth bird, etc.

[47 FR 23435, May 28, 1982, as amended at 66 FR 22905, May 7, 2001]

§ 381.68 Maximum inspection rates—New turkey inspection system.

(d) Establishments operating under the line speed limits authorized in this section shall comply with all other applicable requirements of the laws, including, but not limited to, 29 U.S.C. 654(a).

[79 FR 49635, Aug. 21, 2014]

Subpart J—Ante Mortem Inspection

§ 381.70 Ante mortem inspection; when required; extent.

(a) An ante mortem inspection of poultry shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made of poultry on the day of slaughter in any official establishment.

(b) The examination and inspection of ratites will be on the day of slaughter, except:

(1) When it is necessary for humane reasons to slaughter an injured animal at night or on a Sunday or holiday, and the FSIS veterinary medical officer cannot be obtained; or

(2) In low volume establishments, when ante mortem inspection cannot be done on the day of slaughter, and the birds to be slaughtered have received ante mortem inspection in the last 24 hours, provided the establishment has an identification and control system over birds that have received ante mortem inspection.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001]

§ 381.71 Condemnation on ante mortem inspection.

(a) Birds plainly showing on ante mortem inspection any disease or condition, that under §§ 381.80 to 381.93, inclusive, would cause condemnation of their carcasses on post mortem inspection, shall be condemned. Birds which on ante mortem inspection are condemned shall not be dressed, nor shall they be conveyed into any department of the official establishment where poultry products are prepared or held. Poultry which has been condemned on ante mortem inspection and has been killed or died otherwise shall under the supervision of an inspector of the Inspection Service, be disposed of as provided in § 381.95.

(b) Dead-on-arrival ratites and ratites condemned on ante mortem inspection will be tagged "U.S. Condemned" by an establishment employee under FSIS supervision and disposed of by one of the methods prescribed in § 381.95.

(c) All seriously crippled ratites and non-ambulatory ratites, commonly termed "downers," shall be identified as "U.S. Suspects."

(d) Ratites exhibiting signs of drug or chemical poisoning shall be withheld from slaughter.

(e) Ratites identified as "U.S. Suspects" or "U.S. Condemned" may be set aside for treatment. The "U.S. Suspect" or "U.S. Condemned" identification device will be removed by an establishment employee under FSIS supervision following treatment if the bird is found to be free of disease. Such a bird found to have recovered from the condition for which it was treated may be released for slaughter or for purposes other than slaughter, provided that in the latter instance permission is first obtained from the local, State, or Federal sanitary official having jurisdiction over movement of such birds.

(f) When it is necessary for humane reasons to slaughter an injured ratite at night or Sunday or a holiday, and the Agency veterinary medical officer cannot be obtained, the carcass and all parts shall be kept for inspection, with the head and all viscera except the gastrointestinal tract held by the natural attachment. If all parts are not so kept for inspection, the carcass shall be condemned. If on inspection of a carcass slaughtered in the absence of an inspector, any lesion or other evidence is found indicating that the bird was sick or diseased, or affected with any other condition requiring condemnation of the animal on ante mortem inspection, or if there is lacking evidence of the condition that rendered emergency slaughter necessary, the carcass shall be condemned. Ratites that are sick, dying, or that have been treated with a drug or chemical and presented for slaughter before the required withdrawal period, are not covered by emergency slaughter provisions.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001; 67 FR 13258, Mar. 22, 2002]

§ 381.72 Segregation of suspects on ante mortem inspection.

(a) All birds, except ratites, that on ante mortem inspection do not plainly show, but are suspected of being affected with, any disease or condition that under §§ 381.80 to 381.93 of this Part may cause condemnation in whole or in part on post mortem inspection, shall be segregated from the other poultry and held for separate slaughter, evisceration, and post

Inspection System (NTI), and Ratite Inspection.

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in every official establishment. Each carcass, or all parts comprising such carcass, must be examined by an inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned. Each carcass eviscerated shall be prepared as ready-to-cook poultry.

(b)

(1) There are six systems of post-mortem inspection: the New Poultry Inspection System (NPIS), which may be used for young chickens and turkeys; the Streamlined Inspection System (SIS) and the New Line Speed Inspection System (NELS), both of which may be used only for broilers and cornish game hens; the New Turkey Inspection (NTI) System, which may be used only for turkeys; Traditional Inspection, which may be used for all poultry, except for ratites; and Ratite Inspection.

(i) The SIS shall be used only for broilers and cornish game hens if:

(*a*) The Administrator determines that SIS will increase inspector efficiency; or

(*b*) The operator requests SIS and the Administrator determines that the system will result in no loss of inspection efficiency.

(ii) The NELS Inspection System shall be used only for broilers and cornish game hens if:

(*a*) The operator requests the NELS Inspection System, and

(*b*) The Administrator determines that the establishment has the intent and capability to operate at line speeds greater than 70 birds per minute, and meets all the facility requirements in § 381.36(d).

(iii) The NTI System shall be used only for turkeys if:

(*a*) The operator requests it, and

(*b*) The Administrator determines that the establishment meets all the facility requirements in § 381.36(e).

(iv) The NPIS may be used for young chickens and turkeys if the official establishment requests to use it and meets or agrees to meet the requirements of paragraph (b)(6) of this section and the Administrator approves the establishment's request. The Administrator may permit establishments that slaughter classes of poultry other than young chickens and turkeys to operate under the New Poultry Inspection System under a waiver from the provisions of the regulations as provided in § 381.3(b).

(v) Traditional Inspection shall be used for turkeys when neither the NTI System nor the NPIS is used. For other classes of poultry, Traditional Inspection shall be used when SIS, NELS, and the NPIS are not used.

(2) Official establishments that operate under Traditional Inspection, SIS, NELS, NTI, or Ratite Inspection must meet the following requirements:

(i) No viscera or any part thereof may be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless its identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made.

(ii) Each carcass to be eviscerated must be opened so as to expose the organs and the body cavity for proper examination by the inspector.

(iii) If a carcass is frozen, it must be thoroughly thawed before being opened for examination by an inspector.

(3) The following requirements are applicable to SIS:

(i) ***Definitions.*** For purposes of this paragraph, the following definitions shall apply:

(*a*) ***Cumulative sum (CUSUM).*** A statistical concept used by the establishment and monitored by the inspector whereby compliance is determined based on sample results collected over a period of time. For purposes of determining compliance with the finished product standards, the CUSUM is equal to the sum of prior test results plus the weighted result of the current test minus the tolerance, with the condition that the resulting CUSUM cannot go below zero.

(*b*) ***Tolerance number.*** A weighted measure that equates to product being produced at a national product quality level. See Table 2.

(1) The helper, time permitting, and

(2) One or more plant trimmers positioned after all giblets are harvested and prior to reinspection.

(iv) ***Reinspection.***

(a) Facilities: Reinspection stations are required at both the prechill and postchill locations. The Agency will determine the number of stations needed in those establishments having more than one processing line or more than one chiller. One or more prechill reinspection stations shall be conveniently located at the end of the line or lines prior to chilling. One or more postchill stations must be conveniently located at the end of the chiller or chillers. The prechill and postchill reinspection stations must meet the following provisions:

(1) Floor space shall consist of 3 feet along each conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(2) A table at least 2 feet wide and 2 feet deep and 3 feet in height designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(3) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85 on the table surface.

(4) A separate clip board holder shall be provided for holding the recording sheets.

(5) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(b) Disposition: An inspector shall monitor the establishment's application of the Finished Product Standards program and shall take corrective action including retaining product to prevent adulterated product from leaving the establishment when the inspector determines that the establishment has failed to apply the program as prescribed in paragraph (b)(3)(iv)(c) of this section).

(c) Finished Product Standards: Finished Product Standards (FPS) are criteria applied to processed birds before and after chill to ensure that the product being produced is consistently wholesome and unadulterated. These criteria consist of nonconformances (listed in Table 1), the incidence of which is determined from 10 bird subgroup samples, reduced to a CUSUM number, and measured against the standards (Table 2). The standards are applied to permit the Agency to estimate when the production process is in control and when it is out of control. The establishment is responsible for maintaining FPS which, in turn, is monitored by the inspector. FPS is applied in two separate parts. The first is called prechill testing. It is designed to ensure that the slaughter and evisceration procedures are in control. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system. The second part of the FPS is called postchill testing. It is designed to monitor the production through the chill system to ensure that it meets the postchill FPS. This test is independent of the prechill test. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples as they exit the chilling system. When the system is operating within compliance, the establishment applies the FPS to product samples at the prechill reinspection station. Testing time and time between tests are such that birds represented by the test are still within the chiller. If an out-of-compliance condition is found, the product leaving the chiller is segregated for rework and retested before it may proceed into commerce. A second 10 bird subgroup sample of the birds is taken after they leave the chiller to ensure that the product meets the postchill FPS. Since the product is closer to the end of processing, the controls on releasing reworked product are stricter than controls under prechill testing, again to ensure that no adulterated product enters into commerce.

(d) ***Prechill testing.*** The prechill FPS have been divided into processing and trim categories. The processing category is designed to monitor the output of the dressing and evisceration procedures. The trim category monitors the establishment's ability to remove unwholesome lesions and conditions from inspected and passed carcasses. Each category is monitored independently of the other category using a separate CUSUM for each category.

(1) ***Actions to be taken when the process is in control.*** If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(i) Establishment Actions. The establishment shall:

(A) Randomly select and record subgroup sampling times for each production unit of time before product reaches the prechill reinspection station on the production line. In no case shall the time between tests exceed 1 hour of production time.

(C) Conduct subgroup retests on carcasses leaving the chill system. Apply the prechill criteria in Table 1 (A) or (B), depending upon which category caused the action, and apply prechill Finished Product Standards as listed in Table 2 to determine product compliance. In no case shall the time between retests exceed 30 minutes of production time. Apply prechill standard criteria at the postchill location after notifying the establishment's production supervisor. If any of these subgroup retests on product leaving the chill system result in a subgroup total exceeding tolerance, identify for rework subsequent product at the postchill location. All noncomplying product will be brought into compliance prior to release into commerce. Product from the chiller will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(D) Conduct additional subgroup tests at the prechill reinspection station to determine the adequacy of production corrective action. If the prechill tests results in a subgroup total exceeding the tolerance, notify the production supervisor. The number of additional tests at the postchill reinspection station using prechill standards is increased as required to include the product in the chiller represented by this additional prechill test.

(E) After two consecutive additional prechill subgroup tests result in subgroup totals equal to or less than tolerance:

—Resume random time prechill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*d*)(*1*) of this section.
—Identify product entering the chill system that will mark the end of the retest action upon arrival at the postchill sampling location. Such identification may include tagging or empty space in chillers, depending upon the establishment's identification method.
—Once all product identified as needing retesting has arrived at the postchill sampling location, random time postchill FPS testing resumes.
—If two consecutive additional prechill subgroup tests demonstrate process control with subgroup totals equal to or less than tolerance, but they do not cause CUSUM to fall to the start line or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions by making spot-check observations to ensure that all program requirements are met.

(e) ***Postchill testing.*** Postchill subgroups shall be collected after the product leaves the chiller but before the product is divided into separate processes. Each bird sampled shall be observed and its conformance measured against the postchill criteria. The subgroup nonconformance weights shall be totaled and the CUSUM calculated by subtracting the tolerance from the sum of the subgroup total and the starting CUSUM.

(*1*) ***Actions to be taken when the process is in control.*** If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(*i*) Establishment Actions. The establishment shall conduct a 10-bird subgroup test for each chiller system at a randomly selected time of production. In no case shall the time between tests exceed 2 hours of production time.

(*ii*) Inspector Actions. The inspector shall:

(*A*) Select random times for postchill monitoring.

(*B*) Monitor each chill system twice per shift.

(*C*) Conduct subgroup tests at preselected random times.

(*2*) ***Actions to be taken when the subgroup absolute limit is exceeded.*** If either an inspector or establishment subgroup test exceeds the subgroup absolute limit of tolerance plus 5(T + 5), the establishment shall determine if any of the last 5 postchill monitoring subgroups resulted in a CUSUM above the start number.

(*i*) If all of the past 5 postchill monitoring subgroups resulted in a CUSUM at or below the start number, the establishment shall immediately retest a subgroup to determine sample validity. If this retest subgroup total exceeds tolerance, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(e)(*3*) of this section.

(vi) After the 10 bird subgroup tests are completed, the prechill and postchill processing nonconformances shall be corrected on all bird samples prior to returning the samples to the product flow. Samples with trim nonconformances shall be returned to the trim station for correction prior to their return to the product flow.

TABLE 1—DEFINITIONS OF NONCONFORMANCES

A Processing Nonconformances

1 Extraneous material ≤$^{1}/_{16}$"

—Include any specks, tiny smears, or stains of material that measure $^{1}/_{16}$" or less in the greatest dimension.

Examples: Ingesta, unattached feathers, grease, bile remnants, and/or whole gall bladder or spleen, embryonic yolk, etc.

—Factor is one.

—1 to 5 = 1 defect: 6 to 10 = 2 defects; 11 or more = 3 defects. A maximum of three incidents per carcass.

2 Extraneous material >$^{1}/_{16}$" to 1"

—The same material as line 1, but measuring >$^{1}/_{16}$" to 1" in the longest dimension.

—Factor is one.

—A maximum of three incidents per carcass.

3 Extraneous material >1"

—The same material as lines 1 to 2, but measuring greater than one inch.

—Factor is two.

—A maximum of two incidents per carcass.

4 Oil glands remnant—less than two whole glands

—Recognizable fragment(s) of one or both oil glands equals one incident.

—Factor is one.

—Maximum of one incident per carcass.

5 Oil glands—two whole glands

—Both whole oil glands with no missing fragments equals one incident. If the oil glands are cut, but no fragment is removed, consider them to be whole. But if even a small fragment is removed, use line 4.

—Factor is two.

—A maximum of one incident per carcass.

6 Lung ≥$^{1}/_{4}$" whole

13 Crop—whole

—Any complete crop.

—Factor is five.

—A maximum of one incident per carcass.

14 Trachea ≤1"

—Identifiable portion of trachea less than or equal to one inch long.

—Factor is one.

—A maximum of one incident per carcass.

15 Trachea >1"

—Identifiable portion of trachea greater than one inch.

—Factor is two.

—A maximum of one incident per carcass.

16 Hair ≥$^{1}/_{4}$" 26 or more.

—Hair which is one-fourth inch long or longer measured from the top of the follicle to the end of the hair. 26 or more hairs equal one incident.

—Factor is one.

—A maximum of one incident per carcass.

17 Feather and/or Pinfeathers ≤1"

—Attached feathers or protruding pinfeathers less than or equal to one inch long. Scored 5 to 10 per carcass as one incident, 11 to 15 per carcass as two incidents, and 16 or more as three incidents.

—Factor is one.

—A maximum of three incidents per carcass.

18 Feathers >1"

—Attached feathers longer than one inch. Scored 1 to 3 per carcass as one incident 4 to 6 per carcass as two incidents, and 7 or more as three incidents.

—Factor is one.

—A maximum of three incidents per carcass.

19 Long Shank—both condyles covered

—If the complete tibiotarsal joint is covered, it equals one incident.

—Factor is two.

7 Trimmable lesions/Condition

—A trimmable tumor or identifiable portion of a tumor on any part of the carcass.

—Trimmable Synovitis/airsacculitis (saddle/frog) lesions that have not been removed.

—Lesion/condition subject to removal following an approved cleanout process. Examples: airsacculitis, salpingitis, nephritis, spleen, or liver conditions requiring removal of the kidneys.

Note: All establishments shall develop and maintain a permanent marking system that identifies carcasses with removable lesions/conditions on the inside surfaces. When removable lesions/conditions are identified inside the carcass by the inspector, the helper will be notified to apply the permanent mark. When removable inside lesions/conditions are found on a subgroup sample without the permanent mark, the error is not recorded in line 7. The affected carcass(s) will be hungback for IIC disposition and corrective action.

—Factor is five.

—A maximum of one incident per carcass.

8 Failure to complete task as indicated by marking system.

Example: Synovitis, airsacculitis, inflammatory process, contamination, etc.

—The helper, under the inspector's direction, will apply a mark to the carcass, indicating to the trimmer(s) that specific action must be taken on that carcass. When airsac and kidney cleanout, or synovitis part removal, or carcass removal from the line is not completed, or only partially completed, this occurrence is recorded as one defect.

—Factor is five. It will also be recorded as a line 7 defect for a total factor of 10.

—A maximum of one incident per carcass.

9 Compound fracture

—Any bone fracture (i.e., leg or wing) that has caused an opening through the skin. May be accompanied with a bruise, but not always. Do not count the bruise in line 3 or 4 if it is associated with the compound fracture.

—Factor is two.

—A maximum of three incidents per carcass.

10 Wingtip compound fracture

—Same criteria as line 9, but only for wingtips.

Note: Bruises not associated with the fracture should be recorded in the appropriate lines.

—Factor is one.

—A maximum of two incidents per carcass.

11 Untrimmed short hock

—A maximum of three incidents per carcass.

3 Extraneous material >1"

—The same material as line 2, but measuring greater than one inch.

—Factor is two.

—A maximum of two incidents per carcass.

Table 2—Finished Product Standards

	SIS
Prechill Processing Nonconformance	
Tolerance number (T)	25
Subgroup Absolute Limit (T + 5)	30
Action number	22
Start number	11
Prechill Trim Nonconformance	
Tolerance number (T)	12
Subgroup Absolute Limit (T + 5)	17
Action number	15
Start number	8
Postchill Nonconformance	
Tolerance number (T)	5
Subgroup Absolute Limit (T + 5)	10
Action number	10
Start number	5

(4) The following requirements are also applicable to NELS inspection:

(i) Inspection under NELS is conducted in two phases, as post-mortem inspection phase and a reinspection phase.

(a) ***Post-mortem inspection.*** The establishment shall provide three inspection stations on each eviscerating line in compliance with the facility requirements § 381.36(d)(1). The three inspectors shall inspect the inside, viscera, and outside of all birds presented. Each inspector shall be flanked by two establishment employees —the presenter and the helper. The presenter shall ensure that the bird is properly eviscerated and presented for inspection and the viscera uniformly trailing or leading. The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Poultry carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to

(C) The establishment must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chiller. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program. These procedures must cover, at a minimum, establishment sorting activities required under paragraph (b)(6)(ii) of this section.

(D) The establishment must maintain records to document that the products resulting from its slaughter operation meet the definition of ready-to-cook poultry in § 381.1. These records are subject to review and evaluation by FSIS personnel.

(iii) ***Presentation for online carcass inspection.*** To ensure the online carcass inspector may properly inspect every carcass, the establishment must present carcasses as follows:

(A) Each carcass, except carcasses and parts identified as "major portions" under 9 CFR 381.179(b)(22), must be held by a single shackle;

(B) Both hocks of each carcass must be held by the shackle;

(C) The back side of the carcass must be faced toward the inspector;

(D) There must be minimal carcass swinging motion;

(E) The establishment must ensure that it can sufficiently identify viscera and parts corresponding with each carcass inspected by the online carcass inspector so that if the carcass inspector condemns a carcass all corresponding viscera and parts are also condemned.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0008)

[47 FR 23435, May 28, 1982, as amended at 49 FR 42555, Oct. 23, 1984; 50 FR 37513, Sept. 16, 1985; 50 FR 38097, Sept. 20, 1985; 51 FR 3574, Jan. 29, 1986; 53 FR 46861, Nov. 21, 1988; 62 FR 5143, Feb. 4, 1997; 65 FR 34390, May 30, 2000; 66 FR 22906, May 7, 2001; 79 FR 49635, Aug. 21, 2014; 88 FR 55913, Aug. 17, 2023]

§ 381.77 Carcasses held for further examination.

Each carcass, including all parts thereof, in which there is any lesion of disease, or other condition which might render such carcass or any part thereof adulterated and with respect to which a final decision cannot be made on first examination by the inspector, shall be held for further examination. The identity of each such carcass, including all parts thereof, shall be maintained until a final examination has been completed.

§ 381.78 Condemnation of carcasses and parts: separation of poultry suspected of containing biological residues.

(a) At the time of any inspection under this subpart each carcass, or any part thereof, which is found to be adulterated shall be condemned, except that any such articles which may be made not adulterated by reprocessing, need not be so condemned if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated.

(b) When a lot of poultry suspected of containing biological residues is inspected in an official establishment, all carcasses and any parts of carcasses in such lot which are condemned shall be kept separate from all other condemned carcasses or parts.

[37 FR 9706, May 16, 1972, as amended at 48 FR 22899, May 23, 1983; 48 FR 23807, May 27, 1983]

§ 381.79 Passing of carcasses and parts.

Each carcass and all organs and other parts of carcasses which are found to be not adulterated shall be passed for human food.

§ 381.80 General; biological residues.

(a) The carcasses or parts of carcasses of all poultry inspected at an official establishment and found at the time of post mortem inspection, or at any subsequent inspection, to be affected with any of the diseases or conditions named in other sections in this subpart, shall be disposed of in accordance with the section pertaining to the disease or condition. Owing to the fact that it is impracticable to formulate rules for each specific disease or conditions and to designate at just what

§ 381.90 Cadavers.

Carcasses of poultry showing evidence of having died from causes other than slaughter shall be condemned.

§ 381.91 Contamination.

(a) Carcasses of poultry contaminated by volatile oils, paints, poisons, gases, scald vat water in the air sac system, or other substances which render the carcasses adulterated shall be condemned. Any organ or other part of a carcass which has been accidentally multilated in the course of processing shall be condemned, and if the whole carcass is affected, the whole carcass shall be condemned.

(b) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents need not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut must be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone or may be re-processed as provided in subparagraph (b)(1) or (2) of this section.

(1) ***Online reprocessing.*** Poultry carcasses accidentally contaminated with digestive tract contents may be cleaned by applying an online reprocessing antimicrobial intervention to all carcasses after evisceration and before the carcasses enter the chiller if the parameters for use of the antimicrobial intervention system have been approved by the Administrator. Establishments must incorporate procedures for the use of any online reprocessing antimicrobial intervention system into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

(2) ***Offline reprocessing.*** Contaminated inner surfaces that are not cut may be cleaned at an approved reprocessing station away from the main processing line by any method that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. All visible specks of contamination must be removed, and if the inner surfaces are reprocessed other than solely by trimming, all surfaces of the carcass must be treated with chlorinated water containing 20 ppm to 50 ppm available chlorine or another approved antimicrobial substance in accordance with the parameters approved by the Administrator. Establishments must incorporate procedures for the use of any offline reprocessing into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

[37 FR 9706, May 16, 1972, as amended at 43 FR 12847, Mar. 28, 1978; 79 FR 49636, Aug. 21, 2014]

§ 381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§ 381.93 Decomposition.

Carcasses of poultry deleteriously affected by post mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

§ 381.94 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards for establishments that slaughter ratites.

(a) ***Criteria for verifying process control; E. coli testing.***

(1) Each official establishment that slaughters ratites shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter ratites and livestock, shall test the type of ratites or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

Subpart L—Handling and Disposal of Condemned or Other Inedible Products at Official Establishments

§ 381.95 Disposal of condemned poultry products.

All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crankcase oil, or

(3) Any phenolic disinfectant conforming to commercial standards CS 70-41 or CS 71-41 which shall be used in at least 2 percent emulsion or solution.

(d) Any other substance or method that the Administrator approves in specific cases, which will denature the poultry product to the extent necessary to accomplish the purposes of this section.

(e) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (b) of this section or by burying under the supervision of an inspector.

Subpart M—Official Marks, Devices, and Certificates; Export Certificates; Certification Procedures

§ 381.96 Wording and form of the official inspection legend.

Except as otherwise provided in this subpart, the official inspection legend required to be used with respect to inspected and passed poultry products shall include wording as follows: "Inspected for wholesomeness by U.S. Department of Agriculture." This wording shall be contained within a circle. The form and arrangement of such wording shall be exactly as indicated in the example in Figure 1, except that the appropriate official establishment number shall be shown, and if the establishment number appears elsewhere on the labeling material in the manner prescribed in § 381.123(b), it may be omitted from the inspection mark. The administrator may approve the use of abbreviations of such inspection mark; and such approved abbreviations shall have the same force and effect as the inspection mark. The official inspection legend, or the approved abbreviation thereof, shall be printed on consumer packages and other immediate containers of inspected and passed poultry products, or on labels to be securely affixed to such containers of such products and may be printed or stenciled thereon, but shall not be applied by rubber stamping. When applied by a stencil, the legend shall not be less than 4 inches in diameter. An official brand must be applied to inspected and passed carcasses and parts of ratites that are shipped unpacked.

§ 381.101 Official U.S. Condemned mark.

The term "U.S. Condemned" as shown below is an official mark and the devices used by the Department for applying such mark are official devices.

U.S.
CONDEMNED
FIGURE 4

§ 381.102 [Reserved]

§ 381.103 Official poultry condemnation certificates; issuance and form.

Upon request by the operator of the establishment, the inspector in charge shall issue a poultry condemnation certificate (Form MP-514-1), showing the total number of poultry in the lot and the numbers condemned and the reasons for such condemnations.

The official poultry condemnation certificate authorized by this subpart is a paper certificate (Form MP-514-1), for signature by an inspector, bearing the legend

U.S. Department of Agriculture Animal and Plant Health Inspection Service

poultry condemnation certificate

and the seal of the United States Department of Agriculture, with a certification that the poultry enumerated on the form were inspected and condemned for the listed causes in compliance with the regulations of the Department. A statement to the effect that certain figures on the certificate were derived from information supplied by plant management, and a signature line for an authorized plant official is also shown.

§ 381.104 Export inspection marks.

The export inspection mark required in § 381.105 must be either a mark that contains a unique identifier that links the consignment to the export certificate or an official mark with the following form:[1]

[81 FR 42234, June 29, 2016]

FOOTNOTES - 381.104

[1] The number "1234567" is given as an example only. The number on the mark will correspond to the printed number on the export certificate.

§ 381.109 Form of official poultry inspection certificate.

(a) The official poultry inspection certificate authorized by this subpart is a paper certificate (Form MP-505) for signature by an inspector, bearing the legend

U.S. Department of Agriculture Animal and Plant Health Inspection Service Meat and Poultry Inspection Program

poultry inspection certificate

and the seal of the U.S. Department of Agriculture, with a certification that the poultry described therein had been inspected in compliance with the Regulations of the Secretary of Agriculture Governing the Inspection of Poultry and Poultry Products.

(b) The certificate also bears a serial number such as "B 3208" and shows the respective name and address of the applicant, the shipper or seller and the receiver or buyer and the net weight in pounds of amount passed, amount rejected or condemned, type of poultry, lot number and class, and such other information as the Administrator may prescribe or approve in specific cases.

§ 381.110 Erasures or alterations made on certificates.

Erasures or alterations not initialed by the issuing inspector shall not be permitted on any official certificate or any copy thereof. All certificates rendered useless through clerical error or otherwise and all certificates canceled for whatever cause shall be voided and initialed, and one copy shall be retained in the inspector's file; and the original and all other copies shall be forwarded to the appropriate program supervisor.

§ 381.111 Data to be entered in proper spaces.

All certificates shall be so executed that the data entered thereon will appear in the proper spaces on each copy of the certificate.

§ 381.112 Official mark for maintaining the identity and integrity of samples.

The official mark for use in sealing containers of samples submitted under any requirements in this part and section 11(b) of the Poultry Products Inspection Act shall bear the designation "Sample Seal" accompanied by the official USDA logo as shown below. Any seal approved by the Administrator for applying such mark shall be deemed an official device for purposes of the Act. Such device shall be supplied to inspectors, compliance officers, and other designated Agency officials by the United States Department of Agriculture.

[52 FR 41958, Nov. 2, 1987]

Subpart N—Labeling and Containers

§ 381.115 Containers of inspected and passed poultry products required to be labeled.

Except as may be authorized in specific cases by the Administrator with respect to shipment of poultry products between official establishments, each shipping container and each immediate container of any inspected and passed poultry product shall at the time it leaves the official establishment bear a label which contains information, and has been approved, in accordance with this subpart.

§ 381.117 Name of product and other labeling.

(a) The label shall show the name of the product, which, in the case of a poultry product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in subpart P, shall be the name of the food specified in the standard, and in the case of any other poultry product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation.

(b) The name of the product required to be shown on labels for fresh or frozen raw whole carcasses of poultry shall be in either of the following forms: The name of the kind (such as chicken, turkey, or duck) preceded by the qualifying term "young" or "mature" or "old", whichever is appropriate; or the appropriate class name as described in § 381.170(a). The name of the kind may be used in addition to the class name, but the name of the kind alone without the qualifying age or class term is not acceptable as the name of the product, except that the name "chicken" may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen cut-up young chickens, or a half of a young chicken, and the name "duckling" may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen young ducks. The class name may be appropriately modified by changing the word form, such as using the term "roasting chicken", rather than "roaster." The appropriate names for cut-up parts are set forth in § 381.170(b). When naming parts cut from young poultry, the identity of both the kind of poultry and the name of the part shall be included in the product name. The product name for parts or portions cut from mature poultry shall include, along with the part or portion name, the class name or the qualifying term "mature." The name of the product for cooked or heat processed poultry products shall include the kind name of the poultry from which the product was prepared but need not include the class name or the qualifying term "mature."

(c) Poultry products containing light and dark chicken or turkey meat in quantities other than the natural proportions, as indicated in Table 1 in this paragraph, must have a qualifying statement in conjunction with the name of the product indicating, as shown in Table 1, the types of meat actually used, except that when the product contains less than 10 percent cooked deboned poultry meat or is processed in such a manner that the character of the light and dark meat is not distinguishable, the qualifying statement will not be required, unless the product bears a label referring to the light or dark meat content. In the latter case, the qualifying statement is required if the light and dark meat are not present in natural proportions. The qualifying statement must be in type at least one-half the size and of equal boldness as the name of the product; e.g., Boned Turkey (Dark Meat).

TABLE 1

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50-65	50-35
Light or white meat	100	0
Dark meat	0	100
Light and dark meat	51-65	49-35
Dark and light meat	35-49	65-51
Mostly white meat	66 or more	34 or less
Mostly dark meat	34 or less	66 or more

(d) Boneless poultry products shall be labeled in a manner that accurately describes their actual form and composition. The product name shall specify the form of the product (e.g., emulsified, finely chopped, etc.), and the kind name of the poultry, and if the product does not consist of natural proportions of skin and fat, as they occur in the whole carcass, shall also include terminology that describes the actual composition. If the product is cooked, it shall be so labeled. For the purpose of this paragraph, natural proportions of skin, as found on a whole chicken or turkey carcass, will be considered to be as follows:

(i) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided,* That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as "Contains _____ percent or less of _____," or "Less than _____ percent of _____." The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with subpart P of this part and § 424.21(c) of subchapter E, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(b) For the purpose of this paragraph, the term "chicken meat," unless modified by an appropriate adjective, is construed to mean deboned white and dark meat; whereas the term "chicken" may include other edible parts such as skin and fat not in excess of their natural proportions, in addition to the chicken meat. If the term "chicken meat" is listed and the product also contains skin, giblets, or fat, it is necessary to list each such ingredient. Similar principles shall be followed in listing ingredients of poultry products processed from other kinds of poultry.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(i) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as "natural flavor and coloring," "natural flavoring and coloring," "flavor and coloring" or "flavoring and coloring" unless designated by their common or usual name.

(ii) Any ingredient not designated in paragraphs (c) (1) and (2) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(d) On containers of frozen dinners, entrees, and pizzas, and similarly packaged products in cartons, the ingredient statement may be placed on the front riser panel: *Provided,* That the words "see ingredients," followed immediately by an arrow pointing to the front riser panel, are placed on the principal display panel immediately above the location of such statement, without intervening printing or designs.

(e) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(f) Establishments may interchange the identity of two kinds of poultry (e.g., chicken and turkey, chicken meat and turkey meat) used in a product formulation without changing the product's ingredient statement or product name under the following conditions:

(1)

(i) The two kinds of poultry used must comprise at least 70 percent by weight of the poultry and the poultry ingredients [e.g. giblets, skin or fat in excess of natural proportions, or mechanically separated (kind)] used; and,

(ii) Neither of the two kinds of poultry used can be less than 30 percent by weight of the total poultry and poultry ingredients used;

this paragraph (c). An unused tare weight, as defined in section 381.121b of this subchapter, may be printed adjacent to the statement of net quantity of contents when the product is packaged totally with impervious packaging material and is packed with a usable medium.

(2) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel, in lines generally parallel to the base: *Provided,* That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph. The declaration may appear in more than one line.

(3) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on containers, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on containers, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenth inch in height on containers, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on containers, the principal display panel of which has an area of more than 100 but not more than 400 square inches;

(v) Not less than one-half inch in height on containers, the principal display panel of which has an area of more than 400 square inches.

(vi) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). This height standard pertains to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(4) The statement shall appear as a distinct item on the principal display panel and shall be separated, from other label information appearing to the left or right of the statement, by a space at least equal in width to twice the width of the letter "N" of the style of type used in the quantity of contents statement and shall be separated from other label information appearing above or below the statement by a space at least equal in height to the height of the lettering used in the statement.

(5) The terms "net weight" or "net wt." shall be used when stating the net quantity of contents in terms of weight, and the term "net contents" or "contents" when stating the net quantity of contents in terms of fluid measure. Except as provided in § 381.128, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semi-solid, viscous, or a mixture of solid and liquid. On packages containing less than 1 pound or 1 pint, the statement shall be expressed in ounces or fractions of a pint, respectively. On packages containing 1 pound or 1 pint or more, and less than 4 pounds or 1 gallon, the statement shall be expressed in ounces or in pounds with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fraction of the pint or quart. For example, a declaration of three-fourths pound avoirdupois weight shall be expressed as "Net Wt. 12 oz."; a declaration of $1\frac{1}{2}$ pounds avoirdupois weight shall be expressed as "Net Wt. 24 oz.," "Net Wt. 1 lb. 8 oz.," "Net Wt. $1\frac{1}{2}$ lb.," or "Net Wt. 1.5 lbs.". However, on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. The numbers may be written in provided the unit designation is printed. Paragraphs (c)(8) and (9) of this section permit certain exceptions to this paragraph (c)(5) for multi-unit packages, and random weight consumer size and small packages (less than $\frac{1}{2}$ ounce), respectively.

(6) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in section 381.121b of this subchapter. The statement shall not include any term qualifying a unit of weight, measure, or count such as "jumbo quart," "full gallon," "giant quart," "when packed," "minimum," or words of similar importance except as provided in paragraph (b) of this section.

(b) The official establishment number of the official establishment in which the product was processed under inspection and placed as follows:

(1) Within the official inspection legend in the form required by subpart M of this part; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix "P"; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as "Plant No. on Package Closure" or "Plant No. on Pan", if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix "P".

[47 FR 29515, July 7, 1982]

§ 381.124 Dietary food claims.

If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403 and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

§ 381.125 Special handling label requirements.

(a) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: "Keep Refrigerated," "Keep Frozen," "Keep Refrigerated or Frozen," "Perishable—Keep Under Refrigeration," or such similar statement as the Administrator may approve in specific cases. The immediate containers for products that are frozen during distribution and intended to be thawed prior to or during display for sale shall bear the statement "Shipped/Stored and Handled Frozen for Your Protection, Keep Refrigerated or Freeze." For all canned perishable products, the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be shown in letters one-half inch in height.

(b) Safe handling instructions shall be provided for all poultry products not processed in accordance with the provisions of § 381.150(a) or that have not undergone other processing that would render them ready-to-eat, except as exempted under paragraph (b)(4) of this section.

(1)

(i) Safe handling instructions shall accompany the poultry products, specified in this paragraph (b), destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading "Safe Handling Instructions" which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (b)(2) and (b)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2)

(i) The labels of the poultry products, specified in this paragraph (b) and prepared from inspected and passed poultry, shall include the following rationale statement as part of the safe handling instructions, "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

accords to the specifications of the foreign purchaser, (b) that it is not in conflict with the Act or the laws of the country to which it is intended for export, and (c) that the outside of the shipping container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of the regulations shall apply.

§ 381.129 False or misleading labeling or containers.

(a) No poultry product subject to the Act shall have any false or misleading labeling or any container that is so made, formed, or filled as to be misleading. However, established trade names and other labeling and containers which are not false or misleading and which are approved by the Administrator in the regulations or in specific cases are permitted.

(b) No statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, shall appear on any label. For example:

(1) Official grade designations such as the letter grades A, B, and C may be used in labeling individual carcasses of poultry or containers of poultry products only if such articles have been graded by a licensed grader of the Federal or Federal-State poultry grading service and found to qualify for the indicated grade.

(2) Statements, words, pictures, designs, or devices having geographical significance with reference to a particular locality must be made in accordance with § 317.8(b)(1) of this chapter.

(3) "Fresh frozen", "quick frozen", "frozen fresh", and terms of similar import apply only to ready-to-cook poultry processed in accordance with § 381.66(f)(1). Ready-to-cook poultry handled in any other manner and dressed poultry may be labeled "frozen" only if it is frozen in accordance with § 381.66(f)(2) under Department supervision and is in fact in a frozen state. "Individually quick frozen (Kind)" and terms of similar import are applicable only to poultry products that are frozen as stated on the label and whose component parts can be easily separated at time of packing.

(4) Poultry products labeled with a term quoted in any paragraph of § 381.170(b) shall comply with the specifications in the applicable paragraph. However, parts of poultry may be cut in any manner the processor desires as long as the labeling appropriately reflects the contents of the container of such poultry.

(5) The terms "All," "Pure," "100%," and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(6)

(i) A raw poultry product whose internal temperature has ever been below 26 °F may not bear a label declaration of "fresh." A raw poultry product bearing a label declaration of "fresh" but whose internal temperature has ever been below 26 °F is mislabeled. The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26 °F standard by 1 degree (i.e., have a temperature of 25 °F) and still be labeled "fresh." The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26 °F standard by 2 degrees (i.e., have a temperature of 24 °F) and still be labeled "fresh." The average temperature of poultry product lots of each specific product type must be 26 °F. Product described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0°F must be labeled with the descriptive term "frozen," except when such labeling duplicates or conflicts with the labeling requirements in § 381.125 of this subchapter. The word "previously" may be placed next to the term "frozen" on an optional basis. The descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it must be prominently affixed to the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product described in this paragraph is subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(iii) Raw poultry product whose internal temperature has ever been below 26 °F, but is above 0 °F, is not required to bear any specific descriptive term. Raw poultry product whose internal temperature has ever been below 26 °F, but is above 0 °F, may bear labeling with an optional, descriptive term, provided the optional, descriptive term does not cause the raw poultry product to become misbranded. If used, an optional, descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the optional, descriptive term is affixed to the label, it must be prominently affixed on the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(iv) ***Handling and relabeling of products.***

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the Circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

§ 381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.

(a) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph do not apply to marking devices containing the official inspection legend shown in Figure 5 of § 381.102.

(b) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a marking device containing the official inspection legend shown in Figure 5 of § 381.102 or any simulation of that legend.

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the marking device manufacturer.

(3) The manufacturer of the marking devices shall engrave or otherwise mark each marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such marking device that does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

[50 FR 21423, May 24, 1985]

§§ 381.132-381.133 [Reserved]

§ 381.134 Requirement of formulas.

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 45196, Sept. 1, 1994. Redesignated at 60 FR 67457, Dec. 29, 1995]

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with the FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]

Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country eligible to export such poultry and poultry products to the United States under § 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with § 381.115 or § 381.205, except that poultry products inspected and passed and identified as such under the laws of an "at least equal" State or territory listed in § 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official

(f) ***Labeling Logo.*** Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

(g) ***Termination of Quality Control Systems.***

(1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or a quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Adminstrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict, The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)

(1) ***Operating Schedule Under Total Plant Quality Control.*** An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(2) ***Stabilization.*** There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than a 1 $\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with § 381.125. In addition, the statement "Partially Cooked: For Safety, Cook Until Well Done" must appear on the principal display panel in letters no smaller than $^1/_2$ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 746, Jan. 6, 1999]

§ 381.151 Adulteration of product by polluted water; procedure for handling.

(a) In the event there is polluted water (including but not limited to flood water) in an official establishment, all poultry products and ingredients for use in the preparation of such products that have been rendered adulterated by the water shall be condemned.

(b) After the polluted water has receded from an official establishment, all walls, ceilings, posts, and floors of the rooms and compartments involved, including the equipment therein, shall, under the supervision of an inspector, be cleaned thoroughly by the official establishment personnel. An adequate supply of hot water under pressure is essential to make such cleaning effective. After cleaning a solution of sodium hypochlorite containing approximately one-half of 1 percent available chlorine (5,000 p/m) or other equivalent disinfectant approved by the Administrator[1] shall be applied to the surface of the rooms and equipment and rinsed with potable water before use.

(c) Hermetically sealed containers of poultry product which have been contaminated by polluted water shall be examined promptly by the official establishment under supervision of an inspector and rehandled as follows:

(1) Separate and condemn all poultry products in damaged or extensively rusted containers.

(2) Remove paper labels and wash the remaining containers in warm soapy water, using a brush where necessary to remove rust or other foreign material. Disinfect these containers by either of the following methods:

(i) Immerse in a solution of sodium hypochlorite containing not less than 100 p/m of available chlorine or other equivalent disinfectant approved by the Administrator,[1] rinse in potable water, and dry thoroughly; or

(ii) Immerse in 212 °F. water, bring temperature of the water back to 212 °F. and maintain the temperature at 212 °F. for 5 minutes, then remove containers from water and cool them to 95 °F. and dry thoroughly.

(3) After handling as described in paragraph (c)(2) of this section, the containers may be relacquered, if necessary, and then relabeled with approved labels applicable to the product therein.

(4) The identity of the canned poultry product shall be maintained throughout all stages of the rehandling operations, to insure correct labeling of containers.

[38 FR 34456, Dec. 14, 1973]

FOOTNOTES - 381.151

[1] A list of approved disinfectants is available upon request to Scientific Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

Label terminology	Percent light meat	Percent dark meat
Light or white meat	100	0.
Dark meat	0	100.
Light and dark meat	51-65	49-35.
Dark and light meat	35-49	65-51.
Mostly white meat	66 or more	34 or less.
Mostly dark meat	34 or less	66 or more.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.157 Canned boned poultry and baby or geriatric food.

(a) Canned boned poultry shall, unless otherwise specified in this section, be prepared from cooked deboned poultry meat and may contain skin and fat not in excess of natural whole carcass proportions. Gelatin, stabilizers, or similar solidifying or emulsifying agents shall not be added to product labeled "Boned (Kind)—Solid Pack," but may be added in quantities not in excess of a total of 0.5 percent of the total ingredients in the preparation of other canned boned poultry products and in such cases the common name of the substance shall be included in the name of the product, e.g., "Boned Chicken with Broth—Gelatin Added."

(b) Canned boned poultry, except poultry within paragraph (c) of this section, shall meet the requirements set forth in Table II. The percentages in Table II shall be calculated on the basis of the total ingredients used in the preparation of the product.

(c) Canned boned poultry with natural juices (Boned (Kind) with natural juices) shall be prepared from either raw boned poultry or a mixture of raw boned poultry and cooked boned poultry and shall have no liquid added during the preparation of the product.

(d) Canned shredded poultry (Shredded Kind), consists of poultry meat reduced to a shredded appearance, from the kind of poultry indicated, with meat, skin, and fat not in excess of the natural whole carcass proportions. Canned shredded poultry from specific parts may include skin or fat in excess of the proportions normally found on a whole carcass, but not in excess of the proportions of skin and fat normal to the particular part or parts; and such product shall be labeled in accordance with § 381.117(d).

(e) Canned boned poultry shall be prepared as set forth in Table II, items 1, 2, 3, or 4, whichever is applicable.

TABLE II

Product name	Minimum percent cooked, deboned poultry meat of kind indicated, with skin, fat, and seasoning	Maximum percent liquid that may be added [1]
1. Boned (Kind)—solid pack	95	5

[1] Liquid may be in the form of, but is not limited to, broth or extractives.

[2] Alternatively, product may be prepared from raw boned poultry in combination with cooked boned poultry so long as the product complies with the specified standard.

[3] Total amount of liquid added shall be included in the name of the product; e.g., "Boned Chicken with 25 percent broth."

TABLE III

	Minimum cooked deboned poultry meat of kind indicated		Minimum raw deboned poultry meat of kind indicated	
	Percent	**Weight**	**Percent**	**Weight**
(Kind) Pies	14	or $1^1/_8$ oz. per 8-oz. pie [1]	25	or 2 oz. per 8-oz. pie. [1]
(Kind) Dinners	18	or 2 oz. [2 3]		

[1] *14 percent or $1^1/_8$ oz., whichever is greater; or 25 percent or 2 oz., whichever is greater.*

[2] *Excluding weight of appetizers, desserts, etc.*

[3] *18 percent or 2 oz., whichever is greater. A minimum of 45 percent, or 5 ounces per dinner, whichever is greater, of cooked poultry including bone and breading may be used in lieu of minimum 18 percent or 2 ounces of cooked deboned poultry meat and the cooked poultry including bone and breading shall not contain more than 30 percent breading.*

§ 381.159 Poultry rolls.

(a) Binders or extenders may be added in accordance with a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders in poultry rolls: transglutaminase enzyme at up to 65 ppm. When binding agents are added in excess of 3 percent for cooked rolls and 2 percent for raw rolls, the common name of the agent or the term "Binders Added" shall be included in the name of the product; e.g., "Turkey Roll-Gelatin Added."

(b) With respect to heat processed rolls, 2 percent or less liquid based on the weight of the finished product without liquid may remain with or be returned to product labeled as "(Kind) Roll."

(c) Heat processed rolls which have more than 2 percent liquid remaining with or returned to the product shall be labeled as "(Kind) Roll with Natural Juices." If more than 2 percent of any liquid other than natural cookout juices is added, the product must be labeled to indicate that fact; e.g., "Turkey Roll with Broth." Liquid shall not be returned or added to product within this paragraph graph in excess of the amount normally cooked out during preparation.

[37 FR 9706, May 16, 1972, as amended at 55 FR 34684, Aug. 24, 1990; 66 FR 54916, Oct. 31, 2001]

§ 381.160 (Kind) burgers; (Kind) patties.

Such product consists of 100 percent poultry of the kind indicated, with skin and fat not in excess of natural proportions. Product containing fillers or binders shall be named "(Kind) Patties."

§ 381.161 "(Kind) A La Kiev."

Such product consists of poultry meat of the kind indicated, stuffed with butter which may be seasoned and the product may be wrapped in sufficient skin to cover the meat. It may be dipped in batter, fried, and frozen.

§ 381.162 "(Kind) steak or fillet."

Such product consists of a boneless slice or strip of poultry meat of the kind indicated.

§ 381.163 "(Kind) baked" or "(Kind) roasted."

Product name [1]	Minimum percent cooked deboned poultry meat of kind indicated	Minimum percent cooked poultry of kind indicated, indicating bone
Noodles or Dumplings with (Kind) [2]	6	
(Kind) Stew	12	
(Kind) Fricassee of Wings		40
(Kind) Noodles or Dumplings [2]	15	30
(Kind) with Vegetables	15	
Gravy with sliced (Kind)	15	
(Kind) Tetrazzini	15	
(Kind) chili with beans	17	
Creamed (Kind)	20	
(Kind) Cacciatore	20	40
(Kind) Fricassee	20	40
(Kind) A-La-King	20	
(Kind) croquettes	25	
Slice (Kind) with Gravy and Dressing	25	
(Kind) Salad [3]	25	
(Kind) chili	28	
(Kind) Hash	30	
Sliced (Kind) with Gravy	35	

[1] The product name may contain other appropriate descriptive terms such as "noodle"; e.g., "Chicken Noodle Soup."

[2] This standard also applies to products named (Kind) with rice or similar starches.

[3] The 25 percent-standard listed includes poultry meat plus proportions of skin and fat natural to the poultry used.

Product name	Percent skin	
	Raw	Cooked
Chicken Roll	20	25

§ 381.169 [Reserved]

§ 381.170 Standards for kinds and classes, and for cuts of raw poultry.

(a) The following standards specify the various classes of the specified kinds of poultry and the requirements for each class:

(1) *Chickens* —

(i) ***Rock Cornish game hen or Cornish game hen.*** A "Rock Cornish game hen" or "Cornish game hen" is a young, immature chicken (less than 5 weeks of age), of either sex, with a ready-to-cook carcass weight of not more than 2 pounds.

(ii) ***Broiler or fryer.*** A "broiler" or "fryer" is a young chicken (less than 10 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iii) ***Roaster or roasting chicken.*** A "roaster" or "roasting chicken" is a young chicken (less than 12 weeks of age), of either sex, with a ready-to-cook carcass weight of 5.5 pounds or more, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is somewhat less flexible than that of a broiler or fryer.

(iv) ***Capon.*** A "capon" is a surgically neutered male chicken (less than 4 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(v) ***Hen, fowl, baking chicken, or stewing chicken.*** A "hen," "fowl," "baking chicken," or "stewing chicken" is an adult female chicken (more than 10 months of age) with meat less tender than that of a roaster or roasting chicken and a nonflexible breastbone tip.

(vi) ***Cock or rooster.*** A "cock" or "rooster" is an adult male chicken with coarse skin, toughened and darkened meat, and a nonflexible breastbone tip.

(2) *Turkeys* —

(i) ***Fryer-roaster turkey.*** A "fryer-roaster turkey" is an immature turkey (less than 12 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin, and flexible breastbone cartilage.

(ii) ***Young turkey.*** A "young turkey" is a turkey (less than 8 months of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is less flexible than that of a fryer-roaster turkey.

(iii) ***Yearling turkey.*** A "yearling turkey" is a turkey (less than 15 months of age), of either sex, that is reasonably tender-meated with reasonably smooth-textured skin.

(iv) ***Mature or old (hen or tom) turkey.*** A "mature turkey" or "old turkey" is an adult turkey (more than 15 months of age), of either sex, with coarse skin and toughened flesh. Sex designation is optional.

(3) *Ducks* —

(i) ***Duckling.*** A "duckling" is a young duck (less than 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) ***Roaster duck.*** A "roaster duck" is a young duck (less than 16 weeks of age), of either sex, that is tender-meated and has a bill that is not completely hardened and a windpipe that is easily dented.

(iii) ***Mature duck or old duck.*** A "mature duck" or an "old duck" is an adult duck (more than 6 months of age), of either sex, with toughened flesh, a hardened bill, and a hardened windpipe.

(4) *Geese* —

(i) ***Young goose.*** A "young goose" is an immature goose, of either sex, that is tender-meated and has a windpipe that is easily dented.

(17) "Legs with pelvic bone" consists of a poultry leg with adhering meat and skin and pelvic bone.

(18) "Wing drummette" consists of the humerus of a poultry wing with adhering skin and meat attached.

(19) "Wing portion" consists of a poultry wing except that the drummette has been removed.

(20) "Cut-up Poultry" is any cut-up or disjointed portion of poultry or any edible part thereof, as described in this section.

(21) "Giblets" consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

(22) "Major portions" of eviscerated poultry carcasses are either carcasses from which parts may be missing, or the front or rear portions of transversely-split carcasses.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 63 FR 48960, Sept. 11, 1998; 76 FR 68064, Nov. 3, 2011; 81 FR 21709, Apr. 13, 2016]

§ 381.171 Definition and standard for "Turkey Ham."

(a) "Turkey Ham" shall be fabricated from boneless, turkey thigh meat with skin and the surface fat attached to the skin removed. The thighs shall be that cut of poultry described in § 381.170(b)(5) of this part.

(b) The product may or may not be smoked, and shall be cured using one or more of the approved curing agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. The product may also contain cure accelerators, phosphates, and flavoring agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B; common salt, sugars, spices, spice extractives, dehydrated garlic, and dehydrated onions; and water for purpose of dissolving and dispersing the substances specified above.

(c) The cooked finished product weight shall be no more than the original weight of the turkey thigh meat used prior to curing.

(d) The product name on the label shall show the word "Turkey" in the same size, style, color, and with the same background as the word "Ham" and shall precede and be adjacent to it.

(e) The product name shall be qualified with the statement "Cured Turkey Thigh Meat." The qualifying statement shall be contiguous to the product name, without intervening type or designs, shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

(f) If the product is fabricated from pieces of turkey thigh meat that result from the cutting through the muscle (as opposed the whole thighs intact or whole thighs with some incidental separation of muscle tissue during removal of the bone), the product name shall be further qualified by a descriptive statement. The product name of product fabricated from such pieces of turkey thigh meat equivalent in size to a one-half inch cube or greater shall be further qualified to specify that the product is "Chunked and Formed." The product name of product fabricated from such pieces of turkey thigh meat smaller than the equivalent of a one-half inch cube shall be further qualified to specify that the product is "Ground and Formed" or "Chopped and Formed" as appropriate. The qualifying statement shall immediately follow and be contiguous to the statement required in paragraph (e) of this section, and shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

[44 FR 51190, Aug. 31, 1979; 64 FR 72175, Dec. 23, 1999]

§ 381.172 Requirements for substitute standardized poultry products named by use of an expressed nutrient content claim and a standardized term.

(a) ***Description.*** The poultry products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 381.413(d), for a standardized product defined in this subpart and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in this subpart. The expressed nutrient content claim shall comply with the requirements of § 381.413 and with the requirements in subpart Y of this part which define the particular nutrient content claim that is used. The poultry product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(c) "Mechanically Separated (Kind of Poultry)" shall not have a calcium content exceeding 0.235 percent when made from mature chickens or from turkeys as defined in § 381.170(a)(l)(vi) and (vii) and (a)(2), respectively, or 0.175 percent when made from other poultry, based on the weight of product that has not been heat treated, as a measure of a bone solids content of not more than 1 percent.

(d) "Mechanically Separated (Kind of Poultry)" may be used in the formulation of poultry products in accordance with § 381.174 and meat food products in accordance with subchapter A of this chapter.

(e) Product resulting from the mechanical separation process that fails to meet the bone particle size or calcium content requirements for "Mechanically Separated (Kind of Poultry)" shall be used only in producing poultry extractives, including fats, stocks, and broths and labeled as "Mechanically Separated (Kind of Poultry) for Further Processing."

[60 FR 55983, Nov. 3, 1995]

§ 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

(a) A poultry product required to be prepared from a particular kind of poultry (e.g., chicken) shall not contain "Mechanically Separated (Kind of Poultry)" described in § 381.173, that is made from any other kind of poultry (e.g., Mechanically Separated Turkey).

(b) "Mechanically Separated (Kind of Poultry)" described in § 381.173 may be used in the formulation of any poultry or meat food product, provided such use conforms with any applicable requirements of the definitions and standards of identity or composition in this subchapter or part 319 of this chapter, and provided that it is identified as "Mechanically Separated (Kind of Poultry)."

[60 FR 55983, Nov. 3, 1995]

Subpart Q—Records, Registration, and Reports

§ 381.175 Records required to be kept.

(a) Every person within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep such records as are properly necessary for the effective enforcement of the Act:

(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a poultry products broker, wholesaler, or otherwise) or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any poultry or poultry carcass, or part or product of a poultry carcass, is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act.

(i) The name or description of the poultry or other articles;

(ii) The net weight of the poultry or other articles;

(iii) The number of outside containers;

(iv) The name and address of the buyer of the poultry or other articles sold by such person, and the name and address of the seller of the poultry or other articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 57 FR 53982, Nov. 16, 1992; 69 FR 255, Jan. 5, 2004]

§ 381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

(b) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

[37 FR 9706, May 16, 1972, as amended at 61 FR 38868, July 25, 1996]

§ 381.181 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any poultry product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the appropriate program supervisor, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation or receive for transportation, in commerce, any such product which is capable of use as human food and is in fact adulterated or misbranded at the time of such sale, transportation, offer, or receipt: *Provided,* That any such allegedly adulterated or misbranded product may be transported to any official establishment for reinspection.

§ 381.182 Reports of inspection work.

Reports of the inspection work carried on within official establishments shall be forwarded to the Administrator by the inspector in charge in such a manner as may be specified by the Administrator.

Subpart R—Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

§ 381.185 Assistance to State and Territorial programs.

(a) The Administrator is authorized, under paragraph (a) of section 5 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering the poultry product inspection program of such jurisdiction, with a view to assuring that it imposes and enforces requirements at least equal to those under sections 2 through 4, 6 through 10, and 12 through 22 of the Act, with respect to establishments at which poultry are slaughtered or poultry products are processed for use as human food, solely for distribution within such jurisdiction, and with respect to the poultry products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a mandatory law imposing ante mortem and post mortem inspection, reinspection, and sanitation requirements (at least equal to those under the Federal Act), with respect to all or certain classes of persons engaged in slaughtering poultry or otherwise processing poultry products for use as human food solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 5 of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those provided in section 11 of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased poultry; and products not intended for human food) when he determines that such cooperation would effectuate the purposes of the Act.

[40 FR 55310, Nov. 28, 1975]

§ 381.190 Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from any official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with the regulations.

(b)

(1) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any slaughtered poultry or other poultry product which is capable of use as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except as otherwise provided in this paragraph (b) and subpart C or T.

(2)

(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment directly for export as human food, if they have been examined and found to be suitable for such purpose, by an inspector and are labeled as prescribed in this paragraph.

(ii) The containers of all such products shall bear a label showing:

(A) The name of the products;

(B) the name and address of the packer or distributor, and, when the name of the distributor is shown, it shall be qualified by such terms as "packed for," "distributed by," or "distributors"; and

(C) the official establishment number of the establishment where packed.

(iii) Such products shall not bear the official inspection legend.

(3)

(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment and in commerce directly to another official establishment for processing before export, provided the receiving establishment maintains records that:

(A) Identify the source of the incoming undenatured poultry product;

(B) Identify the location of the product at all times during processing and preparation for export; and

(C) Contain a written certification from an official of the receiving establishment that the undenatured poultry product intended for export has not been, and will not be, commingled with any product intended for consumption in the United States.

(ii) The receiving establishment may only ship the undenatured poultry product intended for export in accordance with the inspection and labeling requirements of paragraph (b)(2) of this section.

(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, poultry products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 381.221, any poultry product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Inspection Service's discretion and shall be adequate to determine if poultry product in such conveyance is, or when moved could become, adulterated.

(i) Except as provided in paragraph (ii) of paragraph (b)(3) of this section, the name of the article must be stated on the label as "Animal Food," "Pet Food," or "(name of species) Food" (e.g., "Dog Food" or "Cat Food"). To be considered conspicuous, the name of the article, wherever it appears on the label, must be stated in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from carcasses of poultry.

(ii) Notwithstanding the provisions of paragraph (i) of paragraph (b)(3) of this section, the article's name may be stated on the label to show that it is or contains poultry carcass-source material and that the article is for animals; e.g., "Chicken for Pets" or "Turkey Dinner for Cats": *Provided,* That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any poultry carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any poultry carcass, but shall not be less than $^1/_8$ inch high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in the article of poultry carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feed manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate), or to processed dry animal food.

[49 FR 47479, Dec. 5, 1984]

§ 381.194 Transportation and other transactions concerning dead, dying, disabled, or diseased poultry, and parts of carcasses of poultry that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation or receive for transportation, in commerce, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, unless such poultry and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by § 381.179, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of section 5(c) of the Act.

(b) Buy in commerce or import any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by § 381.179, or is the operator of an establishment inspected as required by paragraph (a) of this section and such poultry or parts of carcasses are to be delivered to establishments eligible to receive them under paragraph (a) of this section.

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided,* That any such dead, dying, disabled, or diseased poultry, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Director, Compliance Staff, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[40 FR 55310, Nov. 28, 1975]

Subpart T—Imported Poultry Products

§ 381.195 Definitions; requirements for importation into the United States.

(a) When used in this part, the following terms are defined to mean:

(B) Post mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;

(C) Official controls by the national government over establishment construction, facilities, and equipment;

(D) Direct and continuous official supervision of slaughtering of poultry and processing of poultry products, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section to assure that adulterated or misbranded poultry products are not processed for export to the United States;

(E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified, and the maintenance of a single standard of inspection and sanitation throughout all certified establishments;

(F) Requirements for sanitation at certified establishments and for sanitary handling of poultry products;

(G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

(I) Other matters for which requirements are contained in the Act or the regulations in this part.

(iii) Countries desiring to establish eligibility for importation of poultry products into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign poultry inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii). Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of poultry products into the United States depends on the results of periodic reviews of the foreign poultry inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system as the Administrator may find pertinent to and necessary for the determinations required by this section.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those applicable to the Federal system in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system to each establishment certified in accordance with paragraph (a)(3) of this section to ensure that requirements referred to in paragraphs (a)(2)(ii)(A) through (H) of this section are being met: Provided, That such visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(H) of this section, copies of which shall be made available to the representative of the Department at the time of the representative's review upon request by that representative to a responsible foreign inspection official: *Provided,* that such reports are not required during a period when the establishment is not operating or not engaged in producing products for exportation to the United States.

(C) Random sampling and testing at the point of slaughter of carcasses, including internal organs and fat, for residues identified by the exporting country's inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: *Provided,* that such testing is required only on samples taken of carcasses from which poultry or poultry products intended for importation into the United States are produced.

(3) Only those establishments that are determined and certified to the Agency by a responsible official of the foreign meat inspection system as fully meeting the requirements of paragraphs (a)(2)(i) and (ii) of this section are eligible to have their products imported into the United States. Establishment eligibility is subject to review by the Agency (including observations of the establishments by Program representatives at times prearranged with the foreign meat inspection system officials). Foreign establishment certifications must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

[79 FR 56234, Sept. 19, 2014]

§ 381.198 Import inspection application.

(a) Applicants must submit an import inspection application to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted (electronically or on paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 381.207 and 381.209.

[79 FR 56234, Sept. 19, 2014]

§ 381.199 Inspection of poultry products offered for entry.

(a)

(1) Except as provided in § 381.209 and paragraph (c) of this section, all slaughtered poultry and poultry products offered for entry from any foreign country shall be reinspected by a Program import inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system shall be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic inspection system.

(b) Inspectors may take, without cost to the United States, from each consignment of poultry products offered for entry, such samples of the products as are deemed necessary to determine the eligibility of the products for entry into the commerce of the United States.

(c) Poultry products imported under § 381.207 shall not be sampled and inspected under this section unless there is reason for suspecting the presence therein of a substance in violation of that section, and in such case they shall be sampled and inspected in accordance with paragraph (a) of this section.

(d) In addition to the provisions specified in paragraphs (a), (b), and (c) of this section, the following requirements apply to imported canned product.

(1) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(b) Except as provided in paragraph (a) of this section, no product required by this subpart 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 subpart as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this subpart.

(c) The consignee, or his agent, shall furnish such facilities and shall provide such assistance for handling and marking poultry products offered for entry as the inspector may require.

[37 FR 9706, May 16, 1972, as amended at 51 FR 37710, Oct. 24, 1986; 54 FR 41050, Oct. 5, 1989; 56 FR 65180, Dec. 16, 1991]

§ 381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.

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

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a)

(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this part, to the Director of Customs at the original port of entry.

(2) When product has been identified as "U.S. refused entry," the inspector shall request the Director of Customs to refuse admission to such product and to direct that it be exported by the owner or consignee within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation, or an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. "Refused entry" product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(4) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to paragraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States without the expressed consent of the Administrator, based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term "lot" shall refer to that product identified on MP Form 410 in the original request for inspection for importation pursuant to § 381.198.

(4) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(2) of this section for "refused entry" product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(5) If the owner or consignee fails to take the required action within the time specified under paragraph (a)(4) of this section, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate forum.

(6) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative detention in accordance with section 19 of the Act, and seizure and condemnation in accordance with section 20 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under this subpart and subsequently designated "U.S. Refused Entry" or found in any request not to comply with the requirements in this subpart.

FIGURE 1

(c) When products are refused entry into the United States, the official mark to be applied to the products refused entry shall be in the following form:

UNITED STATES
REFUSED ENTRY

FIGURE 2

(d) The import warning notice prescribed in § 381.200(c) is an official mark.

(e) The ordering and manufacture of brands shall be in accordance with the provisions contained in § 317.3(c) of the Federal meat inspection regulations.

(f) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports to an Import Field Office Supervisor, the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following:

(i) That stamping under this subpart will be limited to those lots of product which can be inspected on the day that certificates for the product are examined;

(ii) That all products which have been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP-410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of § 381.177.

§ 381.208 Poultry products offered for entry and entered to be handled and transported as domestic; entry into official establishments; transportation.

(a) All poultry products, after entry into the United States in compliance with this subpart, shall be deemed and treated and, except as provided in § 381.207, shall be handled and transported as domestic products, and shall be subject to the applicable provisions of this part and to the provisions of the Poultry Products Inspection Act and the Federal Food, Drug, and Cosmetic Act.

(b) Poultry products entered in accordance with this subpart may, subject to the provisions of the regulations, be taken into official establishments and be mixed with or added to poultry products that are inspected and passed or exempted from inspection in such establishments.

(c) Imported poultry products which have been inspected, passed, and marked under this subpart may be transported in commerce, only upon compliance with the applicable regulations.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989]

§ 381.209 Returned United States inspected and marked poultry products; exemption.

Poultry products which have been inspected and passed by the U.S. Department of Agriculture and are so marked, and are returned from foreign countries, may be imported if they are not adulterated or misbranded at the time of such return. Such products are exempted from further requirements under this part. Such returned shipments shall be reported to the Administrator by letter prior to arrival at the United States port of entry.

Subpart U—Detention; Seizure and Condemnation; Criminal Offenses

§ 381.210 Poultry and other articles subject to administrative detention.

Any poultry carcass, or part thereof; or any product made wholly or in part from any poultry carcass or part thereof; or any dead, dying, disabled, or diseased poultry is subject to detention for a period not to exceed 20 days when found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in commerce or otherwise subject to the Act, and there is reason to believe that any such poultry or other article is adulterated or misbranded and is capable of use as human food or has not been inspected, in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia; or that it has been or is intended to be distributed in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia.

§ 381.211 Method of detention; form of detention tag.

An authorized representative of the Secretary shall detain any poultry or other article to be detained under this subpart, by affixing an official "U.S. Detained" tag (FSIS Form 8400-2) to such article.

[55 FR 47843, Nov. 16, 1990]

§ 381.212 Notification of detention to the owner of the poultry or other article, or the owner's agent, and person having custody.

(a) When any poultry or other article is detained under this subpart, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the poultry or other article detained, and

(2) Promptly furnish a copy of a completed "Notice of Detention" (FSIS Form 8080-1) to the immediate custodian of the detained poultry or other article.

(b) If the owner of the detained poultry or other article, or the owner's agent, is not the immediate custodian at the time of detention and if the owner, or owner's agent, can be ascertained and notified, an authorized representative of the Secretary shall furnish a copy of the completed "Notice of Detention" to the owner, or the owner's agent. Such copy shall be served, as soon as possible, by delivering the notification to the owner, or the owner's agent, or by certifying and mailing the notification to the owner, or the owner's agent, at his or her last known residence or principal office or place of business.

[55 FR 47843, Nov. 16, 1990]

Subpart V—Special Provisions for Designated States and Territories; Criteria and Procedure for Designating Establishments With Operations Which Would Clearly Endanger the Public Health; Disposition of Poultry Products Therein

§ 381.220 Definition of "State".

For purposes of this subpart, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized territory.

§ 381.221 [Reserved]

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

The provisions of the regulations in this part apply to operations and transactions wholly within each State designated under paragraph 5(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

(a) Each establishment located in such a designated State, shall be granted inspection required under § 381.6(b) only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

(b) Section 381.26 will apply to establishments required to have inspection under § 381.6(b), except that existing interconnections between official and unofficial establishments or between official establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible poultry product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of the regulations. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible poultry product does not enter the official establishment contrary to the regulations.

(c) Sections 381.49 and 381.51 shall apply to such establishments, except that separate facilities for men and women workers will not be required when the majority of the workers in the establishment are related by blood or marriage, provided that this will not conflict with municipal or State requirements; and except that separation of toilet soil lines from house drainage lines to a point outside the buildings will not be required in existing construction when positive acting backflow devices are installed.

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Front Line Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 4(h) of the Act.

(2) The Front Line Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the FSIS Labeling and Program Delivery Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff at headquarters, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by § 412.1 or their use must be discontinued.

(4) The Front Line Supervisor will also review all shipping containers to ensure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated poultry products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him 10 days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act as though engaged in commerce.

(3) Thereafter the inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated poultry products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Poultry products on hand at the time of designation of an establishment under this section are subject to retention or detention, and seizure and condemnation in accordance with § 381.145 or subpart U of this part: *Provided,* That poultry products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any poultry products unless it first obtains inspection or qualifies for exemption under § 381.10 of this subpart. All other provisions of the regulations shall apply to establishments designated under this section to the same extent and in the same manner as if they were engaged in commerce, except that the exceptions provided for in § 381.222 shall apply to such establishments.

[37 FR 9706, May 16, 1972, as amended at 90 FR 27227, June 26, 2025]

Subpart X [Reserved]

Subpart Y—Nutrition Labeling

Source: 58 FR 675, Jan. 6, 1993, unless otherwise noted.

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling must be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444, unless the product is exempted under § 381.500. Nutrition labeling must be provided for the major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials, except as exempted under § 381.500. For all other products that require nutrition labeling, including ground or chopped poultry products described in § 381.401, nutrition labeling must be provided in accordance with the provisions of § 381.409, except as exempted under § 381.500.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and that are not major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials.

[75 FR 82166, Dec. 29, 2010]

§ 381.401 Required nutrition labeling of ground or chopped poultry products.

Nutrition labels must be provided for all ground or chopped poultry (kind) with or without added seasonings (including, but not limited to, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of § 381.409, except as exempted under § 381.500.

[75 FR 82166, Dec. 29, 2010]

§ 381.402 Location of nutrition information.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 381.412(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., $^1/_8$ quiche, $^1/_4$ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 381.412(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 381.412(c). In expressing the fractional slice, manufacturers shall use $^1/_2$, $^1/_3$, $^1/_4$, $^1/_5$, $^1/_6$, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 381.412(c).

(7) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., $^1/_4$ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in $^1/_4$- or $^1/_3$-cup increments, tablespoons in whole number of tablespoons for quantities less than $^1/_4$ cup but greater than or equal to 2 tablespoons (tbsp), 1, $1^1/_3$, $1^1/_2$, or $1^2/_3$ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in $^1/_4$-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term "about" (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., wing, slice, link, or patty).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit. The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401, including those that have been previously frozen.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401 and products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) The serving size for meal-type products and main-dish products as defined in § 381.413(l) and § 381.413 (m) in single-serve containers will be the entire edible content of the package. Serving size for meal-type products and main-dish products in multi-serve containers will be based on the reference amount applicable to the product in § 381.412(b) if the product is listed in § 381.412(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in § 381.412(b) will be based on the reference amount according to § 381.412(c), (d), and (e).

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 381.409(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, "Energy Value of Foods —Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the "Energy Value of Foods—Basis and Derivation," Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC, or

be indented and expressed as grams per serving to the nearest 0.5 ($^1/_2$)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for "fat free," label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 ($^1/_2$)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.).

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed

go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250-3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of _____ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1.0 gram
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B_6, 2.0 milligrams

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading "Nutrition Facts," the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount Per Serving," and "% Daily Value*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section or on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value*"), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column heading "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

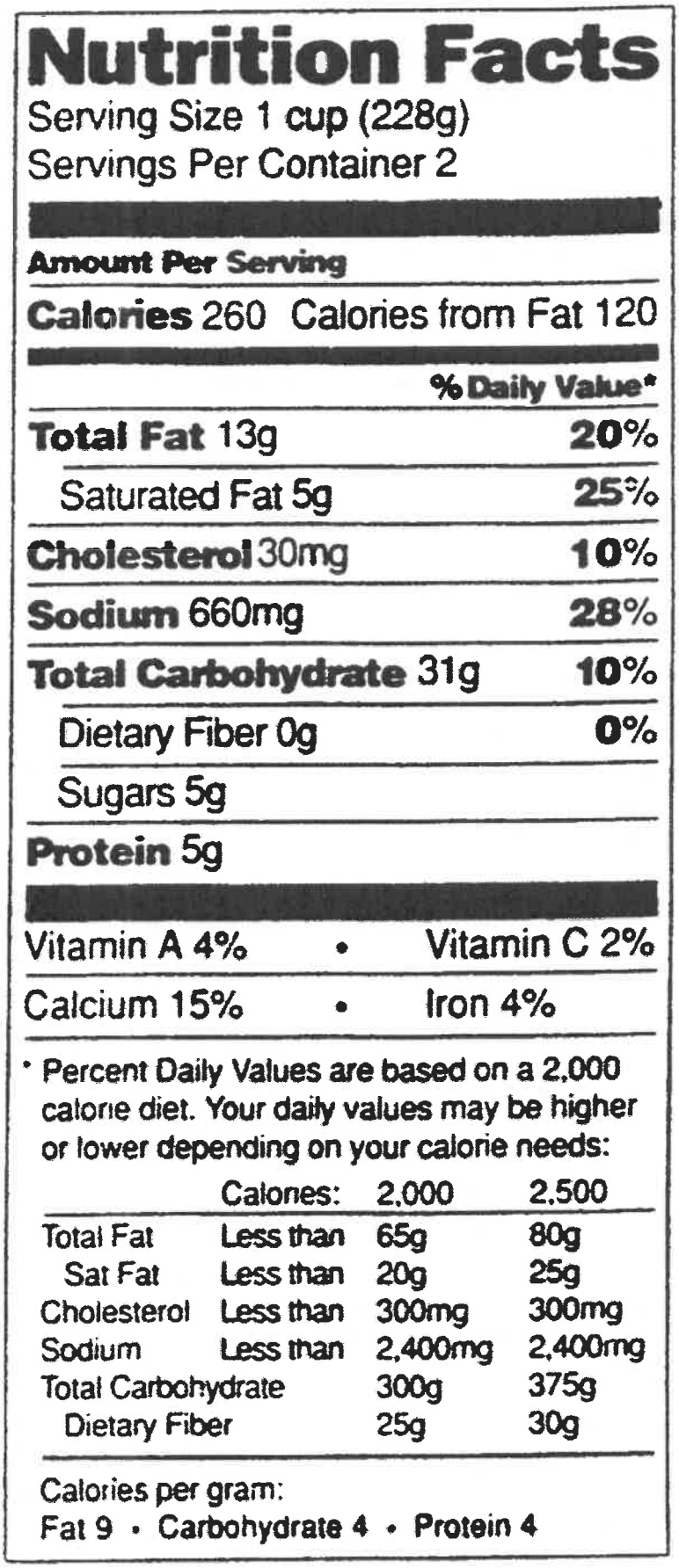
(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 381.500(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount

right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(4) Presenting the required information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 381.409(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The "Official Methods of Analysis" is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

Table 1—Reference Amounts Customarily Consumed per Eating Occasion—Infant and Toddler Foods [1 2 3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain poultry and poultry sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

Table 2—Reference Amounts Customarily Consumed per Eating Occasion—General Food Supply [1 2 3 4 5]

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry)	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	1/4 cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry		
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	1/4 cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977-78 and the 1987-88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.

[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., poultry lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:
(i) A statement of the objective of the labeling application;
(ii) A description of the product;
(iii) A complete sample product label including nutrition label, using the format established by regulation;
(iv) A description of the form in which the product will be marketed;
(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);
(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;
(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);
(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);
(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.
(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.
(A) In expressing the Reference Amount in grams, the following general rules shall be followed:
(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.
(2) For quantities less than 10 grams, exact gram weights shall be used.
(B) [Reserved]
(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:
(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.
(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.
(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.
(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.
(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.
(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.
(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.
(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.
Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart Y of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(c) Information that is required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than $^{1}/_{16}$-inch minimum height, except as permitted by § 381.500(d)(2).

(e)

(1) Because the use of a "free" or "low" claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., "low sodium chicken noodle soup").

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., "chicken breast meat, a low sodium food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 381.413, 381.454, 381.456, 381.460, 381.461, 381.462, and 381.480, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than $^{1}/_{16}$ inch in height, except as permitted by § 381.500(d)(2).

(h) [Reserved]

quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than $^{1}/_{16}$-inch minimum height, except as permitted by § 381.500(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a "low" claim for that nutrient.

(k) The term "modified" may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "modified fat 'product' "). This statement of identity must be immediately followed by the comparative statement such as "contains 35 percent less fat than 'reference product' " The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal-type" product will be defined as a product that:

(1) Makes a major contribution to the diet by:

(i) Weighing at least 10 ounces per labeled serving; and

(ii) Containing not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (l)(1)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entrèe. Such representations may be made by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main-dish" product will be defined as a food that:

(1) Makes a major contribution to the meal by:

(i) Weighing at least 6 ounces per labeled serving; and

(ii) Containing not less than 40 grams of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (m)(1)lii)(E) of this section.

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

§ 381.445 Nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped products described in § 381.401.

(a)

(1) Nutrition information on the major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 381.500. If nutrition information is presented on the label, it must be provided in accordance with the provisions of § 381.409. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 381.409.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 381.409 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 381.409 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 381.409(c)(8)) and footnote required by § 381.409(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 381.409(f).

(d) The nutrition label data for products covered in paragraphs (a)(1) and (a)(2) must be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and for products covered in paragraphs (a)(1) and (a)(2) must be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(f) If the nutrition information is provided in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 209, Jan. 3, 1995; 75 FR 82166, Dec. 29, 2010]

§§ 381.446-381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source," "high," and "more."

serving").

(2) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' "), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or in a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz").

[60 FR 210, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite."

(a) ***General requirements.*** A claim using the terms "light" or "lite" to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) ***"Light" claims.*** The terms "light" or "lite" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 381.413(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third ($33^{1}/_{3}$ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 381.413(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 381.413(j)(1); and

(3) As required in § 381.413(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., "$^{1}/_{3}$ fewer calories and 50 percent less fat than the market leader"); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving"); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(3) The terms "light" or "lite" may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms "light" or "lite" may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by $^1/_3$ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., "light in color" or "light in texture") so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., "color" or "texture") is in the same style, color, and at least one-half the type size as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term "lightly salted" may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 381.413(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not "low in sodium" as defined in § 381.461(b)(4), the statement "not a low sodium food," shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 381.413(j)(2).

[60 FR 210, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§§ 381.457-381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

(a) ***General requirements.*** A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) ***Calorie content claims.***

(1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(c) ***Sugar content claims.***

(1) Terms such as "sugar free," "free of sugar," "no sugar," "zero sugar," "without sugar," "sugarless," "trivial source of sugar," "negligible source of sugar," or "dietarily insignificant source of sugar" may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., "sugar free," or "no sugar," as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 381.409(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar;" and

(iii)

(A) It is labeled "low calorie" or "reduced calorie" or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie product," "not a low calorie product," or "not for weight control."

(2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used only if:

(i) No amount of sugars, as defined in § 381.409(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not "low calorie" or "calorie reduced" (unless the product meets the requirements for a "low" or "reduced calorie" product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms "reduced sugar," "reduced in sugar," "sugar reduced," "less sugar," "lower sugar," or "lower in sugar" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 318.413(m), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "this product contains 25 percent less sugar than our regular product"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sugar content has been lowered from 8 g to 6 g per serving").

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms "low sodium," "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)

(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms "reduced sodium," "reduced in sodium," "sodium reduced," "less sodium," "lower sodium," or "lower in sodium" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(l); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product', 50 percent less sodium than regular 'product' "); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been lowered from 300 to 150 mg per serving").

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low sodium."

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 381.413(j)(l); and

(ii) As required in § 381.413(j)(2) for relative claims:

(i)

(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat," "reduced in fat," "fat reduced," "less fat," "lower fat," or "lower in fat" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat—50 percent less fat than our regular 'product' "); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fat content has been reduced from 8 g to 4 g per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low fat."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' "); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., "fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz").

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low fat."

(6) The term "_____ percent fat free" may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section;

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced saturated fat 'product', 50 percent less saturated fat than our regular 'product' "); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz").

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low saturated fat."

(d) ***Cholesterol content claims.***

(1) The terms "cholesterol free," "free of cholesterol," "zero cholesterol," "without cholesterol," "no cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," or "dietarily insignificant source of cholesterol" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol";

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., "cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' "); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "contains no cholesterol compared with 30 mg in one serving of 'reference product' ").

(2) The terms "low in cholesterol," "low cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," or "little cholesterol" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)

(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "25% less cholesterol than 'reference product' "); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low cholesterol."

(e) ***"Lean" and "Extra Lean" claims.***

(1) The term "lean" may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m).

(2) The term "extra lean" may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m).

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped poultry products described in § 381.401 when the product does not meet the criteria for "low fat," defined in § 381.462(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background, as the statement of the lean percentage.

[60 FR 214, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004; 75 FR 82167, Dec. 29, 2010]

§ 381.463 Nutrient content claims for "healthy."

(a) The term "healthy," or any other derivative of the term "health," may be used on the labeling of any poultry product, provided that the product is labeled in accordance with § 381.409 and § 381.413.

(b)

(1) The product shall meet the requirements for "low fat" and "low saturated fat," as defined in § 381.462, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for "extra lean" in § 381.462.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 381.413(m), and meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for "extra lean" in § 381.462.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)

(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____
(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____
(Indicate authority)

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)

(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____

(Date)

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583-0088.)

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

§§ 381.470-381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) ***General requirements.*** Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) ***Nonnutritive ingredients.***

(1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) ***"Low calorie" foods.*** A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 381.460.

(d) ***"Reduced calorie" foods and other comparative claims.*** A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).

(e) ***"Label terms suggesting usefulness as low calorie or reduced calorie foods".***

(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the product is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., "for low sodium diets."

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to multi-ingredient ground or chopped poultry products described in § 381.401 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1); and

(iii) Products that are ground or chopped at an individual customer's request.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)

(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading "Percent Daily Value" required in § 381.409(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading "Percent Daily Value"; and

(v) Such labeling shall not include the footnote specified in § 381.409(d)(9).

(d)

(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information call 1-800-123-4567").

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of $^{1}/_{16}$-inch minimum height, except that individual serving-size packages of poultry products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than $^{1}/_{32}$-inch minimum height.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995; 75 FR 82167, Dec. 29, 2010; 76 FR 76891, Dec. 9, 2011]

Subpart Z—Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products

Source: 76 FR 24756, May 2, 2011, unless otherwise noted.

§ 381.511 Definitions.

Cooperative interstate shipment program. A cooperative poultry products inspection program described in § 381.187 of this part.

Cooperative State poultry products inspection program. A cooperative State-Federal poultry products inspection program described in § 381.185 of this part.

Designated personnel. State inspection personnel that have been trained in the enforcement of the Act and any additional State program requirements in order to provide inspection services to selected establishments.

Interstate commerce. "Interstate commerce" has the same meaning as "commerce" under § 381.1 of this part.

(8) Establishments located in States without a cooperative State poultry products inspection program; and

(9) Establishments located in a State whose agreement for a cooperative interstate shipment program was terminated by the Administrator as provided in § 381.187(d) of this part.

(d) An establishment that meets the conditions in paragraph (a) of this section and that is not an ineligible establishment under paragraph (c) of this section may apply for selection into a cooperative interstate shipment program through the State in which the establishment is located.

[76 FR 24756, May 2, 2011, as amended at 76 FR 81360, Dec. 28, 2011]

§ 381.514 State request for cooperative agreement.

(a) State participation in a cooperative interstate shipment program under this subpart is limited to States that have implemented cooperative State poultry products inspection programs.

(b) To request an agreement for a cooperative interstate shipment program under this subpart, a State must submit a written request to the Administrator through the FSIS District Office for the FSIS District in which the State is located. In the request the State must:

(1) Identify establishments in the State that have requested to be selected for the program that the State recommends for initial selection into the program, if any;

(2) Demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program established under this subpart; and

(3) Agree that, if the State enters into an agreement with FSIS for a cooperative interstate shipment program, the State will:

(i) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;

(ii) Notify the selected establishment coordinator for the State of the results of any laboratory analyses that indicate that a product prepared in a selected establishment may be adulterated or may otherwise present a food safety concern; and

(iii) When necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments.

(c) If the Administrator determines that a State that has submitted a request to participate in a cooperative interstate shipment program qualifies to enter into a cooperative agreement for such a program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments located in the State.

(d) After the Administrator and a State have signed an agreement for a cooperative interstate shipment program as provided in paragraph (c) of this section, the Administrator will:

(1) Appoint an FSIS employee as the FSIS selected establishment coordinator for the State and

(2) Coordinate with the State to select establishments to participate in the program as provided in § 381.515(b) of this subpart.

§ 381.515 Establishment selection; official number for selected establishments.

(a) An establishment operating under a cooperative State poultry products inspection program will qualify for selection into a cooperative interstate shipment program if the establishment:

(1) Has submitted a request to the State to be selected for the program;

(2) Has the appropriate number of employees under § 381.513(a) of this subpart;

(3) Is not ineligible to participate in a cooperative interstate shipment program under § 381.513(c) of this subpart;

(4) Is in compliance with all requirements under the cooperative State poultry products inspection program; and

corrective action plan, or the selected establishment coordinator for the State determines that the corrective action plan is inadequate, the Administrator will terminate the agreement for the cooperative interstate shipment program as provided in § 381.187(d) of this part.

§ 381.518 Quarterly reports.

(a) The selected establishment coordinator will prepare a report on a quarterly basis that describes the status of each selected establishment under his or her jurisdiction.

(b) The quarterly report required in paragraph (a) of this section will:

(1) Include the selected establishment coordinator's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and

(2) Identify those selected establishment that the selected establishment coordinator has verified are in compliance with the Act and implementing regulations in this chapter, those that have been deselected under § 381.520 of this subpart, and those that are transitioning to become official establishments under § 381.521 of this subpart.

(c) The selected establishment coordinator is to submit the quarterly report to the Administrator through the District Manager for the State where the selected establishments identified in the report are located.

§ 381.519 Enforcement authority.

(a) To facilitate oversight and enforcement of this subpart, selected establishments operating under a cooperative interstate shipment program must, upon request, give the FSIS selected establishment coordinator or other FSIS officials access to all establishment records required under the Act and the implementing regulations in this chapter. The Administrator may deselect any selected establishment that refuses to comply with this paragraph.

(b) Selected establishment coordinators may initiate any appropriate enforcement action provided for in part 500 of this chapter if they determine that a selected establishment under their jurisdiction is operating in manner that is inconsistent with the Act and the implementing regulations in this chapter. Selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 of this chapter.

(c) If inspection at a selected establishment is suspended for any of the reasons specified in § 500.3 or § 500.4 of this chapter, FSIS will:

(1) Provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or

(2) Move to deselect the establishment as provided in § 381.520 of this subpart.

(d) The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis. In making this decision, FSIS, in consultation with the State where the selected establishment is located, will consider, among other factors:

(1) The non-compliance that led to the suspension;

(2) The selected establishment's compliance history; and

(3) The corrective actions proposed by the selected establishment.

§ 381.520 Deselection of ineligible establishments.

(a) The Administrator will deselect a selected establishment that becomes ineligible to participate in a cooperative interstate shipment program for any reason listed under § 381.513(c) of this subpart.

(b) An establishment that has been deselected must transition to become an official establishment as provided in § 381.521 of this subpart.

§ 381.521 Transition to official establishment.

(a) If an establishment is deselected from a cooperative interstate shipment program as provided in § 381.520 of this subpart, FSIS, in coordination with the State where the establishment is located, will develop and implement a plan to transition the establishment to become an official establishment. Except that an establishment that was deselected from a cooperative