

§ 381.1

- 381.303 Critical factors and the application of the process schedule.
- 381.304 Operations in the thermal processing area.
- 381.305 Equipment and procedures for heat processing systems.
- 381.306 Processing and production records.
- 381.307 Record review and maintenance.
- 381.308 Deviations in processing.
- 381.309 Finished product inspection.
- 381.310 Personnel and training.
- 381.311 Recall procedure.

Subpart Y—Nutrition Labeling

- 381.400 Nutrition labeling of poultry products.
- 381.401 [Reserved]
- 381.402 Location of nutrition information.
- 381.403–381.407 [Reserved]
- 381.408 Labeling of poultry products with number of servings.
- 381.409 Nutrition label content.
- 381.410–381.411 [Reserved]
- 381.412 Reference amounts customarily consumed per eating occasion.
- 381.413 Nutrient content claims; general principles.
- 381.414–381.442 [Reserved]
- 381.443 Significant participation for voluntary nutrition labeling.
- 381.444 Identification of major cuts of poultry products.
- 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
- 381.446–381.453 [Reserved]
- 381.454 Nutrient content claims for “good source,” “high,” and “more”.
- 381.455 [Reserved]
- 381.456 Nutrient content claims for “light” or “lite”.
- 381.457–381.459 [Reserved]
- 381.460 Nutrient content claims for calorie content.
- 381.461 Nutrient content claims for the sodium content.
- 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.
- 381.463 Nutrient content claims for “healthy.”
- 381.464–381.468 [Reserved]
- 381.469 Labeling applications for nutrient content claims.
- 381.470–381.479 [Reserved]
- 381.480 Label statements relating to usefulness in reducing or maintaining body weight.
- 381.481–381.499 [Reserved]
- 381.500 Exemption from nutrition labeling.

AUTHORITY: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

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9 CFR Ch. III (1–1–10 Edition)

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.

Capable of use as human food. The term "capable of use as human food" applies to any carcass, or part or product of a carcass of any poultry, unless it is denatured or otherwise identified as required by the regulations, or it is naturally inedible by humans.

Carcass. This term means all parts, including viscera, of any slaughtered poultry.

Commerce. "Commerce" means commerce between any State, any territory, or the District of Columbia, and any place outside thereof; or within any territory not organized with a legislative body, or the District of Columbia.

Consumer package. "Consumer package" means any container in which a poultry product is enclosed for the purpose of display and sale to household consumers.

Container. The term "container" includes any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Edible. This term means that an article is intended for use as human food.

Egg Products Inspection Act. "Egg Products Inspection Act" means the Act so entitled, approved December 29, 1970 (84 Stat. 1620, 21 U.S.C. 1031 et seq.).

Federal Food, Drug, and Cosmetic Act. "Federal Food, Drug, and Cosmetic Act" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and acts amendatory thereof or supplementary thereto (21 U.S.C. 301 et seq.).

Federal Meat Inspection Act. "Federal Meat Inspection Act" means the Act so

§ 381.1

9 CFR Ch. III (1–1–10 Edition)

entitled, approved March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act, 81 Stat. 584 (21 U.S.C. 601 et seq.).

Free from protruding pinfeathers. “Free from protruding pinfeathers” means that the carcass is free from protruding pinfeathers which are visible to an inspector during an examination of the carcass at normal operating speeds. However, a carcass may be considered as being free from protruding pinfeathers if it has a generally clean appearance (especially on the breast), and if not more than an occasional protruding pinfeather is in evidence during a more careful examination of the carcass.

Giblets. “Giblets” means the liver from which the bile sac has been removed, the heart from which the pericardial sac has been removed, and the gizzard from which the lining and contents have been removed: *Provided*, That each such organ has been properly trimmed and washed.

Immediate container. “Immediate container” includes any consumer package; or any other container in which poultry products, not consumer packaged, are packed.

Inedible. This term means any carcass or any part of a carcass that is either naturally inedible by humans or is rendered unfit for human food by reason of adulteration or denaturing.

Inspected for wholesomeness. This term means that the poultry product so identified has been inspected and was found at the time of such inspection to be not adulterated.

Inspection. “Inspection” means any inspection required by the regulations to determine whether any poultry or poultry products comply with the requirements of the Act and the regulations.

Label. This term applies to any display of written, printed, or graphic matter upon any article or the immediate container (not including package liners) of any article.

Labeling. This term applies to all labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers, or (ii) accompanying such article.

Misbranded. This term applies to any poultry product under one or more of the following circumstances:

(i) If its labeling is false or misleading in any particular;

(ii) If it is offered for sale under the name of another food;

(iii) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and immediately thereafter, the name of the food imitated;

(iv) If its container is so made, formed, or filled as to be misleading;

(v) If in a package or other container, unless it bears a label showing:

(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 sub-

part 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 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.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for poultry products.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for the purposes of the Act and the regulations as under the Federal Food, Drug, and Cosmetic Act.

Poultry. “Poultry” means any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead.

Poultry product. (i) This term means any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15. Except where the context requires otherwise (e.g., in paragraph (b)(42) of this section), this term is limited to articles capable of use as human food.

(ii) *Poultry food product.* This term means any product capable of use as human food which is made in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15.

Poultry products broker. “Poultry products broker” means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of such articles other than for his

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

§ 381.1

9 CFR Ch. III (1–1–10 Edition)

own account or as an employee of another person.

Process. Process used as a verb means to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed. The term “process” does not refer to freezing of poultry products, except when freezing is incidental to operations otherwise classed as “processing” under this paragraph.

Process authority. A person or organization with expert knowledge in poultry production process control and relevant regulations.

Process schedule. A written description of processing procedures, consisting of any number of specific, distinct, and ordered operations directly under control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

Ready-to-cook poultry. “Ready-to-cook poultry” means any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down), from which the head, feet, crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without the giblets, and which is suitable for cooking without need of further processing. Ready-to-cook poultry also means any cut-up or disjointed portion of poultry or other parts of poultry, such as reproductive organs, head, or feet that are suitable for cooking without need of further processing.

Regulations. “Regulations” means the provisions of this entire part.

Renderer. “Renderer” means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption pursuant to the regulations.

Shipping container. “Shipping container” means any container used or intended for use in packaging the product packed in an immediate container.

Slaughter. “Slaughter” means the act of killing poultry for human food.

State. Except as otherwise provided in § 381.220 “State” means any State of the United States and the Commonwealth of Puerto Rico.

Supervision. This term means the controls, as prescribed in instructions to Inspection Service employees, to be exercised by them over particular operations to insure that such operations are conducted in compliance with the Act and the regulations in this part.

Territory. The term “territory” means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

United States. This term means the States, the District of Columbia, and the territories of the United States.

U.S. Condemned. This term means that the poultry carcass, or part or product of a poultry carcass, so identified was inspected and found to be adulterated and is condemned.

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 by-product” 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]

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 Ad-

ministrator 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

(C) Commitment to correcting deficiencies noted by Inspection Service employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

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

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter and evisceration operations