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therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(c) *For miscellaneous reasons.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person, without a hearing, by the official in charge of the appropriate regional office, with the concurrence of the Regional Director (1) for administrative reasons such as the nonavailability of personnel to perform the service; (2) for the failure to pay for service; (3) in case the application or request relates to birds or products which are not eligible for service under this part 362; or (4) in case the person is a partnership, corporation, or other person from whom the benefits of the service are currently being withheld under paragraph (a) of this section. Notice of such rejection, denial, or withdrawal, and the reasons therefor, shall promptly be given to the person involved. The operator or applicant of such plant shall be notified of such decisions to reject an application or request for service or to deny or withdraw the benefits of the service, and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. Such decision shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the person making such decision shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(d) *Scope and applicability of rules of practice.* The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 362).

[41 FR 23715, June 11, 1976, as amended at 43 FR 11148, Mar. 17, 1978]

§ 362.5 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the services and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

[41 FR 23715, June 11, 1976, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

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

Administrator. ''Administrator'' means the Administrator of the Food Safety and Inspection Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

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.

Circuit supervisor. This term refers to the official of the Inspection Service who is assigned responsibility for supervising the conduct of inspection at a specific group of official establishments.

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.

Department. ''Department'' means the United States Department of Agriculture.

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 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.

Import Field Office (IFO). The office of the supervisor of import inspection activities for a particular importing field area. The areas are as follows:

IFO #1. Boston, MA—Covering the States of Massachusetts, New York (excluding New York City), Connecticut, Rhode Island, Vermont, New Hampshire, and Maine.

IFO #2. New York, NY—Covering the areas of New York City and northern New Jersey.

IFO #3. Philadelphia, PA—Covering the State of Pennsylvania and the area of southern New Jersey.

IFO #4. Baltimore, MD—Covering the States of Maryland, Delaware, West Virginia, Virginia and Kentucky.

IFO #5. Charleston, SC—Covering the States of Tennessee, North Carolina, South Carolina, Georgia, and Florida (excluding south Florida).

IFO #6. Miami, FL—Covering the areas of southern Florida, Puerto Rico and the Virgin Islands.

IFO #7. New Orleans, LA—Covering the States of Louisiana, Mississippi, Alabama, Arkansas, Texas, Oklahoma, Kansas, New Mexico and Colorado.

IFO #8. San Pedro, CA—Covering the States of Hawaii, Arizona, Utah, Nevada, the area of southern California, American Samoa, Guam, and the Northern Marianas.

IFO #9. Tacoma, WA—Covering the States of Washington, Oregon, Idaho, Montana, Wyoming, North Dakota, South Dakota, Alaska, and Nebraska, and the area of northern California.

IFO #10. Detroit, MI—Covering the States of Michigan, Wisconsin, Minnesota, Iowa, Missouri, Illinois, Indiana and Ohio.

Import Supervisor. The official in charge of import inspection activities within each of the import field offices.

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.

Inspection Service. ''Inspection Service'' means the organizational unit

within the Department having the responsibility for carrying out the provisions of the Act.

Inspection Service employee. This term refers to any employee of the Inspection Service who is authorized to perform any function under the regulations.

Inspection Service supervisor. This term refers to any employee of the Inspection Service who is delegated authority to exercise supervision over certain phases of the inspection program at a designated level.[1]

Inspector. ''Inspector'' means (*a*) an employee or official of the U.S. Government authorized by the Administrator to inspect poultry and poultry products under the authority of this Act, or (*b*) any employee or official of the government of any State or Territory or the District of Columbia authorized by the Administrator to inspect poultry and poultry products under the authority of this Act, under an agreement entered into between the Administrator and the appropriate State or other agency.

Inspector in Charge. This term means the inspector primarily responsible for the conduct of inspection at any particular official establishment.

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:

[1] Information identifying the employees who have been delegated such authority at various levels may be obtained from an inspector or from the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

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

(*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 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, or guineas), 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 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, vestigial feathers (hair or down as the case may be) and from which the head, feet, crop, oil gland, trachea, esophagus, entrails, mature reproductive organs, and lungs have been removed, and in the case of certain mature poultry, as defined in §381.170(a)(1)(vi), (vii) and (2)(iv), the kidneys have been removed in accordance with the requirements of §381.65(d), 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.

Secretary. ''Secretary'' means the Secretary of Agriculture of the United States or his delegate.

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 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]

Subpart B—Administration; Application of Inspection and Other Requirements

§ 381.3 Administration.

(a) General authority to administer the Act has been delegated to the Administrator (29 FR 16210, as amended; 37 FR 6327, 6505).

(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

(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 also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Federal Meat Inspection Act also are processed at such establishment, and

(vi) The size of such establishment.

(e)(1) For the period of experimentation described in paragraph (c) of

this section, the frequency of inspection by Inspection Service employees of operations other than slaughter and evisceration may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (d)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (d)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Inspection Service employees.

(ii) To the extent that frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this part, the Administrator will waive such provisions for the period of experimentation, in accordance with paragraph (b) of this section.

[37 FR 9706, May 16, 1972, as amended at 52 FR 10033, Mar. 30, 1987]

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

§ 381.4 Inspection in accordance with methods prescribed or approved.

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

§ 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 in § 381.221 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.

§ 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 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 owner's name and address and the statement ''Exempted—P.L. 90–492.''

(5) The slaughtering of sound and healthy poultry and processing of poultry products therefrom in any State or territory or the District of Columbia by any poultry producer on his own premises with respect to poultry raised on his premises, and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations: *Provided,* That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when so distributed; (ii) such poultry products when so distributed, bear (in lieu of labeling that would otherwise be required) the producer's name and address and the

statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such producer and distributor do not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (5) or (6) of this section; and (iv) neither such producer or distributor slaughters or processes the products of more poultry than allowed by paragraph (b) of this section.

(6) The slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boardinghouses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers: *Provided*, That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when distributed by such processor; (ii) such poultry products when so distributed bear (in lieu of labeling that would otherwise be required) the processor's name and address and the statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such processor does not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (6) or (5) of this section; and (iv) such processor does not exceed the volume limitation prescribed in paragraph (b) of this section.

(7) The operations and products of small enterprises (including poultry producers) not exempted under paragraphs (a) (1) through (6) of this section that are engaged in any State or territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction; *Provided*, That (i) such poultry is sound and healthy when slaughtered and is slaughtered and/or cut up and handled under such sanitary standards, practices and procedures as result in the preparation of poultry products that are not adulterated when so distributed; and (ii) when so distributed, such poultry products are not misbranded (except that the official inspection legend shall not be used).

(b) No person qualifies for any exemption specified in paragraph (a)(5), (6), or (7) of this section if, in the current calendar year, such person:

(1) Slaughters or processes the products of more than 20,000 poultry, or

(2) Slaughters or processes poultry products at a facility used for slaughtering or processing poultry products by any other person, except when the Administrator grants such exemption after determining, upon review of a person's application, that such an exemption will not impair effectuating the purposes of the Act.

(c) The provisions of the Act and the regulations do not apply to any poultry producer with respect to poultry, of his own raising on his own farm, which he slaughters if:

(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.

(*c*) For purposes of this paragraph, operations conducted as a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirement of this paragraph: *Provided*, That the requirements of §§ 381.175 through 381.178 of this subchapter apply to such facility. *Provided further*, That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary if the

[1] The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447–3219.

Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its poultry products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) A similar retail-type establishment is any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraph (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) A consumer is any household consumer, hotel, or restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail establishment or restaurant claiming exemption under this paragraph (d) in any designated State or organized territory listed in § 381.221 that is also identified in § 381.224 as a jurisdiction that does not have or is not exercising adequate authority with respect to recordkeeping requirements, has been operated in violation of the conditions prescribed in this paragraph (d) for such exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail establishment or restaurant and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator determines that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail establishment or restaurant would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of his total monthly purchases and of his total monthly sales of poultry and poultry products. Such records shall separately show total sales to household consumers and total sales to other consumers, and shall be maintained for the period prescribed in § 381.177. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(4) The adulteration and misbranding provisions of the Act and the regulations other than the requirement of the official inspection legend, apply to articles which are exempted from inspection under this paragraph (d).

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to poultry pizzas containing poultry product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the poultry pizzas are to be served in public or private nonprofit institutions, provided that the poultry pizzas are ready to eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102 (a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, Part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference,

shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist 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 Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, Suite 700, 800 North Capitol Street, NW., Washington, DC, or the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

(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 ½ 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.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair. Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A ¼-inch IPS valve shall be provided immediately upstream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ±3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: Provided, That,

(*1*) The temperature of the wash water shall not be less than 120 °F.

(*2*) The wash water shall be kept clean.

(*3*) Chemicals added for sanitization purposes shall be automatically dispensed.

(*4*) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(*5*) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(*6*) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(*7*) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(*1*) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature	150 °F
Final rinse temperature	180 °F

(*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

(I) 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]

§ 381.11 Exemptions based on religious dietary laws.

(a) Any person who slaughters, processes, or otherwise handles poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws may apply for exemption from specific provisions of the Act or regulations which are in conflict with such religious dietary laws. Any person desiring such an exemption shall apply in writing to the Meat and Poultry Inspection Program, Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250, setting forth the specific provisions of the Act and the regulations from which exemption is sought and setting forth the provisions of the religious dietary laws in support of the requested exemption. In addition, the applicant for such an exemption shall submit a statement from the clerical official having jurisdiction over the enforcement of the religious dietary laws with respect to the poultry or poultry products involved, which identifies the requirements of such laws pertaining to the slaughter of the poultry and the processing or other handling of the poultry products involved, and certifies that such requirements are in conflict with specific provisions of the Act and regulations from which the exemption is sought.

(b) The Administrator, upon a determination that an exemption should be granted, will grant such exemption to the extent necessary to avoid conflict with the religious requirements while still effectuating the purposes of the Act. He may impose such conditions as to sanitary standards, practices, and procedures in granting such exemption as he deems necessary to effectuate the purposes of the Act. Any person who processes poultry or poultry products under exemption from certain requirements as provided in this section shall be subject to all of the other applicable provisions of the Act and the regulations. Processing plants shall meet the sanitary requirements set forth in this part and unless exempted from inspection under the provisions of this subpart, shall be required to qualify for inspection and operate as official establishments. Slaughtered poultry which is prepared under an exemption authorizing the sale of noneviscerated poultry in commerce shall be individually identified with a label approved by the Administrator which identifies the clerical official under whose supervision the poultry was slaughtered.

§ 381.12 Effect of religious dietary laws exemptions on other persons.

Whenever a slaughterer or processor is granted an exemption under § 381.11 with respect to the slaughtering or processing of any poultry or poultry products under this part, under specified conditions, the sale, offer for sale, transportation and other handling in commerce by any person of such poultry and poultry products in accordance with such conditions is hereby authorized, except as restricted by the Act.

§ 381.13 Suspension or termination of exemptions.

(a) The Administrator may, by order, in accordance with the applicable rules of practice suspend or terminate any exemption under § 381.10(a) with respect to any person whenever he finds that such action will aid in effectuating the purposes of the Act. Failure to comply with the conditions of the exemption, including, but not limited to, failure to process poultry and poultry products under clean and sanitary conditions may result in termination of an exemption, in addition to any other penalties provided by law.

(b) Except as provided in § 381.10(c), the Administrator may extend the requirements of the Act to any establishment in any State or organized territory at which poultry products are processed for distribution solely within such jurisdiction if he determines in accordance with the provisions of subparagraph 5(c)(1) of the Act that the establishment is producing adulterated

poultry products which would clearly endanger the public health.

§ 381.14 Inspection concerning purportedly exempted operations.

Inspectors of the Inspection Service are authorized to make inspections in accordance with law to ascertain whether any of the provisions of the Act or the regulations applying to producers, retailers, or other persons purporting to be exempted from any requirements under this subpart have been violated.

§ 381.15 Exemption from definition of "poultry product" of certain human food products containing poultry.

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.

Every application for inspection at any establishment shall be made by the operator on a form furnished by the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and shall include all information called for by that form, including the name of any subsidiary corporation that will prepare any poultry product or conduct any other operation at the establishment for which inspection is requested. The applicant for inspection will be held responsible for compliance by all its subsidiaries with the requirements of the regulations at such establishments if inspection is granted. Processing of poultry products and other operations at the establishment for which inspection is granted may be conducted only by the applicant, except that such a subsidiary of the grantee, may conduct such operations at such establishment.

§ 381.18 Authority of applicant.

Any person applying for inspection service may be required at the discretion of the Administrator to demonstrate that the operator of the establishment authorized him to do so.

§ 381.20 Survey and grant of inspection.

(a) Before inspection is granted, FSIS shall survey the establishment to determine if the construction and facilities of the establishment are in accordance with the regulations. FSIS will grant inspection, subject to § 381.21, when these requirements are met.

(b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

[62 FR 45026, Aug. 25, 1997]

§ 381.21 Refusal of inspection.

(a) Any application for inspection in accordance with this part may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(b)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters of the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended, to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within 1 year after receipt of such request. Further, upon receipt of an application for inspection and a certification as required by subsection 21(b) of the Federal Water Pollution Control Act, the Administrator (as defined in § 381.1) is required by paragraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that paragraph. No grant of inspection can be made until the requirements of said paragraph (2) have been met.

(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although

certification for such facilities is required to be obtained within the 3–year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

[37 FR 9706, May 16, 1972, as amended at 64 FR 66545, Nov. 29, 1999]

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, in accordance with part 416 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]

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.

Any duly authorized representative of the Secretary shall have access at all reasonable times, by day or night, whether the establishment is in operation or not, to the premises or any part thereof of an establishment engaged in processing poultry or poultry products for commerce, upon presentation of appropriate credentials.

§ 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. This badge shall be sufficient identification to entitle the inspector to admittance at all regular entrances and to all parts of the establishment and premises to which the inspector is assigned.

[59 FR 42156, Aug. 17, 1994]

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

[48 FR 11419, Mar. 18, 1983, as amended at 60 FR 67456, Dec. 29, 1995]

Subpart G—Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) *Inspector's Office*. Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the

official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) *Facilities for ante mortem inspection*. Batteries, coops, or other facilities in which live poultry is presented for ante mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out an adequate inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in § 381.76(b) also apply.

(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 (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or ''kickouts'' shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspection. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall 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 shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-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 the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid splashing the mirror (paragraph (d)(1)(vii) of this section) and swinging when entering the inspection station. Guide bars shall not extend in front of the inspection station mirror to avoid obstructing the inspector's view.

(iv) Each inspector's station shall have an easily and rapidly adjustable platform, with a minimum of 14 inches of vertical adjustment, which covers the entire length of the station (4 feet) and has a minimum width of 2 feet. The platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions.

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

(vi) A trough 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 distortion-free mirror, at least 3 feet wide and 2 feet high, shall be mounted at each inspection station so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection platform so that the inspector can position himself/herself opposite it 8 to 12 inches from the downstream edge. The mirror must be maintained abrasion free.

(viii) A minimum of 200-footcandles of shadow-free lighting with minimum color rendering index value of 85[1] where the birds are inspected to facilitate inspection. A light shall also be positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surfaces.

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

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

(xi) Each inspection station shall be provided with receptacle 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 6 feet along the conveyor line. 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 3 feet wide and 2 feet deep, shall be provided for reinspecting the sample birds.

(iv) A minimum of 200-footcandles of shows free lighting with a minimum color rendering index of 85[1] on the table surface.

(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 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 the station.

(e) Facilities for the New Turkey Inspection (NTI) System. The following requirements for lines operating under the NTI System are in addition to the normal requirements to obtain a grant of inspection and to the requirements for the NTI System in § 381.76 (b) and (c).

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

(i) The conveyor line must 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 (e)(1)(iii) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 8 feet along the conveyor line; at least 4 feet for the inspector, and at least 4 feet for the establishment helper.

(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 ½-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

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

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.

[37 FR 9706, May 16, 1972, as amended at 38 FR 9794, Apr. 20, 1973; 47 FR 23434, May 28, 1982; 49 FR 42554, Oct. 23, 1984; 50 FR 37512, Sept. 16, 1985; 52 FR 39209, Oct. 21, 1987; 64 FR 56416, Oct. 20, 1999]

§ 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 5½ 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, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic

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

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]

§ 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.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall be the holiday.

[40 FR 45801, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 51513, Dec. 18, 1985; 52 FR 5, Jan. 2, 1987; 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 381.38(a) and at the rate specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45801, Oct. 3, 1975, as amended at 54 FR 6390, Feb. 10, 1989]

Subpart H [Reserved]

Subpart I—Operating Procedures

§ 381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product shall be strictly in accord with clean and sanitary practices and shall be conducted in such a manner as will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Materials which create any condition that may result in adulteration of poultry products shall not be handled or stored in rooms, compartments, or other places in any official establishment where any poultry product is processed, otherwise handled, or stored.

(c) Poultry shall be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and assure that breathing has stopped prior to scalding. Blood from the killing operation shall be confined to a relatively small area.

(d) Kidneys of mature chickens and mature turkeys (poultry defined in § 381.170(a) (1)(vi) and (vii) and (2)(iv)) shall be removed from their carcasses after the inspectors complete their post-mortem inspection of the poultry viscera, but before completion of the eviscerating operations, and shall not be used for human food.

(e) Poultry carcasses contaminated with visible fecal material shall be prevented from entering the chilling tank.

(f)–(g) [Reserved]

(h) Thawing poultry in water:

(1) *Ready-to-cook poultry*. When frozen ready-to-cook poultry is to be thawed in water, the thawing practices and procedures shall be such as will prevent the product from becoming adulterated by the absorption of moisture and such poultry shall be thawed by one of the following methods:

(i) The poultry may be thawed in continuous running tap water of sufficient volume and for such limited time as is necessary to thaw such poultry. The thawing media shall not exceed 70 °F. in temperature. Complete thawing is necessary to permit thorough examination of ready-to-cook poultry prior to any further processing.

(ii) The practice of placing frozen ready-to-cook poultry into cooking kettles, without prior thawing, is permitted only when a representative sample of the entire lot has been thawed and found to be sound and unadulterated. Thawing may be accomplished in cookers where the water can be heated to enable the cooking process to begin immediately following completion of thawing. Thawing practices and procedures shall result in no net gain in weight over the frozen weight. When whole carcasses or parts are thawed for repackaging as parts, it is not acceptable to recool the parts in slush ice. However, they may be held in tanks of crushed ice with the drains open, pending further processing or packaging.

(iii) The poultry may be thawed in recirculated water, maintained at a temperature not in excess of 50 °F., for such limited time as is necessary to thaw such poultry.

(2) [Reserved]

(i) Cuts for the removal of the viscera shall be limited to those necessary for proper processing operations and inspection. With respect to roaster-style evisceration, opening cuts shall be made in such a manner that the skin between the thighs and rib cage will not be cut or torn open during the drawing operation. No additional cuts shall be made prior to chilling other than those necessary to perform the complete evisceration of the bird. The ''bar-cut'' method of evisceration may be used only when permitted by the inspector in charge upon his determination that this method can be used at the official establishment without contaminating the poultry. With respect to poultry that is to be opened by the ''bar-cut'' method, particular care shall be exercised in making transverse cuts so that the thigh areas will not be opened and the flesh at the posterior end of the keel will not be exposed. An occasional bird that is unintentionally opened in the aforesaid areas will be permitted. The type of opening cut is part of the chilling procedure and any change in such cut requires establishing a new procedure under § 381.66.

(j) The area at the junction of the neck with the body of the eviscerated bird shall be positively opened prior to final washing so that water will drain freely from the body cavity and not become trapped in the area between the neck skin and the neck.

(k) Ready–to–cook poultry shall be adequately drained after chilling, to remove ice and free water prior to packaging or packing.

(l) Cut–up poultry shall be processed from chilled carcasses and the parts shall not be rechilled in ice and water or water, but may be temporarily held in containers of crushed ice which are continuously drained pending further processing and packaging. Upon approval by the Administrator, and under such conditions as he may prescribe in specific cases, cut-up poultry may be processed from unchilled eviscerated poultry. Such poultry parts shall not be chilled in water and ice, but may be chilled either in ice in continuously drained containers or by immediate entry into a freezer. Such poultry parts shall be chilled as provided in § 381.66(b)(2).

(m) All offal resulting from the evisceration operation shall be removed from the official establishment as often as necessary to prevent the development of an insanitary condition.

(n) Containers to be used for packaging poultry products shall be clean, free from substances and odors that would result in adulteration of the products and of sufficient strength and durability to protect the products adequately during normal distribution.

(o) Paper and other material used for lining barrels or other containers in which poultry products are packed shall be of such kinds as do not tear readily during use but remain intact when moistened by the products. Wooden containers to be used for packing poultry products shall be fully lined except when the poultry products to be packed therein are fully wrapped.

(p) Protective coverings shall be used for poultry products while they are in any official establishment or are being transported between official establishments, which are adequate to protect the products against contamination by any foreign substances (including, but not being limited to, dust, dirt, and insects) considering the means employed in transporting the products.

(q)(1) Detached ova may be collected for human food in the official establishment provided it is done in a sanitary manner: *Provided*, The identity of such ova with the carcass shall be maintained past the point of inspection and ova from condemned carcasses shall likewise be condemned and treated as required in § 381.95: *And provided further*, That ova for human food are cooled, packaged, and otherwise handled so as to be fit for human food.

(2) Detached ova harvested for human food may leave the official establishment only for movement to an egg products processing plant for processing as allowed in § 59.440 of the regulations (7 CFR 59.440) under the Egg Products Inspection Act and when moved from the official establishment shall bear labeling which indicates that the ova were harvested under sanitary supervision of the Inspection Service.

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975; 49 FR 3643, Jan. 30, 1984; 62 FR 5143, Feb. 4, 1997]

§ 381.66 Temperatures and chilling and freezing procedures.

(a) *General*. Temperatures and procedures which are necessary for chilling and freezing ready-to-cook poultry, including all edible portions thereof, shall be in accordance with operating procedures which insure the prompt removal of the animal heat and will preserve the condition and wholesomeness of the poultry and assure that the products are not adulterated. A description of the chilling and freezing procedures used at the official establishment shall be filed with the inspector in charge at the establishment.

(b) *General chilling requirements*. (1) All poultry that is slaughtered and eviscerated in the official establishment shall be chilled immediately after processing so that the internal temperature is reduced to 40 °F. or less, as provided in paragraph (b)(2) of this section unless such poultry is to be frozen or cooked immediately at the official establishment. Eviscerated poultry to be shipped from the establishment in packaged form shall be maintained

at 40 °F. or less, except that during further processing and packaging operations, the internal temperature may rise to a maximum of 55 °F.: *Provided,* That immediately after packaging, the poultry is placed under refrigeration at a temperature that will promptly lower the internal temperature of the product to 40 °F. or less, or the poultry is placed in a freezer. Poultry which is to be held at the plant in packaged form in excess of 24 hours shall be held in a room at a temperature of 36 °F. or less.

(2) Major portions of poultry carcasses, as defined in § 381.170(b)(22), and poultry carcasses shall be chilled to 40 °F. or lower within the following specified times:

Weight of carcass	Time (hours)
Under 4 pounds	4
4 to 8 pounds	6
Over 8 pounds	8

(c) *Ice and water chilling.* (1) Only ice produced from potable water may be used for ice and water chilling. The ice shall be handled and stored in a sanitary manner. If of block type, the ice shall be washed by spraying all surfaces with clean water before crushing.

(2)(i) The temperature of the chilling media in the warmest part of any poultry chilling system shall not exceed 65 °F. or the maximum temperature specified in the current chilling procedure filed as required by paragraph (a) of this section, whichever is less. Continuous chillers shall not be used unless a recording thermometer, with a 24-hour recording cycle, is provided to measure the temperature in the warmest part of the chilling system. The temperature recorder shall be readily accessible. The completed temperature charts shall be furnished daily to the inspector.

(ii) With respect to continuous chilling systems, the fresh water intake in the first section of the system, after all sections of the system are filled with water, shall be not less than one-half gallon per frying chicken and proportionately more for other classes of poultry, including not less than 1 gallon per turkey. Sufficient water or ice, or both, shall be added to sections of the chilling system other than the first section, to keep the chilling media clean and to provide a continuous overflow from each section. If there is no loss of water between sections, multiple section chilling systems may be connected so the overflow from subsequent sections serves as water intake for the first section. In this type of installation, the required minimum fresh water intake may be either in the first or the last section of the chilling system. Water used to fill chilling systems shall not be counted toward minimum requirements specified in this paragraph (c)(2)(ii). Continuous chillers shall not be used unless the required minimum fresh water intake is measured through a meter which gives cumulative readings, and the meter shall be readily accessible. Upon approval by the Administrator in specific cases, when the official establishment employs an acceptable method of determining the amount of ice added to the appropriate section of the chilling system, meltage from such ice may be counted toward the required minimum fresh water intake.

(iii) In continuous chillers, whenever the elevators or conveyors removing the poultry from the chilling units are stopped, the agitation, either mechanical or by air, must also be stopped. In addition, unless the termperature of the chilling media is lowered to and maintained at 40 °F. or below, poultry shall not be left in such stopped chillers in excess of 15 minutes.

(iv) Major portions of poultry carcasses, as defined in § 381.170(b)(22), may be chilled in water and ice, including chilling in continuous chillers. Individual parts, including but not limited to drumsticks, thighs, split halves, and split breasts, shall not be cooled in water and ice, but may be cooled in the air, or ice, or under a spray of water with continuous drainage.

(v) Previously chilled poultry carcasses and major portions shall not be rechilled in ice and water, but may be rechilled with ice in continuously drained containers.

(vi) Any owner or operator of an official establishment desiring to utilize a chilling system which includes water reconditioning may, by submitting the information and data specified in paragraphs (c)(2)(vi) (A) and (B) of this section, request the Administrator to

evaluate the efficacy of the water reconditioning system to determine whether a reduction in fresh water intake requirements will be permitted: *Provided,* That the equipment related to the systems has been approved under § 381.53 of subpart H of this subchapter, that operation of the system results in full compliance with the Act and this subchapter, and that the system permits effective and efficient monitoring. The Administrator shall approve requests in accordance with the following standard:

Minimum Percent reduction of micro-organisms in treated water	Minimum Percent light transmission in treated water	Gallons of reconditioned water to replace one gallon of fresh water
60	60	1.75
70	70	1.50
80	80	1.35
90	80	1.25
98	80	1.10

Requests for approval must include:

(A) Information specifying the equipment, as approved under § 381.53, materials, and conditions of use incident to the system. Items which must be so specified include filters; rate of flow; pressures and/or vacuums required for suitable operation; point of exit from the chilling units of water to be reconditioned; point of entry into the chilling units of the reconditioned water; frequency of filter changes, back-flushing, or other system restoration; post-filter treatment; and any other condition the alteration of which could affect the effectiveness of reconditioning; and

(B) Data demonstrating that reconditioning results in achieving and maintaining throughout the operating shift at least a 60 percent reduction in total micro-organisms, that such reduction relates within ∓10 percentage points to a similar reduction in any *coliforms,*[1] *Esherichia coli*[2] and/or *Salmonella spp.*[3] that may be present; and that light transmission of the treated water is maintained throughout the operating shift at no less than 60 percent of that of the fresh water supply.

(3) Previously chilled poultry carcasses and major portions shall be maintained constantly at 40 °F. or below until removed from the vats or tanks for immediate packaging. Such products may be removed from the vats or tanks prior to being cooled to 40 °F. or below, for freezing or cooling in the official establishment. Such products shall not be packed until after they have been chilled to 40 °F. or below, except when the packaging will be followed immediately by freezing at the official establishment.

(4)(i) In order to facilitate continuous processing operations, poultry carcasses and major parts may be held overnight in chilling tanks containing water-saturated ice, refrigerated water, or other approved cooling media that will maintain all poultry in the tanks at a temperature of 40 °F., or lower. Practices (such as reicing, recirculation of the chilling medium, or holding product in refrigerated rooms, or use of increased amounts of ice) shall be employed that will result in all of the poultry in the chilling tanks being maintained at a temperature of 40 °F. or lower throughout the holding period.

(ii) Poultry which is to be held in chilling tanks in excess of 24 hours shall at the end of the 24-hour chilling period be removed from the tanks and repacked in clean ice and in clean tanks which are continually drained, or as an alternative, the tanks shall be

[1] Five tube most probable number (MPN) following procedures in Microbiology Laboratory Guidebook, FSIS, USDA, January 1974, Section 3.4 using 5 replicate tubes of each dilution; and computed using standard MPN tables.

[2] Five tube most probable number (MPN) using procedure in Microbiology Laboratory Guidebook, FSIS, USDA, January 1974, Section 3.5 using 5 replicate tubes of each dilution; and computed using standard MPN tables.

[3] Most probable number (MPN) per 100 ml by 3 tube MPN. To each of three 100, 10, 1, and 0.1 ml sample portions, an equal volume of double strength lactose broth containng 1.2% Tergitol 7 is added. Then determined by procedure in Microbiology Laboratory Guidebook, FSIS, USDA, January 1974, Section 4.0; and computed using standard MPN tables.

drained and reiced and placed in a cooler which will maintain all of the poultry in the tanks at a temperature at 40 °F. or below.

(5) Giblets shall be chilled to 40 °F. or lower within 2 hours from the time they are removed from the inedible viscera, except that when they are cooled with the carcass, the requirements of paragraph (b)(2) of this section shall apply. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets. When continuous chillers are used to chill giblets or necks, the fresh water intake in the chiller shall be not less than 1 gallon per 40 frying chickens processed, and shall be proportionately increased for other classes of poultry. When necks are chilled together with giblets, the minimum fresh water intake shall be not less than 1 gallon per 20 frying chickens processed and shall be proportionately increased for other classes of poultry. The required minimum fresh water intake in giblet and neck chillers shall be measured through a meter which gives cumulative readings, and the meter shall be readily accessible. In continuous giblet or neck chillers, the temperature of the chilling medium shall not exceed 36 °F. in the warmest part of the system.

(d) *Moisture absorption and retention limits.* (1) Poultry washing, chilling, and draining practices and procedures shall be such as will minimize moisture absorption and retention at time of packaging.

(2) With respect to ready-to-cook poultry that is to be frozen, cooked, or consumer packaged, as whole poultry, the maximum moisture absorption and retention during washing, chilling, and draining processes shall not exceed, at the last readily accessible point at which the poultry carcasses can be selected for testing prior to packaging, the percentage limits set forth in the following tables.

TABLE 1—MAXIMUM MOISTURE ABSORPTION AND RETENTION LIMITS FOR ALL CLASSES OF POULTRY, OTHER THAN TURKEYS, TO BE CONSUMER PACKAGED, FROZEN OR COOKED AS WHOLE POULTRY

Average ready-to-cook carcass weight prior to final washer (less necks and giblets)	Average percent increase in weight over weight of carcass prior to final washer (less necks and giblets)	
	Zone A [1]	Zone B [1]
Chickens 4¼ lbs. and under	8.0	8.7
Chickens over 4¼ lbs. and all other classes of poultry other than turkeys	6.0	6.7

[1] Product shall be retained if, out of five consecutive tests more than one test exceeds the Zone A limits or any test exceeds the Zone B limits. These zone limits were based on a statistical analysis of variation between individual birds with regard to moisture absorption. With these limits the chance of passing a lot with average moisture at or above the Zone A limit is less than 15 percent. A lot with average moisture at or above the Zone B limit would have virtually no chance of passing.

TABLE 2—MAXIMUM MOISTURE ABSORPTION AND RETENTION LIMITS FOR ALL TURKEYS TO BE CONSUMER PACKAGED, FROZEN OR COOKED AS WHOLE POULTRY

Average ready-to-cook carcass weight prior to final washer (less necks and giblets)	Average percent increase in weight over weight of carcass prior to final washer (less necks and giblets)	
	Zone A [1]	Zone B [1]
8 lbs. 8 ozs. and under	8.0	9.0
8 lbs. 9 ozs.–15 lbs. 15 ozs	6.0	6.4
16 lbs.–16 lbs. 15 ozs	5.8	6.05
17 lbs.–17 lbs. 15 ozs	5.5	5.75
18 lbs.–18 lbs. 15 ozs	5.3	5.55
19 lbs.–19 lbs. 15 ozs	5.1	5.35
20 lbs.–20 lbs. 15 ozs	4.9	5.15
21 lbs.–21 lbs. 15 ozs	4.8	5.05
22 lbs.–22 lbs. 15 ozs	4.6	4.85
23 lbs.–23 lbs. 15 ozs	4.5	4.75
24 lbs.–26 lbs. 15 ozs	4.4	4.65
27 lbs. and over	4.3	4.55

[1] Product shall be retained if, out of five consecutive tests more than one test exceeds the Zone A limits or any test exceeds the Zone B limits. These zone limits were based on a statistical analysis of variation between individual birds with regard to moisture absorption. With these limits the chance of passing a lot with average moisture at or above the Zone A limit is less than 15 percent. A lot with average moisture at or above the Zone B limit would have virtually no chance of passing.

(3) With respect to ready-to-cook turkey carcasses that are to be cut up, the maximum amount of moisture absorption and retention shall not exceed (at

the time the first cut is made) the percentage limits set forth in the following table:

TABLE 3—MAXIMUM MOISTURE ABSORPTION AND RETENTION LIMITS FOR ALL CLASSES OF TURKEYS TO BE CUT UP

Average ready-to-cook carcass weight prior to final washer (less necks and giblets)	Average percent increase in weight over weight of carcass prior to final washer (less necks and giblets)	
	Zone A [1]	Zone B [1]
8 lbs. 8 ozs. and under	9.0	10.0
8 lbs. 9 ozs.–15 lbs. 15 ozs	7.0	7.4
16 lbs.–16 lbs. 15 ozs	6.8	7.05
17 lbs.–17 lbs. 15 ozs	6.5	6.75
18 lbs.–18 lbs. 15 ozs	6.3	6.55
19 lbs.–19 lbs. 15 ozs	6.1	6.35
20 lbs.–20 lbs. 15 ozs	5.9	6.15
21 lbs.–21 lbs. 15 ozs	5.8	6.05
22 lbs.–22 lbs. 15 ozs	5.6	5.85
23 lbs.–23 lbs. 15 ozs	5.5	5.75
24 lbs.–26 lbs. 15 ozs	5.4	5.65
27 lbs. and over	5.3	5.55

[1] Product shall be retained if, out of five consecutive tests more than one test exceeds the Zone A limits or any test exceeds the Zone B limits. These zone limits were based on a statistical analysis of variation between individual birds with regard to moisture absorption. With these limits the chance of passing a lot with average moisture at or above the Zone A limit is less than 15 percent. A lot with average moisture at or above the Zone B limit would have virtually no chance of passing.

(4)(i) With respect to ready-to-cook chicken carcasses, averaging 4¼ pounds or less, that are chilled in continuous chillers and further aged or chilled in slush ice and water, prior to being cut up, the maximum amount of moisture absorption and retention shall not exceed (when placed on the cutup line) the percentage limits set forth in the following table:

AVERAGE PERCENT INCREASE IN WEIGHT OVER WEIGHT OF CARCASS PRIOR TO FINAL WASHER (LESS NECKS AND GIBLETS)

Zone A—10.0 [1]
Zone B—11.0 [1]

[1] Product shall be retained if, out of five consecutive tests, more than one test exceeds the Zone A limits or any test exceeds the Zone B limits. These zone limits were based on a statistical analysis of variation between individual birds with regard to moisture absorption. With these limits the chance of passing a lot with average moisture at or above the Zone A limit is less than 15 percent. A lot with average moisture at or above the Zone B limit would have virtually no chance of passing.

(ii) With respect to ready-to-cook chicken carcasses, averaging 4¼ pounds or less, which are chilled in continuous chillers only, prior to being cut up, the percentage limits set forth in paragraph (d)(5) of this section shall apply.

(5) With respect to ready-to-cook poultry other than that under paragraph (d) (3) or (4)(i) of this section that is to be ice packed, the maximum amount of moisture absorption shall not exceed, at the last readily accessible point at which the poultry carcasses can be selected for testing on the drip line, the percentage limits set forth in the following table:

MAXIMUM MOISTURE ABSORPTION AND RETENTION LIMITS FOR ICE PACK POULTRY

AVERAGE PERCENT INCREASE IN WEIGHT OVER WEIGHT OF CARCASS PRIOR TO FINAL WASHER (LESS NECKS AND GIBLETS)

Zone A—12.0 [1]
Zone B—13.0 [1]

(6) With respect to all ice pack poultry, the loss of moisture during holding and transportation to the first destination shall result in moisture retention that is within the limits, applicable to the class of poultry involved, set forth in Zone A of Tables 1 and 2 in paragraph (d)(2) of this section.

(7) Ten-bird tests shall be conducted at least daily by inspectors to assure compliance with the requirements of paragraphs (d) (1) through (5) of this section, using procedures set forth in the Poultry Inspectors' Handbook. The inspectors' 10-bird test will be used to determine such compliance, except as additional 50-bird tests are required under paragraph (d)(8) of this section.

(8) Each official establishment may make adjustments in its washing, chilling, and draining methods provided it submits to the inspector at the establishment, written notice of the proposed adjustments before any changes are made, and provided further, that the operator of the establishment, immediately after the change, selects, prepares, identifies, and weighs, in accordance with procedures set forth in the Poultry Inspectors'

Handbook,[2] individually a random sample of 50 ready-to-cook poultry carcasses prior to the final washer and again when they are removed from the drip line or other draining device immediately before packing. If the average weight of the 50 poultry carcasses taken before the final washer and their average weight after immediate removal from the drip line or draining device show that the product is in compliance with the Zone A moisture absorption limits, applicable to the class of poultry involved, set forth in this section, the adjusted methods will become the established washing, chilling, and draining system for the establishment. If the results of the weighing of the sample of 50 carcasses show that the product exceeds the Zone A limits set forth in this section, the poultry will be retained in accordance with procedures set forth in the Poultry Inspectors' Handbook. Retained poultry shall not be released from the establishment until they meet the applicable requirements of paragraph (d) (2), (3), (4), or (5) of this section.

(9) The establishment shall provide scales, weights, identification devices, and other supplies necessary to conduct all moisture tests.

(10) When poultry is ice packed in barrels or other containers, the barrels and containers shall be covered and shall have an adequate number of drain holes to permit the water to drain out. However, the Administrator, upon written request and under such conditions as he may prescribe in specific cases, may approve the shipment of poultry in operational type containers, such as chill tanks or lugs, from one official establishment to another official establishment for further processing.

(11)(i) Giblets shall be handled in a manner that will prevent free water from being included in the giblet package. If giblet wrapping material is to be used, the average weight of giblet wrapping material shall be not more than 30 pounds per standard ream (24″ x 36″—500 sheets) when tested in accordance with the Technical Association of the Pulp and Paper Industry (T.A.P.P.I.) Standard T–410, except that the weight of such material may exceed 30 pounds per standard ream if, after absorption, as allowed by paragraph (d)(11)(ii) of this section, the material does not weigh more than the total of a 30-pound standard ream plus the allowable absorption increase.

(ii) Test samples shall be conditioned in accordance with T.A.P.P.I. Standard T–402. The sample to be tested shall consist of 10 sheets representative of the shipment or lot, and individual sheets within the sample may vary within normal tolerance from the prescribed maximum weight, but the average of the sample (10 sheets) shall not weigh in excess of 30 pounds per standard ream (24″ x 36″—500 sheets) except as specified above. The moisture absorption shall not exceed 200 percent of the dry weight of the sample (as conditions in accordance with T.A.P.P.I. Standard T–402) and giblet wrappers (uncreped) shall not exceed the following sizes or equivalents: Chickens and Ducks, 9″ x 12″, Turkeys, 12″ x 14″.

(e) *Air chilling.* In air chilling ready-to-cook poultry, the internal temperature of the carcasses shall be reduced to 40 °F. or less within 16 hours.

(f) *Freezing.* (1) Ready-to-cook poultry which is to be or is labeled with descriptive terms such as ''fresh frozen,'' ''quick frozen'' or ''frozen fresh'' or any other term implying a rapid change from a fresh state to a frozen state shall be placed into a freezer within 48 hours after initial chilling in accordance with paragraph (b) of this section. During this period, if such poultry is not immediately placed into a freezer after chilling and packaging, it shall be held at 36 °F. or lower.

(2) Ready-to-cook poultry shall be frozen in a manner so as to bring the internal temperature of the birds at the center of the package to 0 °F. or below within 72 hours from the time of entering the freezer. Such procedures shall not apply to raw poultry product described in § 381.129(b)(6)(i) of this subchapter.

(3) Upon written request, and under such conditions as may be prescribed by the Administrator, in specific cases, ready-to-cook poultry which is to be frozen immediately may be moved

[2] The Poultry Inspectors' Handbook is available upon request from the Food Safety and Inspection Service of the U.S. Department of Agriculture, Washington, DC 20250.

from the official establishment prior to freezing: *Provided*, That the plant and freezer are so located and such necessary arrangements are made that the Inspection Service will have access to the freezing room and adequate opportunity to determine compliance with the time and temperature requirements specified in paragraph (f)(2) of this section.

(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.

(6) Immersion or spray freezing equipment shall be constructed of noncorrosive metal or other acceptable material. Compounds used in immersion or spray freezing procedures shall be approved by the Administrator.

[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]

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

The maximum birds to be inspected by each inspector per minute under the traditional inspection procedure for the different young chicken slaughter line configurations are specified in the following table. These maximum rates shall not be exceeded. The inspector in charge shall 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. 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—YOUNG CHICKENS—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	16½
24–2	4	16
24–4	4	15½

[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]

§ 381.68 Maximum inspection rates—New turkey inspection system.

(a) The maximum inspection rates for one inspector New Turkey Inspection (NTI–1) and two inspector New Turkey Inspection (NTI–2) are listed in the table below. These line speeds are for lines using standard 9-inch shackles on 12-inch centers with birds hung on every shackle and opened with J-type or Bar-type opening cuts. Maximum rates for those establishments having varying configurations will be established by the Administrator but will not exceed those in the table. Neither the rates in the table nor those established for establishments with varying configurations shall be exceeded under any circumstances.

(b) There are two categories of turkeys for determining inspection rates, ''light turkeys'' and ''heavy turkeys''. Light turkeys are all turkeys weighing less than 16 pounds. Heavy turkeys are all turkeys weighing 16 pounds or more. The weights refer to the bird at the point of post-mortem inspection, with blood, feathers and feet removed.

(c) The inspector in charge may reduce inspection line rates when in his/her judgment the prescribed inspection procedure cannot be adequately performed within the time available because the health conditions of a particular flock dictate a need for a more extended inspection.

MAXIMUM TURKEY INSPECTION RATES

Inspection system	Line configuration	Number of inspectors	Birds/Minute			
			J-Type		Bar-Type	
			(<16#) light	(>16#)[1] heavy	(<#) light	(>16#)[1]) heavy
NTI–1	12–1	1	32	30	25	21
NTI–2	[2] 24–2	2	51	41	45	35

[1] This weight refers to the bird at the point of post-mortem inspection, without blood, feathers, or feet.
[2] The turkeys are suspended on the slaughter line at 12-inch intervals, with two inspectors each looking at alternating birds at 24-inch intervals.

[50 FR 37512, Sept. 16, 1985]

Subpart J—Ante Mortem Inspection

§ 381.70 Ante mortem inspection; when required; extent.

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.

§ 381.71 Condemnation on ante mortem inspection.

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.

§ 381.72 Segregation of suspects on ante mortem inspection.

All birds which 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, inclusive, 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 mortem inspection. The inspector shall be notified when such segregated lots are presented for post mortem inspection and inspection of such birds shall be conducted separately. Such procedure for the correlation of ante mortem and post mortem findings by the inspector, as may be prescribed or approved by the Administrator, shall be carried out.

§ 381.73 Quarantine of diseased poultry.

If live poultry, which is affected by any contagious disease which is transmissible to man, is brought into an official establishment, such poultry shall be segregated. The slaughtering of such poultry shall be deferred and the poultry shall be dealt with in one of the following ways:

(a) If it is determined by a veterinary inspector that further handling of the poultry will not create a health hazard, the lot shall be slaughtered separately, subject to ante mortem and post mortem inspection pursuant to the regulations.

(b) If it is determined by a veterinary inspector that further handling of the poultry will create a health hazard, such poultry may be released for treatment under the control of an appropriate State or Federal agency. If the circumstances are such that release for treatment is impracticable, a careful

bird-by-bird ante mortem inspection shall be made, and all birds found to be, or which are suspected of being, affected with a contagious disease transmissible to man shall be condemned.

§ 381.74 Poultry suspected of having biological residues.

When any poultry at an official establishment is suspected of having been treated with or exposed to any substance that may impart a biological residue that would make their edible tissues adulterated, they shall, at the option of the operator of the establishment, be processed at the establishment and the carcasses and all parts thereof retained under U.S. Retained tags, pending final disposition in accordance with § 381.80, of this part, and other provisions in subpart K; or they shall be slaughtered at the establishment and buried or incinerated in a manner satisfactory to the inspector. Alternatively, such poultry may be returned to the grower, if further holding is likely to result in their not being adulterated by reason of any residue. The Inspection Service will notify the other Federal and State agencies concerned of such action. To aid in determining the amount of residue present in the poultry, officials of the Inspection Service may permit the slaughter of any such poultry for the purpose of collecting tissues for analysis of the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of poultry.

[47 FR 41336, Sept. 20, 1982]

§ 381.75 Poultry used for research.

(a) No poultry used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless the operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Inspection Service, or the Veterinary Biologics unit of Veterinary Services, Animal and Plant Health Inspection Service of the Department or the Environmental Protection Agency, or the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that the use of such biological product, drug, or chemical will not result in the products of such poultry being adulterated, and the Administrator has approved such slaughter.

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

Subpart K—Post Mortem Inspection; Disposition of Carcasses and Parts

§ 381.76 Post-mortem inspection, when required; extent; traditional, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System and the New Turkey Inspection (NTI) System; rate of inspection.

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in an official establishment. No viscera or any part thereof shall be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless their identify with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook poultry. If a carcass is frozen, it shall be thoroughly thawed before being opened for examination by the inspector. Each carcass, or all parts comprising such carcass, shall be examined by the inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned.

(b)(1) There are four systems of post-mortem inspection: Streamlined Inspection System (SIS) and the New Line Speed (NELS) Inspection System, both of which shall be used only for broilers and cornish game hens; the New Turkey Inspection (NTI) System, which shall be used only for turkeys; and Traditional 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) Traditional inspection shall be used for turkeys when the NTI System is not used. For other classes of poultry, Traditional Inspection shall be used when neither the SIS nor the NELS Inspection System is used.

(2) The requirements of paragraph (a) of this section are applicable to all four inspection systems.

(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.

(*c*) *Action number*. A level reached by the CUSUM where the process is out of control and product action is required by the establishment or the inspector. See Table 2.

(*d*) ''Start number''. A value halfway between zero and the action number. The start number is used to determine the starting CUSUM for the first subgroup of a shift and to reset the CUSUM value if the CUSUM is equal to or greater than the action number. See Table 2.

(*e*) *Subgroup*. A 10-bird sample collected before product enters the chiller and after product leaves the chiller.

(*f*) *Subgroup absolute limit*. The tolerance number plus 5. See Table 2.

(*g*) *Prechill testing*. Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system.

(*h*) *Postchill testing*. Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected as the product leaves the chilling system.

(*i*) *Rework*. Reprocessing the product to correct the condition or conditions causing the nonconformances listed in Table 1.

(ii) *General*. (*a*) Under SIS, one inspector inspects the outside, inside, and viscera of each bird. There may be two inspectors on one processing line, each inspecting every other bird. For the establishment to run its processing line(s) at maximum speed, optimal conditions must be maintained so that inspection may be conducted efficiently. The inspector in charge determines the speed at which each processing line may be operated to permit inspection. A variety of conditions may affect this determination including the health of each flock and the manner in which birds are being presented to the inspector for inspection.

(*b*) SIS may be performed by one inspector (SIS–1) or two inspectors (SIS–2). SIS–1 requires that the establishment provide one inspection station for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation. The maximum line speed for SIS–1 is 35 birds per minute. SIS–2 requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line

for evaluation. The maximum line speed for SIS–2 is 70 birds per minute.

(*c*) Under all inspection systems, including SIS, inspectors conduct post-mortem inspection and look for a number of conditions, as specified elsewhere in this subpart, which may indicate adulteration. Adulterated product is condemned and destroyed, except that carcasses and parts which may be made unadulterated by reprocessing (reworking) may be so reprocessed under the supervision of an inspector and reinspected. Under SIS, inspectors also reinspect product by sampling finished birds (both before and after chilling) for nonconformances with finished product standards (see Table 1). If such nonconformances are present at certain statistical levels, it may indicate process difficulties requiring corrective action by the establishment. If the establishment does not take adequate corrective action, the inspector shall initiate corrective actions such as conducting closer post-mortem inspections and requiring reprocessing and reinspection of previously processed carcasses and parts. Thus, SIS is conducted in two phases—a post-mortem inspection phase and a reinspection phase. The following paragraphs describe the inspection requirements (not addressed elsewhere in this subpart) under each.

(iii) *Post-mortem inspection. (a)* Facilities: Each inspection station must comply with the facility requirements in § 381.36(c).

(*b*) Presentation: Each inspector shall be flanked by an establishment employee assigned to be the inspector's helper. The one inspector on the SIS–1 line shall be presented every bird. Each inspector on the SIS–2 line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented.

(*c*) Disposition: 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 trim and reinspection. Carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming of birds passed subject to reinspection shall be performed by:

(*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.

(*B*) Conduct a 10-bird subgroup test at a random time on each poultry slaughter line. These times are preselected by the establishment and available to the inspector prior to the start of the shift/day's operations. All 10 samples of the subgroup shall be collected at the random time.

(*C*) Obtain the weighted value of each nonconformance by multiplying the number recorded for each nonconformance by the ''factor'' in Table 1, sum the total of all the nonconformances, and calculate the CUSUM value for that test.

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

(*A*) Select random times for monitoring subgroup tests for each half-shift on the evisceration line. In establishments that have multiple evisceration lines on a production shift, monitor all lines of product at the random times.

(*B*) Collect the subgroup samples to be monitored at preselected times. All 10 samples of the subgroup shall be collected at the random time selected in paragraph (b)(3)(iv)(*d*)(*1*)(*ii*)(*A*) of this section.

(*C*) Conduct the 10-bird monitoring subgroup test.

(*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 immediate past 5 plant prechill subgroups for that category (processing or trim) resulted in a CUSUM above the start number.

(*i*) If all of the past 5 plant prechill subgroups are at or below the start number, the establishment shall immediately conduct a retest subgroup on that category of prechill to determine sample validity. If retest subgroup total equals tolerance or less, the establishment resumes random time testing. If the 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)(*d*)(*4*) of this section. In either case, the prechill retest results will be used to calculate CUSUM.

(*ii*) If any of the past 5 plant prechill subgroups resulted in a CUSUM above the start number, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section.

(*3*) *Actions to be taken when a trimmable lesion/condition is found.* If either inspection or plant monitoring finds any trimmable lesion or condition as specified in item B(7) of Table 1 during a prechill subgroup test, the establishment shall immediately conduct an additional prechill subgroup test for the same trimmable lesion/condition category. This is a requirement on the subgroup testing for the prechill trim nonconformance that is in addition to the CUSUM test described in paragraph (b)(3)(iv)(*d*)(*1*) of this section.

(*i*) If no additional item in the same category is found on retest, the establishment shall resume random time sampling.

(*ii*) If an additional item in the same category is found on retest, the establishment shall proceed as if CUSUM reaches the action number and shall initiate corrective action set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section for this category only.

(*4*) *Actions to be taken when the CUSUM reaches the action number.* Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Immediately notify the inspector in charge and the production supervisor responsible for the affected evisceration line.

(*B*) Suspend random time prechill testing of the affected nonconformance category (processing or trim). Suspend random time postchill subgroup testing when the processing category is the affected nonconformance category.

(*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.

(*ii*) If any of the past 5 postchill monitoring subgroups resulted in a CUSUM above the start number, 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.

(*3*) *Actions to be taken when the CUSUM reaches the action number*. Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Notify the inspector in charge and the production supervisor responsible for product in the chiller.

(*B*) Suspend random time postchill subgroup testing.

(*C*) Immediately conduct an additional postchill subgroup test. If the retest subgroup total exceeds tolerance, the establishment shall identify subsequent product for rework. Product will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(*D*) After two consecutive additional postchill subgroup tests results in subgroup totals equal to or less than tolerance:

— Resume random time postchill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*e*)(*1*) of this section.

— If the two consecutive additional postchill subgroup totals equal to or less than tolerance do not cause CUSUM to fall to the start number or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions to ensure that program requirements are met.

(v) When the prechill or postchill product has been identified as having been produced when the process was not in control, additional online subgroup testing by the establishment is required to determine its conformance to the standard. If any of the additional plant subgroup testing results in a subgroup total exceeding tolerance, offline product corrective actions must take place. The responsibilities of the establishment and the inspector change depending on the CUSUM.

All corrective actions such as identifying affected product, segregating product, and maintaining control through rework actions are the establishment's responsibility. Corrective actions by the inspector depends upon the establishment's ability to control rework of affected product. If the establishment fails in its responsibilities, the inspector will identify, segregate, and retain affected product to prevent adulterated product from reaching consumers.

(*a*) Offline product. The establishment shall identify the affected product so that it may be segregated and accumulated offline for rework. The inspector shall spot check the establishment's identification, segregation, and control of reworked product to ensure that program requirements are met.

(*b*) Reworked product. Reworked product must be tested by the establishment with a randomly selected subgroup test of the accumulated reworked lot. Before product is released, the random subgroup test must result in a subgroup total equal to or less than tolerance. If the subgroup test of a reworked lot results in a subgroup total exceeding tolerance, the lot must be reworked again before another subgroup is selected. The following actions are required.

(*1*) Establishment Actions. The establishment shall:

(*i*) Select the random subgroup from throughout the lot only after the total lot has been reworked.

(*ii*) Conduct the subgroup test using the same criteria (prechill or postchill) that resulted in the rework action.

(*iii*) Release the lot if the reworked subgroup test resulted in a subgroup total equal to or less than tolerance.

(*iv*) Identify and control the lot to be reworked if the reworked subgroup total again exceeds tolerance.

(*2*) Inspector Actions: The inspector shall spot check the rework procedure to ensure that plant monitoring and production meet the requirements of the program.

(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.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

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 ≥¼″ whole
—Any portion less than a whole lung, and equal to or greater than ¼″ at the greatest dimension, equals one incident.
—Factor is one.
—A maximum of two incidents per carcass.

7 Lung—whole
—Each whole lung equals one incident.
—Factor is two.
—A maximum of two incidents per carcass.

8 Intestine
—Any identifiable portion of the terminal portion of the intestinal tract with a lumen (closed circle) present, or split piece of intestine large enough to be closed to form a lumen.
—Factor is five.
—A maximum of one incident per carcass.

9 Cloaca
—Any identifiable portion of the terminal portion of the intestinal tract with mucosal lining.
—Factor is five.
—A maximum of one incident per carcass.

10 Bursa of Fabricius
—A whole rosebud, or identifiable portion with two or more mucosal folds.
—Factor is two.
—A maximum of one incident per carcass.

11 Esophagus
—Any portion of the esophagus with identifiable mocosal lining.
—Factor is two.
—A maximum of one incident per carcass.

12 Crop—partial—with mucosa
—Any portion of the crop that includes the mucosal lining.
—Factor is two.
—A maximum of one incident per carcass.

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 ≥¼″ 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.
—A maximum of two incidents per carcass.

B Trim nonconformances

1 Breast blister
—Inflammatory tissue, fluid, or pus between the skin and keel must be trimmed if membrane ''slips'' or if firm nodule is greater than ½″ in diameter (dime size).
—Factor is two.
—A maximum of one incident per carcass.

2 Breast blister—partially trimmed
—All inflammatory tissue, including that which adheres tightly to the keel bone, must be removed.
—Factor is two.
—A maximum of one incident per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

3 Bruise ½″ to 1″
—Blood clumps or clots in the superficial layers of tissue, skin, muscle or loose subcutaneous tissue may be slit and the blood completely washed out. When the bruise extends into the deeper layers of muscle, the affected tissue must be removed. Very small bruises less than ½″ (dime size) and areas showing only slight reddening need not be counted as defects.
—Factor is one.
—A maximum of five incidents per carcass.

4 Bruise >1″
—Same criteria as in line three, but greater than one inch in greatest dimension.
—Factor is two.
—A maximum of three incidents per carcass.

5 Bruise black/green ¼″ to 1″
—Bruises ¼″ to 1″ that have changed from red to a black/blue or green color due to age.
—Factor is two.
—A maximum of three incidents per carcass.

6 Bruise Black/green >1″
—Same as line 5, but measuring greater that 1″ in greatest dimension.
—Factor is five.
—A maximum of two incidents per carcass.

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.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

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
—When no cartilage of the hock surface is present and no tendons are attached to the bone.
—Factor is two.
—A maximum of two incidents per carcass.

12 Sores, scabs, inflammatory process, etc. ≤½″
—Any defects such as sores, abscesses, scabs, wounds, dermatitis, inflammatory process, that measure less than or equal to ½″ in the greatest dimension.
—Factor is two.
—A maximum of two incidents per carcass.

13 Sores, scabs, inflammatory process, etc. >½″
—Same as line 12, but greatest dimension is greater than ½″, or a cluster of smaller lesions in close proximity >½″, this category also includes turkey leg edema.
—Factor is five.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

—A maximum of one incident per carcass.

14 External mutilation

—Mutilation to the skin and/or muscle that is caused by the slaughter, dressing or eviscerating processes. Skinned elbows (bucked wings) do not trim require unless affected wing joint capsule is also opened.

—Factor is one.

—A maximum of three incidents per carcass.

C Postchill nonconformances—(Designed to monitor those nonconformances added to product during the chilling process)

1 Extraneous material ≤1/16″

—Include specks, grease, or unidentifiable foreign material that measure 1/16″ or less in the greatest dimension.

—Example: Ingesta, grease, or unidentifiable foreign material.

—Factor is one.

—3 to 7=1 defect; 8 to 12=2 defects; 13 or more=3 defects. A maximum of three incidents per carcass.

2 Extraneous material >1/16″ to 1″

—This includes ingesta, grease, or unidentifiable foreign material measureing >1/16″ to 1″ longest dimension.

—Factor is one.

—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 reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming or birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after giblet harvest and prior to reinspection.

(*b*) A reinspection station shall be located at the end of each line. This station shall comply with the facility requirements in § 381.36(d)(2). The inspector shall ensure that the establishment has performed the indicated trimming of carcasses passed subject to reinspection by visually monitoring, checking data, or gathering samples at the station or at other critical points on the line.

(ii)–(iii) [Reserved]

(iv) The maximum inspection rate for NELS shall be 91 birds per minute per eviscerating line.

(5) The following requirements are also applicable to the NTI System:

(i) Inspection under the NTI System is conducted in two phases, a post-mortem inspection phase and a reinspection phase. The NTI–1 Inspection System requires that the establishment provide one inspection station for

each line and adequate reinspection facilitiates so carcasses can be removed from each line for evaluation. The NTI–2 Inspection System requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation.

(*a*) *Post-mortem inspection.* Each inspection station must comply with the facility requirements in § 381.36(e)(1). Each inspector shall be flanked by and establishment employee assigned to be the inspector's helper. The one inspector on an NTI–1 Inspection System shall be presented every bird. Each inspector on an NTI–2 Inspection System line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented. The inspector shall determine which bird shall be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Turkey carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects of birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after the giblet harvest and prior to reinspection.

(*b*) *Reinspection.* A reinspection station shall be located at the end of the lines. This station shall comply with the facility requirements in § 381.36(e)(2). The inspector shall ensure that establishments have performed the indicated trimming of each carcass passed subject to reinspection by visually monitoring, checking data, and/or sampling product at the reinspection station and, if necessary, at other points, critical to the wholesomeness of product, on the eviscerating line.

(ii)–(iii) [Reserved]

(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]

§ 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 stage a disease process results in an adulterated article, the decision as to the disposal of all carcasses, organs or other parts not specifically covered by the regulations, or by instructions of the Administrator issued pursuant thereto, shall be left to the inspector in charge, and if the inspector in charge is in doubt concerning the disposition to be made, specimens from such carcasses shall be forwarded to the Inspection Service laboratory for diagnosis.

(b) All carcasses, organs, or other parts of carcasses of poultry shall be condemned if it is determined on the basis of a sound statistical sample that they are adulterated because of the presence of any biological residues.

§ 381.81 Tuberculosis.

Carcasses of poultry affected with tuberculosis shall be condemned.

§ 381.82 Diseases of the leukosis complex.

Carcasses of poultry affected with any one or more of the several forms of the avian leukosis complex shall be condemned.

§ 381.83 Septicemia or toxemia.

Carcasses of poultry showing evidence of any septicemic or toxemic disease, or showing evidence of an abnormal physiologic state, shall be condemned.

§ 381.84 Airsacculitis.

Carcasses of poultry with evidence of extensive involvement of the air sacs with airsacculitis or those showing airsacculitis along with systemic changes shall be condemned. Less affected carcasses may be passed for food after complete removal and condemnation of all affected tissues including the exudate.

[40 FR 14297, Mar. 31, 1975]

§ 381.85 Special diseases.

Carcasses of poultry showing evidence of any disease which is characterized by the presence, in the meat or other edible parts of the carcass, or organisms or toxins dangerous to the consumer, shall be condemned.

§ 381.86 Inflammatory processes.

Any organ or other part of a carcass which is affected by an inflammatory process shall be condemned and, if there is evidence of general systemic disturbance, the whole carcass shall be condemned.

§ 381.87 Tumors.

Any organ or other part of a carcass which is affected by a tumor shall be condemned and when there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned.

§ 381.88 Parasites.

Organs or other parts of carcasses which are found to be infested with parasites, or which show lesions of such infestation shall be condemned and, if the whole carcass is affected, the whole carcass shall be condemned.

§ 381.89 Bruises.

Any part of a carcass which is badly bruised shall be condemned and, if the whole carcass is affected as a result of the bruise, the whole carcass shall be condemned. Parts of a carcass which show only slight reddening from a bruise may be passed for food.

§ 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)(1) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents shall not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut shall be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone, or 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 soley by trimming, all surfaces of the carcass shall be treated with chlorinated water containing 20 ppm available chlorine.

(2) An area will be designated as an approved reprocessing station only if the Administrator determines that reprocessing operations can be conducted in that area in accordance with all of the requirements of this part, and that the reprocessing methods to be utilized are capable of removing all visible specks of contamination on the inner surface of a carcass. Requests for such approval shall be submitted to the inspector in charge and shall describe the proposed area, proposed methods of reprocessing, and proposed equipment to be utilized. Whenever the Administrator finds that reprocessing operations cannot be conducted in such area in accordance with all of the requirements of this part or that the reprocessing methods utilized are not capable of removing all visible specks of contamination on the inner surface of a carcass, he may withdraw approval of such area, effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, a written confirmation thereof shall be given to the operator as promptly as circumstances permit. The notification shall specify the reasons for such withdrawal and shall afford the operator of the establishment an opportunity to present his views. In any instance where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

[37 FR 9706, May 16, 1972, as amended at 43 FR 12847, Mar. 28, 1978]

§ 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.

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

(1) Each official establishment that slaughters poultry shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry 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.

(2) Sampling requirements.

(i) *Written procedures*. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection*. A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.[1]

(iii) *Sampling frequency*. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

(B) Turkeys, Ducks, Geese, and Guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

(iv) *Sampling frequency alternatives*. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume establishments*.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese, or guineas in the largest number must collect at least one sample during each week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples*. Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of

[1] A copy of FSIS's ''Guidelines for *Escherichia coil* Testing for Process Control Verification in Poultry Slaughter Establishments,'' and ''FSIS Turkey Microbiological Procedures for Sponge Sample Collection and Methods of Analysis'' are available for inspection in the FSIS Docket Room.

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5)(i) *Criteria for Evaluation of test results.* An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

Types of poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Chickens	[1] 100	[1] 1,000	13	3
Turkeys	*NA	*NA	*NA	*NA
Ducks	*NA	*NA	*NA	*NA
Geese	*NA	*NA	*NA	*NA
Guineas	*NA	*NA	*NA	*NA

[1] CFU/ml.
*Values will be added upon completion of data collection programs.

(ii) For types of poultry appearing in paragraph (a)(5)(1) Table 1 of this section that do not have m/N criteria, establishments shall evaluate *E. coli* test results using statistical process control techniques.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; *Salmonella.*

(1) *Raw poultry product performance standards for Salmonella.* (i) An establishment's raw poultry products, when sampled and tested by FSIS for *Salmonella* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2.—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for *Salmonella*) [a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers	20.0%	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are avialable in the FSIS Docket Room.)
[b] Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

(2) *Enforcement.* FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

[61 FR 38866, July 25, 1996, as amended at 62 FR 26218, May 13, 1997; 62 FR 61009, Nov. 14, 1997; 64 FR 66553, Nov. 29, 1999]

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

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. Further, such legend or approved abbreviation thereof, shall be applied to shipping 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 be not less than 4 inches in diameter.

FIGURE 1

§ 381.97 [Reserved]

§ 381.98 Official seal.

The official mark for use in sealing means of conveyance used in transporting poultry products under any requirement in this part shall be the inscription and a serial number as shown below, and any seals approved by the Administrator for applying such mark shall be an official device.

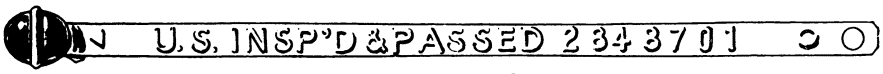

FIGURE 3

§ 381.99 Official retention and rejection tags.

The official marks for use in postmortem inspection and identification of adulterated products, insanitary equipment and facilities are:

(a) A paper tag (a portion of Form MP–35) bearing the legend ''U.S. Retained'' for use on poultry or poultry products under this section.

(b) A paper tag (another portion of Form C&MS 510) bearing the legend ''U.S. Rejected'' for use on equipment, utensils, rooms and compartments under this section.

[64 FR 56417, Oct. 20, 1999]

§381.100 Official detention tag.

The detention tag prescribed in §381.211 is an official device.

§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

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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 Official export certificates, marks and devices.

The form of certificate described in §381.106 is an official export certificate, and the mark shown below is the official mark used on outside containers to identify inspected and passed poultry products for export. Devices used by the Department to apply such a mark are official devices.

[47 FR 29823, July 9, 1982]

§381.105 Export certification; marking of containers.

(a) Upon request or application by any person intending to export any poultry product, any inspector is authorized to issue an official export certificate as prescribed in §381.107 with respect to the shipment to any foreign country of any inspected and passed poultry product, after adequate inspection of the product has been made by the inspector to determine its identity as inspected and passed and eligible for export: *Provided*, that the product is offered for inspection at an official establishment. Each shipping container covered by the export certificate, except ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, shall be marked with an official export stamp as shown in §381.104 bearing the number of the export certificate. Official export certificates will be issued only upon condition that the products covered thereby shall be subject to reinspection at any place and at any time prior to exportation to determine the identity of the products and their eligibility for certification, and such certificates shall

become invalid if such reinspection is refused or discloses that the products are not eligible for certification. If reinspection discloses that any poultry products covered by an export certificate are not eligible for such certification, a superseding certificate setting forth such findings shall be issued and copies shall be furnished to interested persons.

(b) The original and a duplicate of each official export certificate shall be delivered to the person who requested such certificate or his agent. Such person may duplicate such numbers of exact copies of the original as he requires in connection with the exportation of the poultry products. Additional official file copies of the export certificates shall be prepared and distributed by the inspector in accordance with the instructions of the Administrator.

(c) Only one certificate shall be issued for each consignment, except in case of error in the certificate or loss of the certificate originally issued. A request for a new certificate, except in the case of a lost certificate, shall be accompanied by the original and all copies of the first certificate. The new certificate shall carry the following statement: ''This certificate supersedes certificate No. ——— Dated ————. The outside container of the poultry product covered by this certificate is stamped with United States Department of Agriculture Certificate No. ———.''

[37 FR 9706, May 16, 1972, as amended at 50 FR 25204, June 18, 1985]

§ 381.106 Form of official export certificate.

The official export certificate authorized by this subpart is a paper certificate form for signature by an inspector, bearing a letterhead and the seal of the U.S. Department of Agriculture, with a certification that the slaughtered poultry and other poultry products described on the form came from birds that were officially given an ante-mortem and post-mortem inspection and passed in accordance with the regulations of the Department and that such products are wholesome and fit for human consumption. The certificate also bears a serial number, such as ''MPA 002805'', and shows the respective names of the exporter and consignee, the destination, the shipping marks, the names of such products, the total net weight thereof, and such other information as the Administrator may prescribe or approve in specific cases.

[47 FR 29823, July 9, 1982]

§ 381.107 Special procedures as to certification of poultry products for export to certain countries.

When export certificates are required by any foreign country for poultry products exported to such country, the Administrator shall in specific cases prescribe or approve the form of export certificate to be used and the methods and procedures he deems appropriate with respect to the processing of such products, in order to comply with requirements specified by the foreign country regarding the export products. Inspectors shall satisfy themselves that all such requirements are met before issuing such an export certificate. It shall be the responsibility of the exporter to provide any unofficial documentation needed to meet the foreign requirements, before the export certificate will be issued. Such certificates may also cover articles exempted from definition as a poultry product under § 381.15 if they have been inspected and are certified under the regulations in part 362 of this chapter.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 41 FR 23702, June 11, 1976]

§ 381.108 Official poultry inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any veterinary inspector is authorized to issue an official poultry inspection certificate with respect to any lot of slaughtered poultry inspected by him. At any official establishment each such certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of poultry, each such inspector shall sign the certificate with respect to such lot. If the inspection of a lot covered by a certificate

was made by a food inspector, such certificate shall also be signed by the inspector in charge when such inspection was made. Any inspector is authorized to issue a poultry inspection certificate with respect to any other poultry product inspected by him.

(b) The original and one copy of each poultry inspection certificate shall be issued to the applicant who requested such certificate, and one copy shall be retained by the inspector for filing. The inspector who issues any inspection certificate is authorized to furnish an additional copy of such certificate upon the request of an interested party. The person who sold the live poultry involved to the official establishment is an interested party for purposes of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§ 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

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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.

§ 381.116 Wording on labels of immediate containers.

(a) Each label for use on immediate containers for inspected and passed poultry products shall bear on the principal display panel (except as otherwise permitted in the regulations), the items of information required by this subpart. Such items of information shall be in distinctly legible form. Except as provided in § 381.128, all words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(b) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by the regulations with clarity and conspicuousness and without being obscured by design or vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The area that is to bear the principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area on the side of the container that is 40 percent of the product of the height of the container times the circumference, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however,* That there is, immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in §§ 381.118, 381.122, and 381.123. Such panel shall be known as the ''20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel as provided in this § 381.116.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars.

(c) (1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If

there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[37 FR 9706, May 16, 1972, as amended at 40 FR 11347, Mar. 11, 1975; 59 FR 40214, Aug. 8, 1994]

§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:

	Percent	
	Raw	Cooked
Chicken	20	25
Turkey	15	20

Boneless poultry product shall not have a bone solids content of more than 1 percent, calculated on a weight basis.

(e) On the label of any ''Mechanically Separated (Kind of Poultry) '' described in § 381.173, the name of such product shall be followed immediately by the phrase: ''with excess skin'' unless such product is made from poultry product that does not include skin in excess of the natural proportion of skin present on the whole carcass, as specified in paragraph (d) of this section. Appropriate terminology on the label shall indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the establishment at which it is manufactured.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55983, Nov. 3, 1995]

§ 381.118 Ingredients statement.

(a)(1) The label shall show a statement of the ingredients in the poultry product if the product is fabricated from two or more ingredients. Such ingredients shall be listed by their common or usual names in the order of their descending proportions, except as prescribed in paragraph (a)(2) of this section.

(2)(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 § 381.147(f)(4) and subpart P of this part, 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;

(2) The word ''and'' in lieu of a comma must be shown between the declaration of the two kinds of poultry in the ingredients statement and in the product name.

[37 FR 9706, May 16, 1972, as amended at 55 FR 7294, Mar. 1, 1990; 55 FR 26422, June 28, 1990; 58 FR 38049, July 15, 1993; 59 FR 40215, Aug. 8, 1994; 63 FR 11360, Mar. 9, 1998]

§ 381.119 Declaration of artificial flavoring or coloring.

(a) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of any poultry product, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' as applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring added as an ingredient in the formula of the poultry product.

(b) Any poultry product which bears or contains any artificial flavoring other than an artificial smoke flavoring or a smoke flavoring, or bears or contains any artificial coloring shall bear a statement stating that fact on the immediate container or, if there is none, on the product.

§ 381.120 Antioxidants; chemical preservatives; and other additives.

When an antioxidant is added to a poultry product, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement showing the name of the

antioxidant and the purpose for which it is added, such as ''BHA added to help protect the flavor.'' Immediate containers of poultry products packed in, bearing, or containing any chemical preservative shall bear a label stating that fact and naming the additive and the purpose of its use. Immediate containers of poultry products packed in, bearing or containing any other chemical additive shall bear a label naming the additive and the purpose of its use when required by the Administrator in specific cases. When approved proteolytic enzymes as permitted 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 of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement ''Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement. When approved inorganic chlorides as permitted 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 of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement, ''Tenderized with (name of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be used in the solution shall also be included in the statement.

[37 FR 9706, May 16, 1972, as amended at 45 FR 58820, Sept. 5, 1980; 49 FR 18999, May 4, 1984; 64 FR 72175, Dec. 23, 1999]

§ 381.121 Quantity of contents.

(a) The label shall bear a statement of the quantity of contents in terms of weight or measures as provided in paragraph (c)(5) of this section. However, the Administrator may approve the use of labels for certain types of consumer packages which do not bear a statement of the net weight that would otherwise be required under this subparagraph: *Provided,* That the shipping container bears a statement ''Net weight to be marked on consumer packages prior to display and sale'': *And provided further,* That the total net weight of the contents of the shipping container is marked on such container: *And provided further,* That the shipping container bears a statement ''Tare weight of consumer package'' and in close proximity thereto, the actual tare weight (weight of packaging material), weighed to the nearest one-eighth ounce or less, of the individual consumer package in the shipping container. The above-specified statements may be added to approved shipping container labels upon approval by the inspector in charge.

(b) When a poultry product and a nonpoultry product are separately wrapped and are placed in a single immediate container bearing the same name of both products, the net weight on such immediate container may be the total net weight of the products, or such immediate container may show the net weights of the poultry product and the nonpoultry product separately. Notwithstanding the other provisions of this paragraph, the label on consumer size retail packages of stuffed poultry and other stuffed poultry products must show the total net weight of the poultry product, and in close proximity thereto, a statement specifying the minimum weight of the poultry in the product.

(c)(1) The statement of net quantity of contents shall appear (except as otherwise permitted under this paragraph (c)), on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type, in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of 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, semisolid, 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 as a dual declaration both in ounces and (immediately thereafter in parenthesis) 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 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (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 for multi-unit packages, and random weight consumer size and

small packages (less than ½ 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.

(7) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(8) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as otherwise required by this paragraph (c). ''A multiunit retail package'' is a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being sold individually. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph (c)(8) if the labeling of each individual unit complies with the requirements of this paragraph (c).

(9) The following exemptions from the requirements contained in this section are hereby established:

(i) Individually wrapped, random weight consumer size packages of poultry products (as specified in paragraph (c)(10) of this section) and poultry products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined in NBS handbook 133, section 3.18.2, need not bear a net weight statement when shipped from an official establishment provided a net weight shipping statement which meets the requirements of paragraph (c)(6) of this section is applied to the shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement of random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (c)(6) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(10) As used in this section a ''random weight consumer size package'' is one of a lot, shipment or delivery of packages of the same product, with varying weights and with no fixed weight pattern.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 53 FR 28635, July 29, 1988; 55 FR 49835, Nov. 30, 1990]

§381.121a Quantity of contents labeling.

Sections 381.121a through 381.121e of this part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with §381.121 of this part.

[55 FR 49835, Nov. 30, 1990]

§381.121b Definitions and procedures for determining net weight compliance.

(a) For the purpose of §381.121b of this part, the reasonable variations allowed, definitions, and procedures to be used in determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods,'' Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1 and 3 requirements listed in paragraphs (b) and (c) of this section. Those provisions, incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) The following NBS Handbook 133 requirements are not incorporated by reference.

Chapter 2—General Considerations

2.13.1 Polyethylene Sheeting and Film
2.13.2 Textiles
2.13.3 Mulch

Chapter 3—Methods of Test for Packages Labeled by Weight

3.11. Aerosol Packages
3.14. Glazed Raw Seafood and Fish
3.15. Canned Coffee
3.16. Borax
3.17. Flour

Chapter 4—Methods of Test for Packages Labeled by Volume

4.7. Milk
4.8. Mayonnaise and Salad Dressing
4.9. Paint, Varnish, and Lacquers—Nonaerosol
4.11. Peat Moss
4.12. Bark Mulch
4.15. Ice Cream Novelties

Chapter 5—Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethlene Sheeting
5.5. Paper Plates
5.6. Sanitary Paper Products
5.7. Pressed and Blown Glass Tumblers and Stemware

Appendix D: Package Net Contents Regulations

D.1.1 U.S. Department of Health and Human Servcies, Food and Drug Administration
D.1.2 U.S. Department of Agriculture, Food Safety and Inspection Servcie
D.1.3 Federal Trade Commission
D.1.4 Environmental Protection Agency
D.1.5 U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms

(c) The following requirements of Supplement 1 dated September 1990, Supplement 3 dated October 1992, and Supplement 4 dated October 1994, of NIST Handbook 133 are not incorporated by reference.

Supplement 1

Chapter 2 General Considerations

2.13.1. Polyethylene Sheeting and Film
2.13.2. Textiles
2.13.3. Mulch

Chapter 3 Methods of Test for Packages Labeled by Weight

3.11.4. Exhausting the Aerosol Container

Chapter 4 Methods of Test for Packages Labeled by Volume

4.6.4. Method D: Determining the Net Contents of Compressed Gas in Cylinders
4.7. Milk
4.16. Fresh Oysters Labeled by Volume

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

Supplement 3

Chapter 3 Methods of Test for Packages Labeled by Weight

3.17. Flour and Dry Pet Food

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting
5.5. Paper Plates
65.8. Baler Twine

Appendix A. Forms and Worksheets

Supplement 4

3.11 Aerosol Packages
3.11.1 Equipment
3.11.2 Preparation for Test
3.11.3 The Determination of Net Contents: Part 1
3.11.4 Exhausting the Aerosol Container
3.11.5 The Determination of Net Contents: Part 2

[55 FR 49835, Nov. 30, 1990, as amended at 60 FR 12885, Mar. 9, 1995]

§ 381.121c Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weight poultry products sold or otherwise distributed in commerce in federally inspected poultry plants shall be installed, maintained, and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology (NIST) Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices'', 1999 Edition, November 1998, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the FEDERAL REGISTER. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) All scales used to weigh poultry products sold or otherwise distributed in commerce or in State designated under section 5(c) of the Poultry Products Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh poultry products unless it has been found upon test and inspection as specified in NIST Handbook 44 to provide accurate weight. If a scale is inspected or tested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been reinspected and retested by a USDA official, or a State or local government weights and measures official, or a State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a ''Retain'' tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

[55 FR 49836, Nov. 30, 1990, as amended at 60 FR 12885, Mar. 9, 1995; 64 FR 53188, Oct. 1, 1999]

§ 381.121d Scales; testing of.

(a) The operator of each official establishment that weighs poultry food products shall cause such scales to be tested for accuracy in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more fequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures

authority or from a State registered or licensed scale repair firm or person.

[55 FR 49836, Nov. 30, 1990, as amended at 62 FR 45026, Aug. 25, 1997; 65 FR 34390, May 30, 2000]

§ 381.121e Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with § 381.121b of this subchapter shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section, and be reinspected in accordance with the requirements of this part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

[55 FR 49836, Nov. 30, 1990]

§ 381.122 Identification of manufacturer, packer or distributor.

The name and address, including zip code, of the manufacturer, packer, or distributor shall be shown on the label and if only the name and address of the distributor is shown, it shall be qualified by such term as ''packed for,'' ''distributed by,'' or ''distributors.'' The name and place of business of the manufacturer, packer, or distributor may be shown on the principal display panel, on the 20-percent panel of the principal display panel reserved for required information, on the front riser panel of frozen food cartons, or on the information panel.

[37 FR 9706, May 16, 1972, as amended at 59 FR 40215, Aug. 8, 1994]

§ 381.123 Official inspection mark; official establishment number.

The immediate container of every inspected and passed poultry product shall bear:

(a) The official inspection legend; and

(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.

(ii) The labels of the poultry products, specified in this paragraph (b) and prepared pursuant to § 381.10(a) (2), (5), (6), and (7), shall include the following rationale statement as part of the safe handling instructions, ''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.

(3) Poultry products, specified in this paragraph (b), shall bear the labeling statements.

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Poultry products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (b)(1) through (b)(3) of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 14540, Mar. 28, 1994; 64 FR 746, Jan. 6, 1999]

§ 381.126 Date of packing and date of processing; contents of cans.

(a) Either the immediate container or the shipping container of all poultry food products shall be plainly and permanently marked by code or otherwise with the date of packing. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(b) The immediate container for dressed poultry shall be marked with a lot number which shall be the number of the day of the year on which the poultry was slaughtered or a coded number.

(c) All canned products shall be plainly and permanently marked, by code or otherwise, on the containers, with the identity of the contents and date of canning, except that canned products packed in glass containers are not required to be marked with the date of canning if such information appears on the shipping container. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(d) If any marking is by code, the inspector in charge shall be informed as to its meaning.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 35784, Oct. 4, 1974]

§ 381.127 Wording on labels of shipping containers.

(a) Each label for use on a shipping container for inspected and passed poultry products shall bear, in distinctly legible form, the following information:

(1) The official inspection legend.

(2) The official establishment number of the official establishment in which the poultry product was inspected, either within the official inspection mark, or elsewhere on the container clearly visible and in proximity to the official inspection mark.

§ 381.128 Labels in foreign languages.

Any label to be affixed to a container of any dressed poultry or other poultry product for foreign commerce may be printed in a foreign language. However, the official inspection legend and establishment number shall appear on the label in English, but in addition, may be literally translated into such foreign language. Each such label shall be subject to the applicable provisions of §§ 381.115 to 381.141, inclusive. Deviations from the form of labeling required under the regulations may be approved by the Administrator in specific cases and such modified labeling may be used for poultry products to be exported: *Provided*, (a) That the proposed labeling 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) Terms having geographical significance with reference to a particular locality may be used only when the product was produced in that locality.

(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) Raw poultry product whose internal temperature has ever been below 26°F may not bear a label declaration of ''fresh.'' Raw poultry product bearing a label declaration of ''fresh'' but whose internal temperature has ever been below 26°F is mislabeled. The ''fresh'' designation may be deleted from such product in accordance with § 381.133(b)(9)(xxiv). The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26°F standard by 1° (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° (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. (A) Except as provided under paragraph (b)(6)(iii)(C) of this section, when any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, such product

may be transported in commerce to an official establishment after oral permission is obtained from the Area Supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of the relabeling of the product. The Area Supervisor shall record the authorization and other information necessary to identify the product and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(B) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by the inspector, and if it is found that the product is not adulterated, it may be received into the establishment; but if the product is found to be adulterated, it shall at once be condemned and disposed of in accordance with §381.95 of this subchapter. Wholesome product will be relabeled in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate.

(C) When any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, the owner may transport the product in commerce to a retail entity for relabeling in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate, or to other end users, such as hotels, restaurants or similar institutions; or, relabel the product in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate if the product is already at a retail entity. A hotel, restaurant or similar institution is not required to relabel product misbranded under this subpart; *Provided*, That the product is prepared in meals or as entrees only for sale or service directly to individual consumers at such institutions, and that the mark of inspection is removed or obliterated. Oral permission shall be obtained from the Area Officer-in-Charge of the Compliance Program for the area in which the product is located prior to such transportation or relabeling. The Area Officer-in-Charge shall record the authorization and other information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(c) A calendar date may be shown on labeling when declared in accordance with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality'', and such phrases shall be approved by the Administrator as prescribed in §381.132.

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground and formed poultry products, as permitted in §381.147 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 42339, Dec. 5, 1974; 55 FR 5977, Feb. 21, 1990; 60 FR 44412, Aug. 25, 1995; 61 FR 66200, Dec. 17, 1996; 61 FR 68821, Dec. 30, 1996]

§381.130 False or misleading labeling or containers; orders to withhold from use.

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 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form, Application for

Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in §381.133(b) (2)–(9). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in §381.132(d), for all products, except as provided in §381.133(b) (2)–(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in §381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

(d) ''Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in §381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in §381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

[60 FR 67456, Dec. 29, 1995]

§381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in §381.132, to determine

compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(5) Labeling for products not intended for human food, provided they comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or of the word ''pound'' for ''lb.'' or ''ounce'' for ''oz.'';

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words ''prepared for'' or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word ''new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry grade shield; (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for services sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

(xxv) The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only''; and

(xxvi) The use of the descriptive term ''fresh'' in accordance with § 381.129(b)(6)(i) of this subchapter.

(xxvii) The use of the descriptive Term *frozen* as required by § 381.129(b)(6)(ii) of this subchapter.

[60 FR 67457, Dec. 29, 1995, as amended at 61 FR 66201, Dec. 17, 1996]

§ 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]

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.

(b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

[60 FR 67458, Dec. 29, 1995]

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labeling or devices bearing official inspection marks is prohibited and may result in cancellation of the approval.

(b) Labeling and containers bearing any official inspection marks, with or without the official establishment number, may be transported from one official establishment to any other official establishment, only if such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. Approved labeling and containers may be moved without restriction under this part between official establishments operated by the same person if such labeling and containers are approved for use at all such establishments. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subpart.

§ 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend shall remove or deface such legend or destroy the containers upon removal of such articles from the containers.

(b) No person shall alter, detach, deface, or destroy any official identifications prescribed in subpart M that were applied pursuant to the regulations, unless he is authorized to do so by an inspector or this section; and no person shall fail to use any such official identification when required by this part.

§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with official labels shall be done under the supervision of an inspector pursuant to the regulations in part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

§§ 381.141–381.143 [Reserved]

§ 381.144 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(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 listed in § 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 meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in § 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in § 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law.

Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.[1]

[1] Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisor. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan

(c) *Applying for Total Plant Quality Control*. Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe: *Provided*, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d)–(e) [Reserved]

(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 labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by subparts M and N of this part.

applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved.

(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 Adminstrator 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.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspectiom services at the discretion of the circuit supervisor and charged for such services.

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

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

[37 FR 9706, May 16, 1972, as amended at 45 FR 54323, Aug. 15, 1980; 46 FR 48904, Oct. 5, 1981; 50 FR 6, Jan. 2, 1985; 51 FR 32304, Sept. 11, 1986; 57 FR 43598, Sept. 21, 1992; 62 FR 45026, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997; 64 FR 72175, Dec. 23, 1999; 65 FR 34390, May 30, 2000]

§ 381.146 Sampling at official establishments.

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

§ 381.148 Processing and handling requirements for frozen poultry products.

Procedures with respect to processing of frozen ready-to-heat-and-eat poultry products or stuffed ready-to-roast poultry shall be in accordance with sound operating practices and carried out in a manner which will assure freedom from adulteration of the products. Products to be frozen shall be moved into the freezer promptly under such supervision by an inspector as is necessary to assure preservation of the products by prompt and efficient freezing. Adequate freezing facilities shall be provided within the official establishment where products to be frozen are prepared, except that, upon written request, and under such conditions as may be prescribed by the Administrator in specific cases, such products may be moved from the official establishment prior to freezing: *Provided,* That the official establishment and freezer are so located and the necessary arrangements are made so that the Inspection Service will have access to the freezing room and adequate opportunity to determine that the products are being properly handled and frozen.

§ 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 7-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(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 ½ 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]

§ 381.152 Preparation in an official establishment of articles not for human food.

(a) *Requirements applicable when prepared in an edible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food is prepared in any room or compartment, in an official establishment where poultry products are prepared or handled (such room or compartment being herein referred to as an ''edible products department''), sufficient space and equipment shall be provided to assure that the preparation of the article in no way interferes with the preparation or

[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.

other handling of the poultry products. Where necessary, separate equipment shall be provided for the preparation of the article. To assure the maintenance of the requisite sanitary conditions in the edible products department, the operations incident to the preparation of the article shall be subject to the same sanitary requirements as apply to the handling of poultry products in the edible products department. Preparation of the article shall be limited to those hours during which the official establishment operates under the supervision of an inspector. The ingredients used in the preparation of the article shall, unless otherwise approved by the Administrator in specific cases, be such as may be used in the preparation of a poultry product. The article may be stored in, and distributed from, the edible products department if the article is properly identified.

(b) *Requirements applicable when prepared in an inedible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food, is prepared in any part of an official establishment other than an edible products department (such part of the establishment being herein referred to as the ''inedible products department''), the area in which such article is prepared shall be distinctly separated from all edible products departments. Poultry products and inedible products may be brought from any edible products department into any inedible products department, but no poultry product or inedible product may be brought from an inedible products department into an edible products department except that any such articles as are in sealed containers or are handled under conditions prescribed or approved by the Administrator in specific cases may be brought into an edible products department. Diseased carcasses or diseased parts of any carcass shall not be used in the preparation of any animal food unless they have been treated in the manner prescribed in § 381.95(a). Trucks or containers used for the transportation of poultry products or inedible products into an inedible products department shall be cleaned before being returned to or brought into an edible products department. Sufficient space shall be allotted and adequate equipment and facilities provided so that the preparation of the article does not interfere with the preparation of poultry products or the maintenance of the requisite sanitary conditions in the official establishment. The preparation of any such article shall be subject to supervision by an inspector.

(c) *Containers to be labeled.* The immediate container of any such article that is prepared in an official establishment shall be conspicuously labeled so as to distinguish it from human food. Such articles are also subject to the requirements under the Federal Food, Drug, and Cosmetic Act.

§ 381.153 Accreditation of chemistry laboratories.

(a) *Definitions:*

Accreditation—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and subchapter A of this chapter for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and subchapter A of this chapter for the presence and amount of one of several classes of chemical residue, in accordance with the requirements of the Accredited Laboratory Program. Accreditations are granted separately for the food chemistry analysis of official samples and for the analysis of such samples for any one of the several classes of chemical residue. A laboratory may hold more than one accreditation.

Accredited laboratory— A non-Federal analytical laboratory that has met the requirements for accreditation specified in this section and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

AOAC methods—Methods of chemical analysis, Chapter 39, Association of Official Analytical Chemists published in the ''Official Methods of Analysis of the Association of Official Analytical

Chemists'', 15th edition 1990.[1] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Chemical residue misidentification— see ''Correct Chemical Residue Identification'' definition.

Coefficient of variation (CV)— The standard deviation of a distribution of analytical values multipled by 100, and divided by the mean of those values.

Comparison Mean—The average, for a sample, of all accredited and FSIS laboratories' average results, each of which has a large deviation measure of zero, except when only two laboratories perform the analysis, as in the case of split sample analysis by both an accredited laboratory and an FSIS laboratory. In the latter case, the comparison mean is the average of the two laboratories' results. For food chemistry, a result for a laboratory is the obtained analytical value; for chemical residues, a result is the logarithmic transformation of the obtained analytical value.

Correct chemical residue identification—Correct identification by a laboratory of a chemical residue whose concentration, in a sample, is equal to or greater than the minimum reporting level for that residue, as determined by the median of all positive analytical values obtained by laboratories analyzing the sample. Failure of a laboratory to report the presence of such a chemical residue is considered a misidentification. In addition, reporting the presence of a residue at a level equal to or above the minimum reporting level that is not reported by 90 percent or more of all other laboratories analyzing the sample, is considered a misidentification.

CUSUM—A class of statistical procedures for assessing whether or not a process is ''in control''. Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The four CUSUM procedures are:

(1) Positive systematic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM–N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM–V)—monitors the average ''total discrepancy'' (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory's results and the comparison mean;

(4) Individual large discrepancy CUSUM (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

Individual large deviation— An analytical result from a non-Federal laboratory that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

Initial accreditation check sample— A sample prepared and sent by an FSIS laboratory to a non-Federal laboratory to ascertain if the non-Federal laboratory's analytical capability meets the standards for granting accreditation.

Interlaboratory accreditation maintenance check sample—A sample prepared and sent by FSIS to a non-Federal laboratory to assist in determining if acceptable levels of analytical capability are being maintained by the accredited laboratory.

Large deviation measure— A measure that quantifies an unacceptably large

[1] A copy of the ''Official Methods of Analysis of the Association of Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201. 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

difference between a non-Federal laboratory's analytical result and the sample comparison mean.

Minimum proficiency level—The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent. (See Table 2)

Minimum reporting level— The number such that if any obtained analytical value equals or exceeds this number, then the residue is reported together with the obtained analytical value.

Official Sample—A sample selected by an inspector or inspection service employee in accordance with FSIS procedures for regulatory use.

Probation— The period commencing with official notification to an accredited laboratory that its check or split sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation is either fully restored, suspended, or revoked.

QA (quality assurance) recovery— The ratio of a laboratory's unadjusted analytical value of a check sample residue to the residue level fortified by the FSIS laboratory that prepared the sample, multiplied by 100. (See Table 2.)

QC (quality control) recovery— The ratio of a laboratory's unadjusted analytical value of a quality control standard to the fortification level of the standard, multiplied by 100. (See Table 2.)

Refusal of Accreditation—An action taken when a laboratory which is applying for accreditation is denied the accreditation.

Responsibly connected.— Any individual who or entity which is a partner, officer, director, manager, or owner of 10 per centum or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the chemical analysis of FSIS official samples.

Revocation of Accreditation—An action taken against a laboratory which removes its right to analyze official samples.

Split sample—An official sample divided into duplicate portions, one portion to be analyzed by an accredited laboratory (for official regulatory purposes) and the other portion by an FSIS laboratory (for comparison purposes).

Standardizing Constant—The number which is the result of a mathematical adjustment to the ''standardized value.'' Specifically, the number equals the square root of the expected variance of the difference between the accredited or applying laboratory's result and the comparison mean on a sample, taking into consideration the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed the sample.

Standardized Difference—The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

Standardizing Value—A number representing the performance standard deviation of an individual result (see Tables 1 and 2 and footnotes to the Tables for determining exact procedures for calculation).

Suspension of Accreditation—Action taken against a laboratory which temporarily removes its right to analyze official samples. Suspension of accreditation ends when accreditation is either fully restored or revoked.

Systematic laboratory difference—A comparison of one laboratory's results with the comparison means on samples that shows, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference and, conversely, numerically smaller results indicate a negative systematic laboratory difference.

Variability— Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

Variance— The expected average of the squared differences of sample results from an expected sample mean.

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

(By analyte)

Moisture	Protein [1]	Fat [2]	Salt [3]
0.57	0.060	0.26 (0.30)	0.127

[1] To obtain the standardizing value for a sample the appropriate entry in this column is multiplied by $X^{0.65}$ where X is the comparison mean of the sample.

[2] To obtain the standardizing value for a sample, the appropriate entry in this column is multiplied by $X^{0.25}$, where X is the comparison mean of the sample. The appropriate entry is equal to the value in parentheses when X is equal to or greater than 12.5 percent, otherwise it is equal to 0.26.

[3] To obtain the standardizing value for a sample, when the comparison mean of the sample, X, is less than 1.0 percent, the standardizing value equals 0.127, otherwise the appropriate entry is multiplied by $X^{0.25}$. When X is equal to or greater than 4.0 percent for dry salami and pepperoni products, the standardizing value equals 0.22.

TABLE 2.—MINIMUM PROFICIENCY LEVELS, PERCENT EXPECTED RECOVERIES (QC AND QA), AND STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Minimum proficiency level	Percent expected recovery (QC and QA)	Standardizing value [3]
Chlorinated Hydrocarbons: [1]			
Aldrin	0.10 ppm	80–110	0.20
Benzene Hexachloride	0.10. ppm	80–110	0.20
Chlordane	0.30 ppm	80–110	0.20
Dieldrin	0.10 ppm	80–110	0.20
DDT	0.15 ppm	80–110	0.20
DDE	0.10 ppm	80–110	0.20
TDE	0.15 ppm	80–110	0.20
Endrin	0.10 ppm	80–110	0.20
Heptachlor	0.10 ppm	80–110	0.20
Heptachlor Epoxide	0.10 ppm	80–110	0.20
Lindane	0.10 ppm	80–110	0.20
Methoxychlor	0.50 ppm	80–110	0.20
Toxaphene	1.00 ppm	80–110	0.20
Hexachlorobenzene	0.10 ppm	80–110	0.20
Mirex	0.10 ppm	80–110	0.20
Nonachlor	0.15 ppm	80–110	0.20
Polychlorinated Biphenyls	0.50 ppm	80–110	0.20
Arsenic [2]	0.20 ppm	90–105	0.25
Sulfonamides [2]	0.08 ppm	70–120	0.25
Volatile Nitrosamine [2]	5 ppb	70–110	0.25

[1] Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.
[2] Laboratory statistics are only computed for specific chemical residues.
[3] The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

(b) *Laboratories accredited for analysis of protein, moisture, fat, and salt content of poultry and poultry products*—

(1) *Applying for accreditation.* Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory and sent to the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street SW., Washington DC, 20250–3700, and shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought by the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward a check, bank draft, or money order in the amount specified in 9 CFR 391.5 made payable to the U.S. Department

of Agriculture along with the completed application for the accreditation(s) sought for the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

(iv) Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (b)(1) by January 13, 1994 (30 days of the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory will be reset at zero upon acceptance of its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that the laboratory reapply for accreditation by February 11, 1994 (60 days of the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analyses of moisture, protein, fat, and salt content of poultry and poultry products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below, for all four analytes. This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field and having 1 year's experience in food chemistry, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable levels of systematic laboratory difference, variability, and individual large deviations in the analyses of moisture, protein, fat, and salt content using AOAC methods. An applying laboratory will successfully demonstrate these capabilities if its moisture, protein, fat, and salt results from a 36 check sample accreditation study each satisfy the criteria presented below.[2] If the laboratory's analysis of an analyte (or analytes) from the first set of 36 check samples does not meet the criteria for obtaining accreditation, a second set of 36 check samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of samples shall be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory. If the results of the second set of samples do not meet the accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 0.73 minus the product of 0.17 and the standard deviation of the standardized differences.

(B) *Variability:* The estimated standard deviation of the standardized differences must not exceed 1.15.

[2] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

(C) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual samples must be less than 5.0.[3]

(iii) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(iv) Pay the accreditation fee by the date required.

(3) *Criteria for maintaining accreditation*. To maintain accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Report analytical results of the moisture, protein, fat, and salt content of official samples, weekly, on designated forms to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division.

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under this Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, Room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, by certified or registered mail, within 30 days of any change in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced onsite laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to the laboratory's participation in the Accredited Laboratory Program.

(viii) Use official AOAC methods[4] on official and check samples. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analyses of moisture, protein, fat, and salt content. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its moisture, protein, fat, and salt results from interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented in this paragraph (b)(3)(ix).[5]

(A) *Systematic laboratory difference—(1) Positive systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P. This value is computed and evaluated as follows:

[3] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

[4] A copy of the ''Official Methods of Analysis of the Association of Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

[5] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 2.4,
−2.0, if the standardized difference is less than −1.6,
or
the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0. [CUSUM–P values are initialized at zero; that is, the CUSUM-P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 5.2.

(*2*) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N. This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 1.6,
−2.0, if the standardized difference is less than −2.4,
or
the standardized difference plus 0.4, if the standardized difference lies between −2.4 and 1.6, inclusive.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 5.2.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V. This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *Large deviations:* The large deviation measure of the accredited laboratory's result for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[6] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0. [CUSUM–D values are initialized at zero; that is, the CUSUM–

[6] *See* footnote 3.

D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory approved for food chemistry. Mailing expenses will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples specified in paragraphs (b)(2)(ii) (A), (B), and (C) of this section.

(xi) Expeditiously report analytical results of official samples to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division. The Federal inspector at any establishment may assign the analysis of official samples of an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(xii) Pay the required accreditation fee when it is due.

(c) *Laboratories accredited for analysis of a class of chemical residues in poultry and poultry products*—(1) *Applying for accreditation*. Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of the non-Federal analytical laboratory and sent to the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, and shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought by the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward a check, bank draft, or money order in the amount specified in 9 CFR 391.5 made payable to the U.S. Department of Agriculture along with the completed application for the accreditation(s) sought by the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

(iv) Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (c)(1) by January 12, 1994 (30 days of the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory

will be reset at zero upon acceptance of its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that the laboratory reapply for accreditation by February 11, 1994 (60 days of the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analysis of a class of chemical residues in poultry and poultry products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for the analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field and either the supervisor or the analyst assigned to analyze the sample has 3 years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable limits of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification in the analysis of the class of chemical residues for which application was made, using FSIS approved procedures. An applying laboratory will successfully demonstrate these capabilities if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 samples satisfy the criteria presented in this paragraph (c)(2)(ii).[7] In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria (c)(2)(ii)(A), (B), (C), (D), (E), and (F) of this section will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.] If the results of the first set of check samples do not meet these criteria for obtaining accreditation, a second set of at least 14 samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. If the results of the second set of samples do not meet accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and the standard deviation of the standardized differences.

(B) *Variability:* The standard deviation of the standardized differences must not exceed a computed limit. This limit is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability associated with the results from the participating FSIS laboratories.

(C) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual analytical results must be less than 5.0.[8]

(D) *QA recovery:* The average of the QA recoveries of the individual analytical results must lie within the range given in Table 2 under the column entitled ''Percent Expected Recovery.''

(E) *QC recovery:* All QC recoveries must lie within the range given in Table 2 under ''Percent Expected Recovery.'' Supporting documentation must be made available to FSIS upon request.

[7] All statistical computations are rounded to the nearest tenth, unless otherwise noted.

[8] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

(F) *Correct identification:* There must be correct identification of all chemical residues in all samples.

(iii) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(iv) Pay the accreditation fee by the date required.

(3) *Criteria for maintaining accreditation.* To maintain accreditation for analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) [Reserved]

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under the Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, Room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, by certified or registered mail, within 30 days when there is any change in the laboratory's ownership, officers, directors, supervisory personnel, or any other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced onsite laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to the laboratory's participation in the Accredited Laboratory Program.

(viii) Use analytical procedures designated and approved by FSIS.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analysis of samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented below.[9] [10] In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference:*

(1) Positive systematic laboratory difference: The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P.[11] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

[9] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

[10] An analytical result will only be used in the statistical evaluation of the laboratory if the associated comparison mean is equal to or greater than the logarithm of the minimum proficiency level for the residue.

[11] When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: the average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM–P (or CUSUM–N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

2.0, if the standardized difference is greater than 2.5,
−2.0, if the standardized difference is less than −1.5,

or

the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0. [CUSUM–P values are initialized at zero; that is, the CUSUM–P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 4.8.

(2) Negative systematic laboratory difference: The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N.[12] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 1.5,
−2.0, if the standardized difference is less than −2.5,

or

the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 4.8.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.[13] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *Large Deviations:* The large deviation measure of the accredited laboratory's result for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[14] This value is computed and evaluated as follows:

[12] *See* footnote 11.

[13] When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: the square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

[14] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference,

Continued

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value. The new CUSUM–D is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0. [CUSUM–D values are initialized at zero; that is, the CUSUM–D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS Science Laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory accredited for this specific chemical residue. Mailing expenses will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples as specified in paragraphs (c)(2)(ii) (A), (B), (C), (D), (E), and (F) of this section

(xi) Expeditiously report analytical results of official samples to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the judgment of the inspector, there are delays in receiving test results on official samples from an accredited laboratory.

(xii) Every QC recovery associated with reporting of official samples must be within the appropriate range given in Table 2 under ''Percent Expected Recovery.'' Supporting documentation must be made available to FSIS upon request.

(xiii) Demonstrate that acceptable levels of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification are being maintained in the analysis of interlaboratory accreditation maintenance check samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples satisfy the criteria presented below. In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference*—(*1*) *Positive systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P.[15] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 2.5,

−2.0, if the standardized difference is less than −1.5,

or

the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0. [CUSUM–P values are initialized at zero; that is, the CUSUM–P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

[15] *See* footnote 11.

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 4.8.

(*2*) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N.[16] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 1.5,
−2.0, if the standardized difference is less than −2.5,
or
the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 4.8.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.[17] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 or the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *Large deviations:* The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[18] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value The new CUSUM–D is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0. [CUSUM–D values are initialized at zero; that is, the CUSUM–D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(D) Each QC Recovery is within the range given in Table 2 under ''Percent Expected Recovery''. Supporting documentation must be made available to FSIS upon request.

(E) Not more than 1 residue misidentification in any 2 consecutive check samples.

(F) Not more than 2 residue misidentifications in any 8 consecutive check samples.

(xiv) Pay the accreditation fee when it is due.

[16] *See* footnote 11.

[17] *See* footnote 13.

[18] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

(d) *Refusal of accreditation.* Upon a determination by the Administrator, a laboratory will be refused accreditation for the following reasons:

(1) A laboratory shall be refused accreditation for moisture, protein, fat, and salt analysis for failure to meet the requirements of paragraph (b)(1) or (b)(2) of this section.

(2) A laboratory shall be refused accreditation for chemical residue analysis for failure to meet the requirements of paragraph (c)(1) or (c)(2) of this section.

(3) A laboratory shall be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, all official samples which have not been analyzed as of the notification of a loss of accreditation.

(4) A laboratory shall be refused accreditation if the applicant or any individual or entity responsibly connected with the applicant has been convicted of or is under indictment or if charges on an information have been brought against the applicant or responsibly connected individual or entity in any Federal or State court concerning the following violations of law:

(i) Any felony.

(ii) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(iii) Any misdemeanor based upon a false statement to any governmental agency.

(iv) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(e) *Probation of accreditation.* Upon a determination by the Administrator, a laboratory shall be placed on probation for the following reasons:

(1) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis within 12 consecutive months as required by paragraphs (b)(3)(v) and (c)(3)(v) of this section, unless written permission is granted by the Administrator to exceed the time limit.

(2) If the laboratory fails to meet any of the criteria set forth in paragraphs (b)(3)(v) and (b)(3)(ix) and (c)(3)(v) and (c)(3)(ix) of this section.

(f) *Suspension of accreditation.* The accreditation of a laboratory shall be suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or if charges on an information have been brought against the laboratory or responsibly connected individual or entity in any Federal or State court concerning any of the following violations of law:

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(g) *Revocation of accreditation.* The accreditation of a laboratory shall be revoked for the following reasons:

(1) An accredited laboratory which is accredited to perform analysis under paragraph (b) of this section shall have its accreditation revoked for failure to meet any of the requirements of paragraph (b)(3) except for the following circumstances. If the accredited laboratory fails to meet the criteria for reporting the analytical results on interlaboratory accreditation maintenance check samples as set forth in paragraph (b)(3)(v) of this section or if, at any time, the CUSUM results from the analysis of such interlaboratory accreditation maintenance check samples and/or split samples have not satisfied the criteria specified in paragraph (b)(3)(ix) of this section and there have been, during the previous 12 months, no other occasions on which such CUSUM results have not satisfied such criteria, the laboratory shall be placed on probation; but if there have been such other occasions during those 12 months, the laboratory's accreditation will be revoked.

(2) An accredited laboratory which is accredited to perform analysis for a class of chemical residues under paragraph (c) of this section shall have the accreditation to perform this analysis revoked if it fails to meet any of the requirements in paragraph (c)(3) of this

section except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in paragraphs (c)(3)(v), (c)(3)(ix), and (c)(3)(xiii) of this section and it has not so failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has so failed at any time during those 12 months, its accreditation will be revoked.

(3) An accredited laboratory shall have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(i) Altered any official sample or analytical finding, or,

(ii) Substituted any analytical result from any other laboratory for its own.

(4) An accredited laboratory shall have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law:

(i) Any felony.

(ii) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(iii) Any misdemeanor based upon a false statement to any governmental agency.

(iv) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(h) *Notification and hearings.* Accreditation of any laboratory shall be refused, suspended, or revoked under the conditions previously described herein. The owner or operator of the laboratory shall be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing shall be granted if there is any dispute of material fact joined in such responsive statement. The proceeding shall thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for the proceeding. Any such refusal, suspension, or revocation shall be effective upon the receipt by the laboratory of the notification and shall continue in effect until final determination of the matter by the Administrator.

(Reporting and recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[52 FR 2192, Jan. 20, 1987, as amended at 58 FR 65264, 65266–65268, Dec. 13, 1993; 59 FR 33642, 33643, June 30, 1994; 59 FR 66448, Dec. 27, 1994; 60 FR 10305, Feb. 24, 1995]

Subpart P—Definitions and Standards of Identity or Composition

§ 381.155 General.

(a) *Authorization to establish specifications.* (1) The Administrator is authorized to establish specifications or definitions and standards of identity or composition, covering the principal constituents of any poultry product with respect to which a specified name of the product or other labeling terminology may be used, whenever he determines such action is necessary to prevent sale of the product under false or misleading labeling. Further, the Administrator is authorized to prescribe definitions and standards of identity or composition for poultry products whenever he determines such action is otherwise necessary for the protection of the public. The requirements of this subpart are hereby found to be necessary for these purposes and standards are hereby established as set forth in this subpart.

(2) Where cooked poultry meat is specified in this subpart as an ingredient of poultry products, this means poultry meat derived from poultry processed, cooked, and cooled in a manner approved by the Administrator in specific cases without use of liquid or moisture in direct contact with the poultry meat following the cooking and cooling of the poultry.

(3) If, following cooking and cooling of poultry meat to be used in poultry products, liquid or moisture is used in direct contact with such poultry meat

and the percentage of solids, excluding salt, in the poultry meat is found to be below 34 percent when such poultry meat is tested by acceptable methods, the percentage of poultry meat required by this section for any poultry product shall be increased in proportion to the deficiency, or the meat shall be so processed as to raise the solids content, excluding salt, to 34 percent. The official establishment shall furnish adequate facilities for such testing.

§ 381.156 Poultry meat content standards for certain poultry products.

Poultry products with labeling terminology as set forth in Table I shall comply with the specifications for percent light meat and percent dark meat set forth in said table.

TABLE I

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.

[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
2. Boned (Kind)	90	10
3. Boned (Kind) with broth [2]	80	20
4. Boned (Kind) (——) percent broth [2, 3]	50	50

[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.''

(f) Poultry products intended for infant or geriatric use and represented as having a ''high meat'' content shall contain not less than 18.75 percent cooked, deboned poultry meat of the kind indicated, with seasoning.

TABLE IIA

Product name	Minimum percent cooked, deboned, poultry meat of kind indicated, with seasoning	Maximum percent liquid that may be added [1]
1. Strained or chopped (Kind) with broth [2, 3]	43	57
2. High meat dinner [3]	18.75	

[1] Liquid may be in the form of, but not limited to, broth or extractives.
[2] Alternatively, product may be prepared from raw boned poultry meat in combination with cooked bone poultry meat so long as the product complies with the specified standard.
[3] Label must indicate in some manner that product is for infant or geriatric servings.

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

§ 381.158 Poultry dinners (frozen) and pies.

Poultry dinners (frozen) and pies shall meet the requirements set forth in Table III of this section and the percentage or weight specified therein shall be calculated on the basis of total ingredients used in the preparation of the poultry product.

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 1⅛ 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 1⅛ 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 § 381.147(f)(4) of this part. 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]

§ 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."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry source heat, e.g., oven roasted or oven baked.

§ 381.164 "(Kind) barbecued."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry heat and basted with a seasoned sauce.

§ 381.165 "(Kind) barbecued prepared with moist heat."

Such product consists of ready-to-cook poultry of the kind indicated that

has been cooked by the action of moist heat in a barbecue sauce.

§ 381.166 Breaded products.

''Breaded'' is a term applicable to any poultry product which is coated with breading or a batter and breading in an amount not to exceed 30 percent of the weight of the finished breaded product.

§ 381.167 Other poultry dishes and specialty items.

Poultry dishes and specialty items listed in Table IV of this paragraph shall meet the requirements set forth in said table, irrespective of the type of packaging, and the percentages in Table IV shall be calculated on a ready-to-serve basis, except that soup bases in institutional packs which are prepared for sale to institutional users shall have a minimum of 15 percent cooked deboned poultry meat based on the weight of the soup base product.

TABLE IV

Product name [1]	Minimum percent cooked deboned poultry meat of kind indicated	Minimum percent cooked poultry of kind indicated, indicating bone
(Kind) Ravioli	2	
(Kind) Soup	2	
Chop Suey with (Kind)	2	
(Kind) Chop Suey	4	
(Kind) Chow Mein without noodles	4	
(Kind) Tamales	6	
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	
Minced (Kind) Barbecue	40	

[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.

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

§ 381.168 Maximum percent of skin in certain poultry products.

The poultry products listed in Table V shall have not more than the percent of skin specified in the table, when raw and when cooked.

TABLE V

Product name	Percent skin	
	Raw	Cooked
Boneless Turkey Breast or Boneless Turkey Breast Roll	14	
Boneless Turkey Thigh or Boneless Turkey Thigh Roll	8	
Boneless Turkey or Turkey Roll	15	
Boneless Chicken Breast or Boneless Chicken Breast Roll	18	20
Boneless Chicken or Chicken Roll	20	25

§ 381.169 Ready-to-cook poultry products to which solutions are added.

(a) Butter alone, or solutions of poultry broth, poultry stock, water, or edible fats, or mixtures thereof, in which are included functional substances such as spices, flavor enhancers, emulsifiers, phosphates, coloring materials, or other substances, approved by the Administrator in specific cases, may be introduced by injection into the thick muscles (breast and legs) of ready-to-cook poultry carcasses and may be introduced by injection or marinating into any separate bone-in part therefrom, for the purpose of providing a basting medium or similar function. The ingredients of the added materials and the manner of addition to the products must be found acceptable by the Administrator, in all cases. The introduction of the added materials shall increase the weight of the processed product by approximately 3 percent over the weight of the raw product after washing and chilling in compliance with § 381.66. The weight of the added materials introduced into the poultry products as provided in this paragraph shall be included as part of the weight of the poultry for purposes

of the net weight labeling provisions in § 381.121(b).

(b) A raw poultry product, into which added materials are introduced as provided in paragraph (a) of this section must be labeled with a conspicuous, legible, and descriptive name, including terms that concisely describe the method of addition and function of the added material. All major terms in the product name must be printed with the same prominence, except that the words which describe the function of the added materials (such as ''Injected for Flavored Basting'') may be more prominent, provided this does not detract from the conspicuousness of the other terms in the product name (such as ''Young Turkey''). The label must also bear a statement, in bold type, immediately below and adjacent to the product name, listing the common or usual names of the added materials in descending order of predominance. The first part of this statement must consist of terms adequate to inform consumers about the amount and manner of introduction of the solution (such as ''Injected with approximately 3 percent of a solution of ————''), and must be printed at least one-fourth the size of the most prominent letter in the product name, with a minimum size of one-fourth inch for a ready-to-cook turkey and proportionately smaller for other poultry products. The remainder of the solution ingredients shall be declared in type at least one-eighth inch in height. The entire statement must be printed in a color that contrasts with the background and be displayed on the principal display panel.

(c) Approval for use of a label for product under this section depends upon the ability of the processor to control the finished product, within a range of three-tenths of 1 percent accuracy, so that the average percent of basting material in each outgoing lot is not greater than 3.3 percent or less than 2.7 percent of basting material when tested by an approved plant control procedure would be in compliance. As used in this section, ''a lot'' may be any reasonable portion of production designated by the operator of the official establishment, with a maximum of an entire shift's production from one production line. The control procedures to be eligible for approval by the Administrator must:

(1) Assure compliance with all labeling requirements.

(2) Control the variability of the amount of added approved solution within the limits defined above.

(3) Provide for the disposition in accordance with the regulations of all products not in compliance with this section.

(4) Incorporate a system of raw weight identification of a sufficient number of poultry and/or poultry parts to allow effective monitoring of the system by Federal inspectors and official establishment employees.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§ 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 (usually 5 to 6 weeks of age) weighing not more than 2 pounds ready-to-cook weight, which was prepared from a Cornish chicken or the progeny of a Cornish chicken crossed with another breed of chicken.

(ii) *Rock Cornish fryer, roaster, or hen*. A Rock Cornish fryer, roaster, or hen is the progeny of a cross between a purebred Cornish and a purebred Rock chicken, without regard to the weight of the carcass involved; however, the term ''fryer,'' ''roaster,'' or ''hen'' shall apply only if the carcasses are from birds with ages and characteristics that qualify them for such designation under paragraph (a)(1) (iii) or (iv) of this section.

(iii) *Broiler or fryer*. A broiler or fryer is a young chicken (usually under 13 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iv) *Roaster or roasting chicken*. A bird of this class is a young chicken (usually 3 to 5 months of age), of either sex,

that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that may be somewhat less flexible than that of a broiler or fryer.

(v) *Capon*. A capon is a surgically unsexed male chicken (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(vi) *Hen, fowl, or baking or stewing*. A bird of this class is a mature female chicken (usually more than 10 months of age) with meat less tender than that of a roaster, or roasting chicken and nonflexible breastbone tip.

(vii) *Cock or rooster*. A cock or rooster is a mature male chicken with coarse skin, toughened and darkened meat, and hardened breastbone tip.

(2) *Turkeys*—(i) *Fryer-roaster turkey*. A fryer-roaster turkey is a young immature turkey (usually under 16 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 (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin, and breastbone cartilage that is somewhat less flexible than in a fryer-roaster turkey. Sex designation is optional.

(iii) *Yearling turkey*. A yearling turkey is a fully matured turkey (usually under 15 months of age) that is reasonably tender-meated and with reasonably smooth-textured skin. Sex designation is optional.

(iv) *Mature turkey or old turkey* (*hen or tom*). A mature or old turkey is an old turkey of either sex (usually in excess of 15 months of age) with coarse skin and toughened flesh.

(3) *Ducks*—(i) *Broiler duckling or fryer duckling*. A broiler duckling or fryer duckling is a young duck (usually under 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) *Roaster duckling*. A roaster duckling is a young duck (usually under 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 a duck (usually over 6 months of age), of either sex, with toughened flesh, hardened bill, and hardened windpipe.

(4) *Geese*—(i) *Young goose*. A young goose may be of either sex, is tender-meated, and has a windpipe that is easily dented.

(ii) *Mature goose or old goose*. A mature goose or old goose may be of either sex and has toughened flesh and hardened windpipe.

(5) *Guineas*—(i) *Young guinea*. A young guinea may be of either sex, is tender-meated, and has a flexible breastbone cartilage.

(ii) *Mature guinea or old guinea*. A mature guinea or an old guinea may be of either sex, has toughened flesh, and a hardened breastbone.

(b) The following standards specify the requirements for the specified cuts of poultry:

(1) ''Breasts'' shall be separated from the back at the shoulder joint and by a cut running backward and downward from that point along the junction of the vertebral and sternal ribs. The ribs may be removed from the breasts, and the breasts may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as e.g., ''chicken breasts.'' Neck skin shall not be included with the breasts, except that ''turkey breasts'' may include neck skin up to the whisker.

(2) ''Breasts with ribs'' shall be separated from the back at the junction of the vertebral ribs and back. Breasts with ribs may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without

affecting the appropriateness of the labeling as ''breasts with ribs.'' Neck skin shall not be included, except that ''turkey breasts with ribs'' may include neck skin up to the whisker.

(3) ''Wishbones'' (Pulley Bones), with covering muscle and skin tissue, shall be severed from the breast approximately halfway between the end of the wishbone (hypocledium) and front point of the breastbone (cranial process of the sternal crest) to a point where the wishbone joins the shoulder. Neck skin shall not be included with the wishbone.

(4) ''Drumsticks'' shall be separated from the thigh by a cut through the knee joint (femorotibial and patellar joint) and from the hock joint (tarsal joint).

(5) ''Thighs'' shall be disjointed at the hip joint and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(6) ''(Kind) legs'' shall be the poultry product which includes the thigh and the drumstick, i.e., the whole leg, and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(7) ''Wings'' shall include the entire wing with all muscle and skin tissue intact, except that the wingtip may be removed.

(8) ''Backs'' shall include the pelvic bones and all the vertebrae posterior to the shoulder joint. The meat shall not be peeled from the pelvic bones. The vertebral ribs and/or scapula may be removed or included without affecting the appropriateness of the name. Skin shall be substantially intact.

(9) ''Stripped backs'' shall include the vertebrae from the shoulder joint to the tail, and include the pelvic bones. The meat may be stripped off of the pelvic bones.

(10) ''Necks'', with or without neck skin, shall be separated from the carcass at the shoulder joint.

(11) ''Halves'' are prepared by making a full-length back and breast split of an eviscerated poultry carcass so as to produce approximately equal right and left sides.

(12) ''Quarters'' consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) ''Breast quarter'' consists of half a breast with the wing and a portion of the back attached.

(14) ''Breast quarter without wing'' consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) ''Leg quarter'' consists of a poultry thigh and drumstick, with a portion of the back attached.

(16) ''Thigh with back portion'' consists of a poultry thigh with back portion attached.

(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]

§ 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]

§ 381.173 Mechanically Separated (Kind of Poultry).

(a) ''Mechanically Separated (Kind of Poultry)'' is any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses that has a paste-like form and consistency, that may or may not contain skin with attached fat and meeting the other provisions of this section. Examples of such product are ''Mechanically Separated Chicken'' and ''Mechanically Separated Turkey.''

(b) ''Mechanically Separated (Kind of Poultry)'' shall not have a bone solids content of more than 1 percent. At least 98 percent of the bone particles present in ''Mechanically Separated (Kind of Poultry) '' shall have a maximum size no greater than 1.5 mm (millimeter) in their greatest dimension and there shall be no bone particles larger than 2.0 mm in their greatest dimension.

(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

(viii) The name and address of the carrier.

(2) Guaranties provided by suppliers of packaging materials under § 381.144.

(3) Records of canning as required by subpart X of this part 381, of subchapter C, 9 CFR chapter III.

(4) Records of irradiation as required by sections 381.149 of this part.

(5) Records of nutrition labeling as required by subpart Y of this part.

(6) Records of all labeling, along with the product formulation and processing procedures, as prescribed in §§ 381.132 and 381.133.

(Approved by the Office of Management and Budget under control number 0583–0015)

[37 FR 9706, May 16, 1972, as amended at 47 FR 746, Jan. 7, 1982; 49 FR 2236, Jan. 19, 1984; 51 FR 45633, Dec. 19, 1986; 57 FR 43600, Sept. 21, 1992; 58 FR 675, Jan. 6, 1993; 60 FR 67458, Dec. 29, 1995]

§ 381.176 Place of maintenance of records.

Every person engaged in any business described in § 381.175(a) shall maintain the records required by § 381.175 at the

place of business where such business is conducted, except that, if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 381.177 Record retention period.

(a) Every record required to be maintained under this subpart shall be retained for a period not to exceed 2 years after December 31 of the year in which the transaction to which the record relates has occurred, and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such record under this subpart.

(b) Records of canning as required by subpart X of this part 381, subchapter C, 9 CFR chapter III, shall be retained as required in § 381.307; except that records required by § 381.302 (b) and (c) shall be retained as required by those sections.

[37 FR 9706, May 16, 1972, as amended at 51 FR 45633, Dec. 19, 1986]

§ 381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

Every person within any of the classes specified in § 381.175(a) shall, upon the presentation of official credentials by any authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by § 381.175(b) and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records, and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

§ 381.179 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engages in the business as a public warehouseman storing any such articles in or for commerce, 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, shall register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business. Such persons shall register under this section by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, a form containing such information, within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from the Compliance Program, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(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]

§ 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.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or territory) for any year shall not exceed 50 percent of the estimated total cost of the cooperative State (or territorial) program. A cooperative program under this section is called a State-Federal program.

§ 381.186 Cooperation of States and other jurisdictions in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized under stated conditions to utilize employees and facilities of any State in carrying out Federal functions under the Poultry Products Inspection Act. A cooperative program for this purpose is called a Federal-State program. Under paragraph (a) of section 5 of the Poultry Products Inspection Act, the Administrator is also authorized to conduct examinations, investigations, and inspections under the Act through any officer or employee of any State or territory or the District of Columbia commissioned by him for such purpose.

Subpart S—Transportation; Exportation; or Sale of Poultry or Poultry Products

§ 381.189 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this subpart do not apply:

(a) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry thereof for educational, research, or other nonfood purposes shipped under permit issued by the inspector in charge upon his determination that collection and movement thereof will not interfere with inspection or sanitary conditions at the establishment, and the specimens are for nonfood purposes. The person desiring such specimens shall make a written application to the inspector in charge for such permit on Form MP–112 and shall obtain permission from the operator of the official establishment to obtain the specimens. Permits shall be issued for a period not longer than one year. The permit may be revoked by the inspector in charge if he determines after notice and opportunity to present views is afforded to the permittee that any such specimens were not used as stated in the application, or if the collection or handling of the specimens interferes with inspection or the maintenance of sanitary conditions in the establishment. The specimens referred to in this paragraph shall be collected and handled only at such time and place and in such manner as not to interfere with the inspection or to cause any objectionable condition and shall be identified as inedible when they leave the establishment.

(c) To parts of poultry carcasses that are naturally inedible by humans, such as entrails and feathers in their natural state.

[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.

Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that poultry product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Poultry product placed in any means of conveyance that is found by the inspector to be in such condition that the poultry product may have become adulterated shall be removed from the means of conveyance and handled in accordance with §381.145(b).

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 41 FR 23700, June 11, 1976; 60 FR 43358, Aug. 21, 1995]

§381.191 Distribution of inspected products to small lot buyers.

For the purpose of facilitating the distribution in commerce of inspected

poultry products to small lot buyers (such as small restaurants), distributors or jobbers may remove inspected and passed non-consumer-packaged poultry carcasses or consumer-packaged poultry products from shipping containers or immediate containers, other than consumer packages, and place them into other containers which do not bear an official inspection mark: *Provided*, That the individual non-consumer-packaged carcasses bear the official inspection legend and the official establishment number of the establishment that processed the articles; and the consumer-packaged articles are fully labeled in accordance with subpart N: *And provided further*, That the other container is marked with the name and address of the distributor or jobber and bears the statement ''The poultry product contained herein was inspected by the U.S.D.A.'' in the case of poultry products processed in the United States, or the statement ''The poultry products contained herein have been approved for importation under P.P.I.A.'' in the case of imported poultry products.

§ 381.192 Penalties inapplicable to carriers.

No carrier shall be subject to the penalties of the Act, other than the penalties for violation of section 11, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry or poultry products, owned by another person, unless the carrier has knowledge, or is in possession of facts which would cause a reasonable person to believe that such poultry or poultry products were not inspected or marked in accordance with the provisions of the Act or where otherwise not eligible for transportation under the Act, or unless the carrier refuses to furnish on request of a representative of the Secretary, the name and address of the person from whom he received such poultry or poultry products, and copies of all documents, if any there be, pertaining to the delivery of the poultry or poultry products to such carrier.

§ 381.193 Poultry carcasses, etc., not intended for human food.

(a) Except as provided in paragraph (b) of this section, poultry carcasses, and parts and products thereof, that are not intended for use as human food may, after they have been denatured as prescribed in § 381.95, be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, even though they do not comply with all the provisions of the regulations, provided they are marked ''Not fit for human food.'' These requirements do not apply to parts of poultry carcasses that are naturally inedible by humans, such as entrails.

(b)(1) Except as provided in paragraphs (b) (2), (3), and (4) of this section, no animal food processed, in whole or in part, from materials derived from the carcasses of poultry in an official establishment or elsewhere, shall be bought, sold, transported, offered for sale or transportation, or received for transportation in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in § 381.95 so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (b)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of poultry and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the poultry industry need not be denatured in accordance with § 381.95.

(3) Notwithstanding the provisions of paragraph (b)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with § 381.95 if the name of the article clearly conveys the article's intended use for animal food and appears on the label in a conspicuous manner.

(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 ⅛ 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 shall be construed to mean:

(1) *Import (Imported)*. To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) For product from eligible countries other than Canada:

(i) *Offer(ed) for entry*. The point at which the importer presents the imported product to the Program for reinspection.

(ii) *Entry (entered)*. The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with § 327.26 of this part.

(3) For product from Canada:

(i) *Offer(ed) for entry* from establishments participating in the ''streamlined'' inspection procedures. The point at which an official of the Canadian inspection system contacts the Import Field Office for an inspection assignment.

(ii) *Offer(ed) for entry* from nonparticipating establishments. The point at which the importer presents the imported product to the Program for reinspection.

(iii) *Entry (entered)* for product not subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and upon the filing of Customs Form 7533 at the port of entry or at the nearest customs-house in accordance with 19 CFR part 123.

(iv) *Entry (entered)* for product subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and the foreign inspection certificate accompanying the product is stamped as ''Inspected and Passed'' by the import inspector.

(b) No slaughtered poultry, or parts or products thereof, shall be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and they also comply with the regulations prescribed in this subpart to assure that they comply with the standards provided for in the Act: *Provided*, That the provisions of this subpart apply to such articles only if they are capable of use as human food.

(c) Except as provided in § 381.207, slaughtered poultry and other poultry products may be imported only if they were processed solely in countries listed in § 381.196(b). Slaughtered poultry may be imported only if it qualifies as ready-to-cook poultry.

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975; 54 FR 41049, Oct. 5, 1989]

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a)(1) Whenever it shall be determined by the Administrator that the system of poultry inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their poultry products, with requirements equivalent to all the provisions of the Act and the regulations in this part which are applied to official establishments in the United States, and their poultry products, and that reliance can be placed upon certificates required under this subpart from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, poultry products

processed in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section shall be eligible, so far as the regulations in this part are concerned, for importation into the United States from such foreign country after applicable requirements of this part have been met.

(2) The determination of acceptability of a foreign poultry inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of poultry inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which poultry products are processed for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing poultry inspection and to certify or refuse to certify poultry products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations.

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States with respect to:

(A) Ante mortem inspection of poultry for slaughter, which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians;

(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 not less frequently than one such visit per month to each establishment certified in accordance with paragraph (a)(3) of this section to assure that requirements referred to in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(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 Department by a responsible official of the foreign poultry 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. Eligibility of certified establishments is subject to review by the Department (including observations of the establishments by Program representatives at times prearranged with the officials of the foreign inspection system). Certifications of establishments must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may, at his discretion, terminate the eligibility of any foreign establishment for importation of its poultry products into the United States if he has information that such establishment does not comply with the requirements listed in paragraphs (a)(2) (i) and (ii) of this section or if he cannot obtain current information concerning such establishment. The Administrator will provide reasonable notice to the foreign government of the proposed termination of eligibility of any foreign establishment for importation of its poultry products into the United States unless, in his judgment, delay in terminating its eligibility could result in the importation of any adulterated or misbranded poultry products. Certifications of official establishments by the responsible official of the foreign poultry inspection system shall be in the following form:

FOREIGN OFFICIAL POULTRY ESTABLISHMENT CERTIFICATE

I hereby certify that the establishment(s) listed below fully complies (comply) with requirements of (specify foreign country) equivalent to all the provisions of the Poultry Products Inspection Act and regulations issued thereunder, which apply to official establishments in the United States, and their

poultry products, as provided in §381.196(a)(2)(i) and (ii) of the poultry products inspection regulations of the United States.

Control numbers Name
Address

_____
_____
_____

Date_____.

_____
(Signature)

_____
(Official title)

(4) Poultry products from foreign countries not listed in paragraph (b) of this section are not eligible for importation into the United States, except as provided by §§381.207 and 381.209. The listing of any foreign country under this section may be withdrawn whenever it shall be determined by the Administrator that the system of poultry inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the requirements of the Act and the regulations as applied to official establishments in the United States; or that reliance cannot be placed upon certificates required under this subpart from authorities of such foreign country; or that, for lack of current information concerning the system of poultry inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that poultry products from the following countries, covered by foreign poultry inspection certificates of the country of origin as required by §381.197, are eligible under the regulations in this subpart for entry into the United States, after inspection and marking as required by the applicable provisions of this subpart:[1]

Canada.
France.
Great Britain.
Hong Kong.
Israel.
Mexico.[2]

[37 FR 9706, May 16, 1972, as amended at 43 FR 8117, Feb. 28, 1978; 52 FR 23021, June 17, 1987; 54 FR 41049, Oct. 5, 1989; 54 FR 43951, Oct. 30, 1989; 60 FR 38668, July 28, 1995; 61 FR 38868, July 25, 1996; 64 FR 49645, Sept. 14, 1999]

§381.197 Imported products; foreign inspection certificates required.

(a) Except as provided in §§381.207 and 381.209, each consignment containing any slaughtered poultry or other poultry product consigned to the United States from a foreign country shall be accompanied with a foreign inspection certificate substantially in the form illustrated in paragraph (b) of this section.

(b) The form of foreign poultry product inspection certificate shall be as follows:

FOREIGN POULTRY PRODUCT INSPECTION CERTIFICATE

Place _____
(City)

_____
(Country)

Date _____

I hereby certify that the poultry products herein described were derived from poultry which received ante mortem and post mortem inspections at the time of slaughter; and that such poultry products are sound, healthful, wholesome, clean and otherwise fit for human food, and are not adulterated and have not been treated with and do not contain any dye, chemical, preservative, or ingredient not permitted by the regulations governing the inspection of poultry and poultry products of the U.S. Department of Agriculture, filed with me, and that said poultry products have been handled only in a sanitary manner in this country; and are otherwise in compliance with requirements at least equal to those in the Poultry Products Inspection Act and said regulations.

KIND OF PRODUCT

_____
_____
_____

Number of pieces or packages Weight

_____
_____

[1] Listing of any country in this section does not relieve the poultry products of such country from applicable requirements under other Federal laws.

[2] May export to the United States only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry products to the United States.

_____

Identification marks on containers _____

Consignor _____

Address _____

Consignee _____

Destination _____

Shipping marks _____

(Signature) _____

(Name of official of national foreign government authorized to issue inspection certificates for poultry products exported to the United States)

(Official title) _____

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975]

§ 381.198 Importer to make application for inspection of poultry products offered for entry.

(a) Each person who wishes to offer for entry any slaughtered poultry or other poultry product shall make application for inspection to the import supervisor of the import field office at the port where the poultry product is to be offered for entry, or to the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, as long as possible in advance of the anticipated arrival of each consignment of such product, except in the case of poultry product exempted from inspection by §§ 381.207 or 381.209. Each application shall state the approximate date on which the consignment is due to arrive in the United States, the name of the ship or other carrier transporting it, the name of the country where the product was processed, the name of the country from which the product was shipped, the place of destination, the quantity and kind of product, whether fresh, frozen, cured, or canned, and the point of first arrival in the United States.

(b) For participating Canadian establishments, an official of the Canadian meat inspection system shall contact the Import Field Office for an inspection assignment (see § 301.2(yyy)).

(1) If the Automated Import Information System (AIIS) does not designate the consignment for reinspection, the consignment may be transported to its consignee for further distribution.

(2) If the AIIS designates the consignment for reinspection, the official shall:

(i) Select samples in accordance with USDA sampling tables.

(ii) Identify and place samples in the vehicle for easy removal and reinspection by a Program import inspector.

(3) In the event that any one of the requirements provided in paragraph (d)(2) of this section is not met, inspection of the consignment shall be conduced by a Program import inspector in accordance with established procedures provided for in the regulations for other imported products.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 51 FR 37710, Oct. 24, 1986; 54 FR 275, Jan. 5, 1989; 54 FR 41050, Oct. 5, 1989]

§ 381.199 Inspection of poultry products offered for entry.

(a)(1) Except as provided in §§ 381.198(b)(1) and 381.209 of this part, 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, except as provided in § 381.198(b)(1).

(3) The computerized Automated Import Information System (AIIS) shall be consulted for reinspection instructions. The AIIS will assign inspection levels and procedures based on established sampling plans or established product and plant history and established sampling plans.

(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:

(i) If the defective containers are not indicative of an unsafe or unstable product as determined by the Administrator;

(ii) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(iii) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(2) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under the supervision of such inspectors in accordance with § 381.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(*c*), (d)(1)(v), (d)(1)(vii), and (d)(1)(viii) of this subchapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 381.309(d)(1)(i) of this subchapter.

(3) Sampling plans and acceptance levels as prescribed in paragraphs (d)(1) and (d)(2) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[37 FR 9706, May 16, 1972, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 45633, Dec. 19, 1986; 54 FR 275, Jan. 5, 1989; 54 FR 41050, Oct. 5, 1989]

§ 381.200 Poultry products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; facilities and assistance.

(a) No slaughtered poultry or other poultry product required by this subpart to be inspected shall be released from customs custody prior to inspection, but such product may be delivered to the consignee, or his agent, prior to inspection, if the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(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.

(c) Except as provided in § 381.200(a) or (b), no person shall remove or cause to be removed from any place designated as the place of inspection, any poultry product which the regulations in this subpart require to be marked in any way, unless the same has been

clearly and legibly marked in compliance with this subpart.

(d) Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate supervisor of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

(e) 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 establishments.)

(1) 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, 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.)

(2) Incineration or complete destruction by burning.

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

(i) Crude carbolic acid,

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

(iii) 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.

(4) Any other substances 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.

(5) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (e)(2) of this section or by burying under the supervision of an inspector.

[37 FR 9706, May 16, 1972, as amended at 48 FR 15890, Apr. 13, 1983; 50 FR 19908, May 13, 1985; 51 FR 37709, Oct. 24, 1986; 53 FR 17015, May 13, 1988; 54 FR 50735, Dec. 11, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.203 Products offered for entry; charges for storage, cartage, and labor with respect to products which are refused entry.

All charges for storage, cartage, and labor with respect to any product offered for entry which is refused entry pursuant to the regulations shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any other products offered for entry thereafter by or for such owner or consignee.

[54 FR 41050, Oct. 5, 1989]

§ 381.204 Marking of poultry products offered for entry; official import inspection marks and devices.

(a) Except for products offered for entry from Canada, poultry products which upon reinspection are found to be acceptable for entry into the United States shall be marked with the official inspection legend shown in paragraph (b) of this section. Such inspection legend shall be placed upon such

products only after completion of official import inspection and product acceptance.

(b) The official mark for marking poultry products offered for entry as ''U.S. inspected and passed'' shall be in the following form, and any device approved by the Administrator for applying such mark shall be an official device.[2]

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.

[2] The number ''I–42'' is given as an example only. The establishment number of the official establishment or official import inspection establishment where the product was inspected shall be shown on each stamp impression.

(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.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this subpart or any conditions imposed pursuant

thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination in the proceeding.

(Approved by the Office of Management and Budget under control number 0583–0015)

[51 FR 37710, Oct. 24, 1986, as amended at 53 FR 17015, May 13, 1988; 54 FR 41050, Oct. 5, 1989]

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

(a) Immediate containers of poultry products imported into the United States shall bear a label printed in English showing in accordance with subpart N of this part all information required by that section (except that the inspection mark and establishment number assigned by the foreign poultry inspection system and certified to the Inspection Service shall be shown instead of the official dressed poultry identification mark or other official inspection legend, and official establishment number); and in addition the label shall show the name of the country of origin preceded by the words ''Product of,'' which statement shall appear immediately under the name of the product.

(b) The labels shall not be false or misleading in any respect.

(c) All marks and other labeling for use on or with immediate containers shall be approved for use by the Food Safety and Inspection Service in accordance with §§ 381.132 and 381.133 before products bearing such marks and other labeling will be permitted for entry into the United States.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

Shipping containers of imported poultry products are required to bear in a prominent and legible manner the name of the product, the name of the country of origin, the foreign inspection system establishment number of the establishment in which the product was processed, and the inspection mark of the country of origin. Labeling on shipping containers shall be examined at the time of inspection in the United States and if found to be false or misleading, the product shall be refused entry. All labeling used with a shipping container of imported poultry products must be approved in accordance with subpart N of this part.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995]

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

Any poultry product (other than one which is forbidden entry by other Federal law or regulation) from any country in quantities of less than 50 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food, and which is not adulterated and contains no substance not permitted by the Act or regulations, may be imported into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part, except as provided in § 381.199(c): *And provided,* That the Department may with respect to any specific importation, require that the consignee certify that such product is exclusively for the personal use of

said consignee, or for display or laboratory analysis by said consignee, and not for sale or distribution.

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

§ 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]

§ 381.213 Notification of governmental authorities having jurisdiction over article detained; form of written notification.

Within 48 hours after the detention of any poultry or other article pursuant to § 381.211, an authorized representative of the Secretary shall give oral or written notification of such detention to any Federal authorities not connected with the Inspection Service, and any State or other governmental authorities, having jurisdiction over such article. In the event notification is given orally, it shall be confirmed in writing, as promptly as circumstances permit.

§ 381.214 Movement of poultry or other article detained; removal of official marks.

(a) No poultry or other article detained in accordance with the provisions in this subpart shall be moved by any person from the place at which it is located when so detained, until released by an authorized representative of the Secretary: *Provided,* That any such article may be moved from the place at which it is located when so detained, for refrigeration or freezing, or storage purposes if such movement has been approved by an authorized representative of the Secretary and the article so moved will be further detained by an authorized representative of the Secretary after such movement.

(b) Upon terminating the detention of such article, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the released article, and

(2) Furnish copies of a completed ''Notice of Termination of Detention'' (FSIS Form 8400–1) to the persons notified when the article was detained. The notice shall be served by either delivering the notice to such persons or by certifying and mailing the notice to such persons at their last known residences or principal offices or places of business.

(c) All official marks may be required by such representative to be removed from such article before it is released unless it appears to the satisfaction of the representative that the article is eligible to retain such marks.

[37 FR 9706, May 16, 1972, as amended at 55 FR 47843, Nov. 16, 1990]

§ 381.215 Poultry or other articles subject to judicial seizure and condemnation.

Any poultry carcass, or part thereof, or any product made wholly or in part from any poultry carcass or part thereof; except those exempted from the definition of a poultry product in § 381.15, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or is otherwise subject to the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 20 of the Act if such poultry or other article:

(a) Is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act; or

(b) Is capable of use as human food and is adulterated or misbranded; or

(c) In any other way is in violation of the Act.

§ 381.216 Procedure for judicial seizure, condemnation, and disposition.

Any poultry or other article subject to seizure and condemnation under this subpart is liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any U.S. district court, or other proper court specified in section 21 of the Act, within the jurisdiction of which the article is found.

§ 381.217 Authority for condemnation or seizure under other provisions of law.

The provisions of this subpart relating to detention, seizure, condemnation and disposition of poultry or other articles do not derogate from authority for retention, condemnation, or seizure conferred by other provisions of the Act, or other laws.

§ 381.218 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to forcible assaults on, or other interference with, any person while engaged in, or on account of the performance of, his official duties under the Act. Criminal provisions with respect to gifts or offers of bribes to such persons and related offenses are contained in the general criminal code (18 U.S.C. 201).

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 Designation of States under paragraph 5(c) of the Act.

Each of the following States has been designated, under paragraph 5(c) of the Act, as a State in which the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act shall apply to operations and transactions wholly within the State. The Federal provisions apply, effective on the dates shown below:

States	Effective date of application of Federal provisions
Alaska	July 31, 1999.
Arkansas	Jan. 2, 1971.
California	Apr. 1, 1976.
Colorado	Jan. 2, 1971.
Connecticut	Oct. 1, 1975.
Florida	Dec. 2, 1997.
Georgia	Jan. 2, 1971.
Guam	Jan. 21, 1972.
Hawaii	Nov. 1, 1995.
Idaho	Jan. 2, 1971.
Kentucky	July 28, 1971.
Maine	Jan. 2, 1971.
Maryland	Mar. 31, 1991.
Massachusetts	Jan. 12, 1976.
Michigan	Jan. 2, 1971.
Missouri	Aug. 18, 1972.
Nebraska	July 28, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978
New Jersey	Do.
New York	Apr. 10, 1977.
North Dakota	Jan. 2, 1971.
Northern Mariana Islands	Oct. 29, 1979.
Oregon	Jan. 2, 1971.
Pennsylvania	Oct. 31, 1971.
Puerto Rico	Jan. 17, 1972.
Rhode Island	Oct. 1, 1981.
South Dakota	Jan. 2, 1971.
Tennessee	Oct. 1, 1975.
Virgin Islands	Nov. 27, 1971.
Washington	June 1, 1973.

[42 FR 2949, Jan. 14, 1977, as amended at 42 FR 13270, Mar. 10, 1977; 43 FR 29269, July 7, 1978; 44 FR 55809, Sept. 28, 1979; 46 FR 43829, Sept. 1, 1981; 53 FR 20101, June 2, 1988; 55 FR 36609, Sept. 6, 1990; 56 FR 8909, Mar. 4, 1991; 60 FR 49495, Sept. 26, 1995; 60 FR 54414, Oct. 24, 1995; 62 FR 61010, Nov. 14, 1997; 64 FR 37667, July 13, 1999; 65 FR 6887, Feb. 11, 2000]

§ 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 in § 381.221 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 Circuit Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 381.132, will be granted by the Circuit 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 paragraph 4(h) of the Act.

(2) The Circuit 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 Washington, DC; office of the Labels and Packaging 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 Circuit Supervisor (showing any modifications required by the Circuit Supervisor) to the Labels and Packaging Staff, Meat and Poultry Inspection Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, 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 Circuit Supervisor must receive approval as required by § 381.132 or their use must be discontinued.

(4) The Circuit Supervisor will also review all shipping containers to insure 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.

(e) Sections 381.175 through 381.179 apply to operations and transactions not in or for commerce in a State designated under paragraph 5(c) only if the State is also designated under section 11 of the Act and if such provisions are applicable as shown in § 381.224.

(f) Section 381.185(a) will not apply to States designated under paragraph 5(c) of the Act.

(g) Provisions of this part relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 62 FR 45027, Aug. 25, 1997]

§ 381.223 Control and disposition of nonfederally inspected poultry products in States designated under paragraph 5(c) of the Act.

Upon the effective date of designation of a State under paragraph 5(c) of the Act, no poultry products can be processed within the State unless they are prepared under inspection pursuant to the regulations or are exempted from the requirement of inspection under § 381.10, and no unexempted poultry products which were processed without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, poultry products which were processed in any State listed in § 381.187 and inspected and passed under the supervision of a responsible State or local inspection agency or exempted from State inspection can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend shall not be used. Such products may not enter official establishments. After said 90-day period, only federally inspected and passed products may be distributed within the designated State, except as provided in § 381.10.

§ 381.224 Designation of States under section 11 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 11 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(b): §§ 381.175–381.178.	Persons engaged (not in or for commerce) in (1) the business of slaughtering any poultry or processing, freezing, packaging, or labeling any poultry carcasses, or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a poultry products broker, wholesaler, or otherwise), transporting or storing any poultry carcasses, or parts or products thereof; or (3) business as a renderer or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maine	Mar. 31, 1991.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Missouri	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		North Dakota	Oct. 29, 1979.
		Northern Mariana Islands.	Jan. 31, 1975.
		Oregon	May 2, 1974.
		Pennsylvania	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Oct. 1, 1975.
		Tennessee	Nov. 19, 1976.
		Virgin Islands	Jan. 31, 1975.
		Washington	Nov. 12, 1976.

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(c); § 381.179	Persons engaged (not in or for commerce) in business as a poultry products broker; renderer; animal food manufacturer; wholesaler or public warehouseman of poultry carcasses, or parts or products thereof; or buying, selling, or transporting dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maine	Mar. 31, 1991.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Minnesota	Jan. 31, 1975.
		Missouri	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		North Dakota	Oct. 29, 1979.
		Northern Mariana Islands.	Jan. 31, 1975.
		Oregon	May 2, 1974.
		Pennsylvania	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Oct. 1, 1975.
		Tennessee	Nov. 19, 1976.
		Virgin Islands	Jan. 31, 1975.
		Washington	Nov. 12, 1976.
Act, 11(d); 381.194	Persons engaged (not in or for commerce) in the business of buying, selling or transporting any dead, dying, disabled or diseased poultry, or parts or carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Nov. 12, 1976.
		Maine	Mar. 31, 1991.
		Maryland	Nov. 12, 1976.
		Michigan	Oct. 29, 1979.
		New Hampshire	Oct. 29, 1979.
		Northern Mariana Islands.	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Nov. 19, 1976.
		Virgin Islands	Nov. 12, 1976.

[37 FR 9706, May 16, 1972; 65 FR 6888, Feb. 11, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 381.224, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 381.225 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of poultry products therein.

(a) An establishment in any State not listed in § 381.221 that is preparing poultry products solely for distribution within such State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any poultry product processed at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is ''unsafe'' within the meaning of section 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) 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 (for example, it was prepared from a poultry carcass or other ingredients exhibiting spoilage characteristics); or it is, or was prepared from, a poultry carcass which would be required to be condemned under subpart K at official establishments; or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example, if insects or vermin are not effectively controlled at the establishment, or insanitary water is used in preparing poultry products for human food); or

(iv) It is, in whole or in part, the product of poultry that died otherwise than by slaughter; or

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

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by an inspector as one producing adulterated poultry products which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Inspection Service. When it is determined by the Regional Director that any establishment preparing poultry products solely for distribution within any State is producing adulterated poultry products for distribution within such State which would clearly endanger the public 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.

Subpart X—Canning and Canned Products

SOURCE: 51 FR 45634, Dec. 19, 1986, unless otherwise noted.

§ 381.300 Definitions.

(a) *Abnormal container*. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product*. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) *Bleeders*. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product*. A poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term ''product'' as used in this subpart G shall mean ''canned product.''

(e) *Closure technician*. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) *Code lot*. All production of a particular product in a specific size container marked with a specific container code.

(g) *Come-up time*. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(h) *Critical factor*. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace*. That portion of a container not occupied by the product.

(1) *Gross headspace*. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace*. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers*. Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container*. A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(2) *Semirigid container*. A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(3) *Flexible container*. A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests*. Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature*. The temperature, determined at the initiation of a

thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product*. A canned product in which any component has a pH value above 4.6.

(n) *Process schedule*. The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature*. The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time*. The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority*. The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) *Program employee*. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort*. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals*. Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability*. The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process*. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) *Venting*. The removal of air from a retort before the start of process timing.

(x) *Water activity*. The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 381.301 Containers and closures.

(a) *Examination and cleaning of empty containers*. (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*. (1) Visual examinations. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at

least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(*a*) *Micrometer measurement.* For cylindrical containers, measure the following dimensions (Figure 1) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

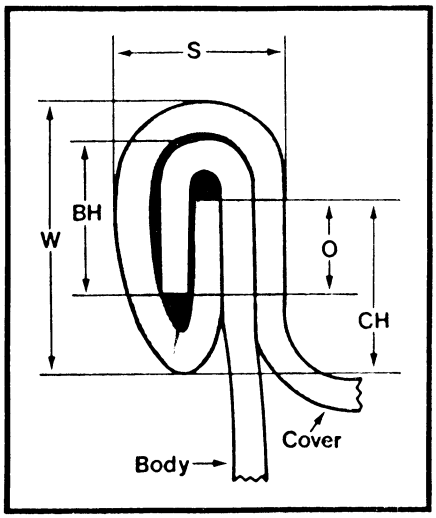
(*1*) Double seam length—W;

(*2*) Double seam thickness—S;

(*3*) Body hook length—BH; and

(*4*) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(*b*) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers.* Examination of noncylindrical containers (e.g., square, rectangular, ''D''-shaped, and irregularly-shaped)

shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers.* (1) *Visual examinations.* A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect

the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

(Approved by the Office of Management and Budget under control number 0583–0015)

§ 381.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 381.300(n) of this subpart) for each canned poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

(Approved by the Office of Management and Budget under control number 0583–0015)

§ 381.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(d) *Steam/air retorts.* (1) Steam/air ratio; and

(2) Heating medium flow rate.

(Approved by the Office of Management and Budget under control number 0583–0015)

§ 381.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by § 381.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 381.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems*—(1) *Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be

maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55 °F/inch (or 12 °C/cm) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations shall not exceed 2 °F (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) *Steam controllers.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to the retorts designed for pressure processing in steam shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam*—(1) *Batch still retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet*. The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) *Crate supports*. Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) *Steam spreader*. Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) *Bleeders and condensate removal*. Bleeders, except those for external wells of temperature devices, shall have ⅛ inch (or 3 mm) or larger openings and shall be wide open during the entire process including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container, a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) *Stacking equipment*. (*a*) Equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(*b*) *Divider plates*. Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This information shall be made available to Program employees for review.

(viii) *Bleeder and vent mufflers*. If mufflers are used on bleeders or vent systems, the establishment shall have on

file documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) *Vents.* (*a*) Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(*b*) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(*c*) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*d*) For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*e*) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(*1*) Venting horizontal retorts.

(*i*) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

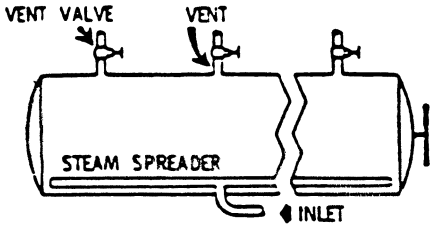


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents shall not be more than 2½ feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*ii*) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

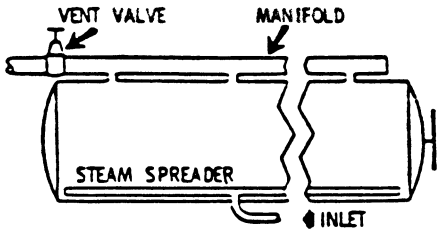


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2½ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2½ inches (6.4

cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(*iii*) Venting through water spreaders.

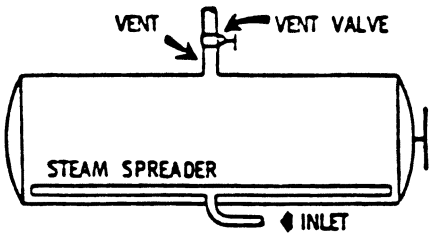


Figure 4.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2½ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1½ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*iv*) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

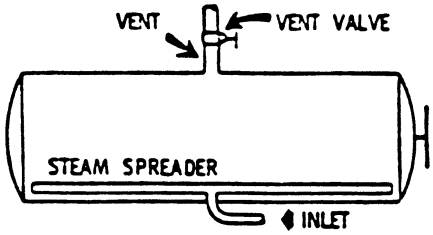


Figure 4.

Specifications (Figure 4): A 2½ inch (6.4 cm) vent equipped with a 2½ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(*2*) Venting vertical retorts.

(*i*) Venting through a 1½ inch (3.8 cm) overflow.

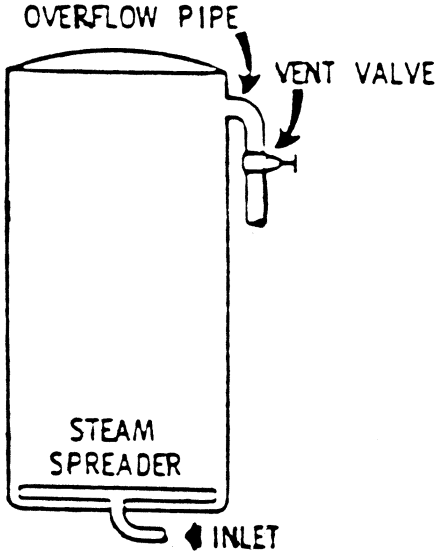


Figure 5.

Specifications (Figure 5): A 1½ inch (3.8 cm) overflow pipe equipped with a 1½ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1½ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(*ii*) Venting through a single 1 inch (2.5 cm) side or top vent.

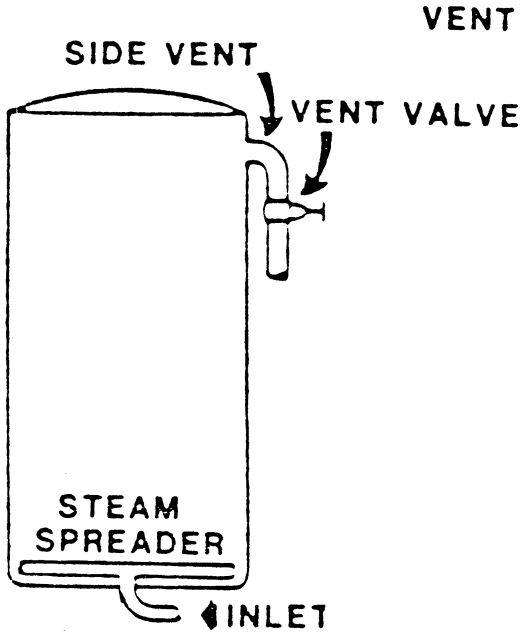


Figure 6.

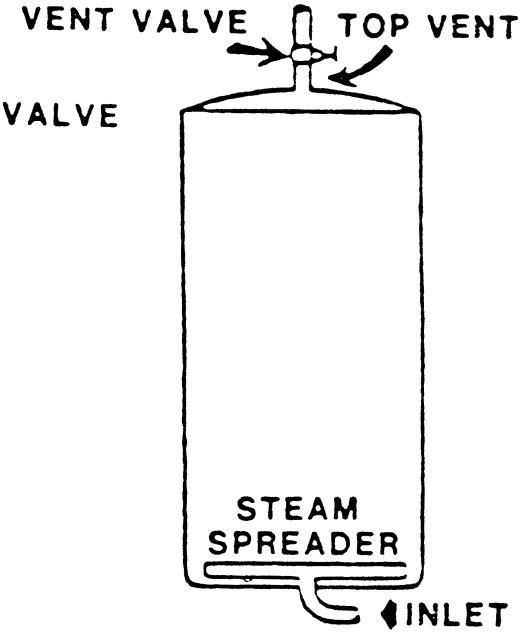


Figure 7.

Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) *Batch agitating retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (or 3 mm) or larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers, at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the

bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort or reel speed timing.* The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(3) *Continuous rotary retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort.

Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort speed timing.* The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) *Hydrostatic retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet*. The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) *Bleeders*. Bleeder openings ¼ inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) *Venting*. Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) *Conveyor speed*. The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers*. If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water*—(1) *Batch still retorts*. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) *Pressure recording device*. Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution*. Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) *Crate supports*. A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) *Stacking equipment*. For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure

that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(vii) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) *Air supply and controls.* In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) *Water recirculation.* When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) *Batch agitating retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperture/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that

there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) *Stacking equipment.* All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) *Air supply and controls.* Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) *Retort or reel speed timing.* The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) *Water recirculation.* If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained

on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry*. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts*. (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) *Recording pressure controller*. A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) *Circulation of steam/air mixture*. A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment manufacturer for details of installation, operation and control.

(e) *Atmospheric cookers*—(1) *Temperature/time recording device*. Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution*. Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems*. All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

(g) *Equipment maintenance*. (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type

of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water.* (1) Potable water shall be used for cooling except as provided for in paragraphs (h) (2) and (3) of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers.* Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

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[51 FR 45634, Dec. 19, 1986, as amended at 65 FR 34390, May 30, 2000]

§ 381.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: Date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 381.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) *Processing in steam*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and

temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in §381.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§381.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation and other data as necessary to enable correlation with the records required in §381.306. Each entry on a record shall be made at the time the specific event occurs, and the

recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 381.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 381.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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[51 FR 45634, Dec. 19, 1986, as amended at 65 FR 34390, May 30, 2000]

§ 381.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or,

(ii) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(iii) Paragraph (d) of this section.

(2) Paragraph (d) of this section.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or,

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 381.302 (a) and (b) and is filed with the inspector in accordance with § 381.302(c); or,

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(*a*) A complete description of the deviation along with all necessary supporting documentation;

(*b*) A copy of the evaluation report; and,

(*c*) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section or in accordance with the following procedures:

(*a*) Emergency stops.

(*1*) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 381.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(*2*) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 381.306.

(*b*) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(*1*) For temperature drops of less than 10 °F (or 5.5 °C) either (*i*) all containers in the retort shall be given an emergency still process (developed per § 381.302(b)) before the reel is restarted; (*ii*) container entry to the retort shall be prevented and an emergency agitating process (developed per § 381.302(b)) shall be used before container entry to the retort is restarted; or (*iii*) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(*2*) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per § 381.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 381.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'' as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(2) *Deviations identified through record review*. Whenever a deviation is noted during review of the processing and production records required by § 381.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) *Process deviation file*. The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the

disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 381.307(e) and shall be made available to Program employees upon request.

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[51 FR 45634, Dec. 19, 1986, as amended at 62 FR 45027, Aug. 25, 1997; 65 FR 34390, May 30, 2000; 65 FR 53533, Sept. 5, 2000]

§ 381.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination; or

(2) An FSIS-approved total quality control system; or

(3) Alternative documented procedures that will ensure that only product that is safe and stable is shipped in commerce; or

(4) Paragraph (d) of this section.

(b)–(c) [Reserved]

(d) Procedures for finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator*. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature*. The incubation temperature shall be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation*. Shelf stable product requiring incubation includes:

(*a*) Low acid products as defined in § 381.300(m); and

(*b*) Acidified low acid products as defined in § 381.300(b).

(iv) *Incubation samples*. (*a*) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(*b*) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(*c*) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time*. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance*. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 381.307(e).

(vii) *Abnormal containers*. The finding of abnormal containers (as defined in § 381.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping*. No product shall be shipped from the establishment before

the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion of the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition.* (i) *Normal containers.* Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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[51 FR 45634, Dec. 19, 1986, as amended at 57 FR 37872, Aug. 21, 1992; 57 FR 55443, Nov. 25, 1992; 62 FR 45027, Aug. 25, 1997; 65 FR 34391, May 30, 2000; 65 FR 53533, Sept. 5, 2000]

§ 381.310 Personnel and training.

All operators of thermal processing systems specified in § 381.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

[51 FR 45634, Dec. 19, 1986]

§ 381.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

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Subpart Y—Nutrition Labeling

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

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling shall be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw products, in accordance with the requirements of § 381.409, except as exempted under § 381.500 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products in accordance with the requirements of §§ 381.409 and 381.445. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 381.443 and 381.444 of this subpart.

[58 FR 675, Jan. 6, 1993, as amended at 60 FR 197, Jan. 3, 1995]

§ 381.401 [Reserved]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of a packaged poultry product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Poultry products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not

provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 40215, Aug. 8, 1994]

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 381.121(c)(7).

§ 381.409 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, the serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amount(s)) that appear in § 381.412(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _____ program'' (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 381.412(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products may be declared on the basis of the product ''as consumed'' as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of ''as packaged'' for products other than single ingredient, raw products, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., chicken wings, and individually packaged products within a multi-serving package), 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 in discrete units (e.g., chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(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., ⅛ quiche, ¼ 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 ½, ⅓, ¼, ⅕, ⅙, 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., ¼ 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 ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1⅔ 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 ¼-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 meal-type products 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).

(v) 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), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 381.412(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size, the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement (e.g., varied (approximately 8 servings per pound)).

(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.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of 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) Serving size for meal-type products as defined in §381.413(l) shall be the entire content (edible portion only) of the package.

(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 Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. 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;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference. Pages 9–11, 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.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference 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.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) ''Calories from fat'': A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of ''calories from fat'' is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total

lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½)-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.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-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.

(A) ''Stearic Acid'' (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (½)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated 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 polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-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 (½)-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 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.

(iii) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (e.g., ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content

shall be indented 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.

(iv) ''Other carbohydrate'' (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented 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.

(7) ''Protein'': A statement of the number of grams of protein 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, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 381.409(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert

Consultation on Protein Quality Evaluation,'' Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' as published by the Food and Agriculture Organization of the United Nations/World Health Organization, 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 Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. 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
Folate, 0.4 milligram
Vitamin B_{12}, 6 micrograms
Biotin, 0.3 milligram
Pantothenic acid, 10 milligrams
Phosphorus, 1.0 gram
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., ''Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	grams (g)	65
Saturated fatty acids	.....do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	.....do	25
Sodium	milligrams (mg)	2400
Potassium	.....do	3500
Protein	grams (g)	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 381.500(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(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.

(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 declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: 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	65 g	80 g
Saturated fat ...	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2400 mg	2400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed ''2,000'' and value of 65 g in the column headed ''2,500.''

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which

the footnote required by paragraph (d)(9) of the section is given to the far 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

(13)(i) Nutrition labeling on the outer label of packages of poultry products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., poultry salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both ''raw'' and ''cooked'') or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of ''Amount Per Serving,'' there shall be two or more column headings accurately describing the forms of the same product (e.g., ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., ½ cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., ''Total fat (2 g)*'') referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading ''% DAILY VALUE'' and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(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

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that

amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, sodium, and protein;

(ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of _____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 381.500(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed 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.''

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 381.402(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title ''Nutrition Facts'' and is allowed for nutrient names for ''Calories,'' ''Total fat,'' ''Cholesterol,'' ''Sodium,'' ''Total carbohydrate,'' and ''Protein.''

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from fat—Fat cal
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
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 Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(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.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

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§§ 381.410–381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground poultry), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(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
Bacon; e.g., poultry breakfast strips.	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1.	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco filings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	114g
Canned poultry, canned chicken, canned [4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; [5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash, poultry lasagna, poultry-filled pasta.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad.	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
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	¼ 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.		

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]—Continued

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ 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.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in §381.413(d), such as a ''low calorie'' version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving

size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) 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.

(4) Data accompanying the labeling application, such as food consumption data, 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.

(5) 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.

(6) 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.

(7) Labeling applications for a new Reference Amount and/or Product Category 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 381.412 with respect to Reference Amount and/or Product Category.

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.

(9) 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.

(10) 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 Reference Amount and/or Product Category 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 Reference Amount and/or Product Category.

(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.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also 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 Reference Amount and/or Product Category.

(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 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.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 207, Jan. 3, 1995]

§ 381.413 Nutrient content claims; general principles.

(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]

(i) Except as provided in § 381.409 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart Y of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 381.121(c) for the net quantity of contents, 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);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 381.462(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either

the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product' '' or ''⅓ fewer calories than 'reference product' ''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by §381.121(c) for net quantity of contents, 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 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'' shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with §381.409 shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with §381.409(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in §381.412(b) through

(e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 381.412(f) (e.g., ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 381.121(c) for net quantity of contents, 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 criteria 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).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 381.409 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 381.469.

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 40215, Aug. 8, 1994; 59 FR 45198, Sept. 1, 1994; 60 FR 208, Jan. 3, 1995]

§§ 381.414–381.442 [Reserved]

§ 381.443 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw poultry products, as identified in § 381.444, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw poultry products, listed in § 381.444, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 381.444 Identification of major cuts of poultry products.

The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw poultry products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer or manufacturer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either ''as consumed'' or ''as packaged.'' In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen.

(2) A retailer may choose to provide nutrition information at the point-of-purchase, 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 requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an ''as packaged'' or ''as consumed,'' basis;

(ii) 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

(iii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 381.409(f) for the mandatory nutrition labeling program.

(d) The nutrition label data should 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 should 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 published form, the Agriculture Handbook No. 8 series, 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 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]

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV), established for that nutrient (excluding total carbohydrate) in § 381.409(c), 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) *''High'' claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains a food that meets the definition of ''high'' in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of broccoli in this meal is high in vitamin C'').

(c) *''Good Source'' claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in § 381.413(l), provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in § 381.462(b)(2) or, in the case of a meal-type product, is not ''low'' in total fat as defined in § 381.462(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *''More'' claims.* (1) 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 a product, except meal-type products as defined in § 381.413(l), 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 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 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 than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient 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., ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per 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), 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 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]

§ 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), 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 (33⅓ 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., ''⅓ 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.

(4) A ''light'' claim may not be made on a product for which the reference

product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; 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 was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); 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.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; 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 was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); 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.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 381.413(l), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in § 381.460(b)(3); or

(B) ''Low in fat'' as defined in § 381.462(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (e.g., ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that the product meets the definition of ''low in sodium'' as defined in § 381.461(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(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 ⅓ 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]

§§ 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.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories 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 does not provide more than 40 calories 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 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.

(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), provided that:

(i) The product contains 120 calories or less 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 calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories 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 calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—''33 ⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories 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., ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(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), provided that:

(i) The product contains at least 25 percent fewer calories 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 calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories 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., ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(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, 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), 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), provided that:

(i) The product contains at least 25 percent less sugars 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 sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sugar 'product'—25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient 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., ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

[60 FR 211, Jan. 3, 1995]

§ 381.461 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in 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) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium 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 sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium;'' and

(iii) 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.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 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 35 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.

(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), 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), 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), 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), 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), 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:

(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'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium 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., ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 213, Jan. 3, 1995; 60 FR 5762, Jan. 30, 1995]

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products 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) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat 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 fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) 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.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(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), 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), 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), 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;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''_____ percent fat free'' is ''_____ percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,'' ''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat 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 saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or

reformulation to lower saturated 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.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated 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 (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated 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 saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or ''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less saturated 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 saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated 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., ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(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 saturated fat.''

(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), 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), 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), 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), 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

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol 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

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) 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 the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol 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 has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''low cholesterol 'product', contains 85 percent less cholesterol than our regular '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., ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) 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 the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute for those products as specified in § 381.413(d), excluding meal-type products as defined in § 381.413(l), provided that:

(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 reference amount customarily consumed; 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 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., ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(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 cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(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).

(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).

[60 FR 214, Jan. 3, 1995]

§ 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 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 360 mg of sodium, except that it shall not contain more than 480 mg of sodium effective through January 1, 2003, 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:

(i) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 480 mg of sodium, except that it shall not contain more than 600 mg of sodium effective through January 1, 2003, per labeled serving size; and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 381.409 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh at least 6 oz but less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh 10 oz or more per serving (container), shall meet the

level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 217, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999]

§§ 381.464–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(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)

(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 nutrient content claim 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 nutrient content claim.

(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 labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also 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 nutrient content claim.

(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 final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term 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 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)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

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 implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation,

and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product 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.

Yours very truly,

Applicant _____

By _____

(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 implied nutrient content claim 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 implied nutrient content claim.

(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 labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or

misleading. The notification letter shall also 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 implied nutrient content claim.

(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.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) ''Sugar free'' and ''no added sugar''. Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in § 381.460(c).

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 217, Jan. 3, 1995]

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry products are exempt from nutrition labeling:

(1) Food products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment.

(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. 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]