List of Subjects in 7 CFR Part 906

Marketing agreements and orders, Texas grapefruit, Oranges.

For the reasons set forth in the preamble, 7 CFR Part 906 is amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN THE LOWER RIO GRANDE VALLEY IN TEXAS

1. The authority citation for 7 CFR Part 906 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Accordingly, the interim final rule amending § 906.340, which was published in the **Federal Register** (53 FR 37729, September 28, 1988; and corrected at 53 FR 43319, October 26, 1988), is adopted as a final rule without change.

Note: This section will appear in the Code of Federal Regulations.

Dated: December 7, 1988.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 88–28451 Filed 12–9–88; 8:45 am]

BILLING CODE 3410–02–M

Food Safety and Inspection Service

9 CFR Parts 301, 304, 305, 313, 318 and 327

[Docket No. 87–022F]

Mandatory Meat Inspection; Definitions

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule; amendment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to arrange the terms defined in § 301.2 (9 CFR 301.2) in alphabetical order and to make minor clerical revisions in certain of those definitions. The definitions of terms in § 301.2 are being rearranged to permit easier reference to them. Four of the definitions are amended by removing the pronoun "his" and replacing it with the pronouns "his/her" to correct gender terminology within the text of the definitions. The definition for "circuit supervisor" is amended to remove the term "circuit" for clarity. The definition of the term "program" is revised to reflect organizational units that are involved in the administration of inspectional activities. In addition, §§ 304.1(b), 305.5(c), 313.1(c), 318.308(d)(vi)(*a*)(*1*), and 327.5(a), which contain references to certain terms defined in § 301.2 are being amended to be consistent with § 301.2 as revised.

EFFECTIVE DATE: December 12, 1988.

FOR FURTHER INFORMATION CONTACT: Ralph E. Stafko, Director, Policy Office, Policy and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 447–8168.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined that this final rule is not a "major rule" within the scope of Executive Order 12291. It would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises or export markets. This rule requires administrative changes only and the costs of such action are minor.

Effect on Small Entities

The Administrator has determined that this action will not have a significant economic impact upon a substantial number of small entities as defined by the Regulatory Flexibility Act, Pub. L. 96–354 (5 U.S.C. 601 *et seq.*) because only nonsubstantive administrative changes are being made and do not effect any member of the public.

It has been decided that the list of terms and definitions in § 301.2 (CFR 301.2) be arranged in alphabetical order so that they will be easier to find in the text. FSIS has considered and adopted the recommendation that the terms be arranged alphabetically in § 301.2, accordingly.

List of Subjects

9 CFR Part 301

Meat inspection.

9 CFR Part 304

Meat inspection.

9 CFR Part 305

Meat inspection.

9 CFR Part 313

Meat inspection.

9 CFR Part 318

Meat inspection.

9 CFR Part 327

Meat inspection.

For reasons set forth in the preamble, Title 9, Subchapter A, Parts 301, 304, 305, 313, 318, and 327 are amended as set forth below.

PART 301—[AMENDED]

1. The authority citation for Part 301 continues to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*

2. Section 301.2 is amended by rearranging and revising the terms in alphabetical order and revising the definition of the term "program" as follows (in effect, paragraphs (a) through (iii) and (kkk) through (yyy) are revised, paragraph (jjj) is added, and paragraph (zzz) is removed):

§ 301.2 Definitions.

* * * * *

(a) *The Act.* The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 21 U.S.C., sec. 601 *et seq.*).

(b) *Administrator.* The Administrator of the Food Safety and Inspection Service or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his/her stead.

(c) *Adulterated.* This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If it bears or contains any such 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;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive) which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) 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;

(iv) 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 deemed adulterated under paragraphs (aa)(2) (ii), (iii), or (iv) 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 subchapter in official establishments;

(3) 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;

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

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

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

(7) 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;

(8) 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; or,

(9) If it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise adulterated.

(d) *Anesthesia.* Loss of sensation or feeling.

(e) *Animal food.* Any article intended for use as food for dogs, cats, or other animals derived wholly, or in part, from the carcass or parts or products of the carcass of any livestock, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Livestock or poultry feeds manufactured from processed livestock byproducts (such as meatmeal tankage, meat and bonemeal, bloodmeal, and feed grade animal fat).

(f) *Animal food manufacturer.* Any person engaged in the business of manufacturing or processing animal food.

(g) *Area.* One or more circuits under the supervision of an area supervisor.

(h) *Area Supervisor.* The official in charge of an area.

(i) *Artificial coloring.* A coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(j) *Artificial flavoring.* A flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(k) *Biological residue.* Any substance, including metabolites, remaining in livestock at time of slaughter or in any of its tissues after slaughter as the result of treatment or exposure of the livestock to a pesticide, organic or inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other therapeutic or prophylactic agent.

(l) *Capable of use as human food.* This term applies to any carcass, or part or product of a carcass, of any livestock, unless it is denatured or otherwise identified as required by the applicable provisions of §§ 314.3, 314.10, 325.11, and 325.13 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., hoofs or horns in their natural state.

(m) *Captive bolt.* A stunning instrument which when activated drives a bolt out of a barrel for a limited distance.

(n) *Carbon dioxide.* A gaseous form of the chemical formula CO_2.

(o) *Carbon dioxide concentration.* Ratio of carbon dioxide gas and atmospheric air.

(p) *Carcass.* All parts, including viscera, of any slaughtered livestock.

(q) *Chemical preservative.* Any chemical that, when added to a meat or meat food product, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices or substances added to meat and meat food products by exposure to wood smoke.

Other definitions, if any, that are applicable only for purposes of a specific part of the regulations in this subchapter, are set forth in such part.

(r) *Circuit.* One or more official establishments included under the supervision of a circuit supervisor.

(s) *Circuit supervisor.* The supervisor of a circuit.

(t) *Commerce.* 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.

(u) *Consciousness.* Responsiveness of the brain to the impressions made by the senses.

(v) *Cutting up.* Any division of any carcass or part thereof, except that the trimming of carcasses or parts thereof to remove surface contaminants is not considered as cutting up.

(w) *Dead livestock.* The body (cadaver) of livestock which has died otherwise than by slaughter.

(x) *The Department.* The United States Department of Agriculture.

(y) *Dying, diseased, or disabled livestock.* Livestock which has or displays symptoms of having any of the following:

(1) Central nervous system disorder;

(2) Abnormal temperature (high or low);

(3) Difficult breathing;

(4) Abnormal swellings;

(5) Lack of muscular coordination;

(6) Inability to walk normally or stand;

(7) Any of the conditions for which livestock is required to be condemned on ante-mortem inspection in accordance with the regulations in Part 309 of this subchapter.

(z) *Edible.* Intended for use as human food.

(aa) *Experimental animal.* Any animal used in any research investigation involving the feeding or other administration of, or subjection to, an experimental biological product, drug, or chemical or any nonexperimental biological product, drug, or chemical used in a manner for which it was not intended.

(bb) *Exposure time.* The period of time an animal is exposed to an anesthesia-producing carbon dioxide concentration.

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

(dd) *Firm.* Any partnership, association, or other unincorporated business organization.

(ee) *Food Safety and Inspection Service.* The Food Safety and Inspection Service of the Department.

(ff) *Further processing.* Smoking, cooking, canning, curing, refining, or

rendering in an official establishment of product previously prepared in official establishments.

(gg) *Immediate container.* The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

(hh) *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).

1IFO #6. Miami, FL—Covering the areas of southern Florida, Puerto Rico and the Virgin Islands.

1IFO #7. New Orleans, LA—Covering the States of Louisiana, Mississippi, Alabama, Arkansas, Texas, Oklahoma, Kansas, New Mexico and Colorado.

1IFO #8. San Pedro, CA—Covering the States of Hawaii, Arizona, Utah, Nevada, the area of southern California, American Samoa, Guam, and the Northern Marianas.

1IFO #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.

1IFO #10. Detroit, MI—Covering the States of Michigan, Wisconsin, Minnesota, Iowa, Missouri, Illinois, Indiana and Ohio.

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

(jj) *Inedible.* Adulterated, uninspected, or not intended for use as human food.

(kk) *Inhumane slaughter or handling in connection with slaughter.* Slaughter or handling in connection with slaughter not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901 through 1906, as amended by the Humane Methods of Slaughter Act of 1978, 92 Stat. 1069) and Part 313 of this subchapter.

(ll) *"Inspected and passed" or "U.S. Inspected and Passed" or "U.S. Inspected and Passed by Department of Agriculture" (or any authorized abbreviation thereof).* This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

(mm) *Inspector.* An inspector of the Program.

(nn) *Inspector in charge.* A designated program employee who is in charge of one or more official establishments within a circuit and is responsible to the circuit supervisor or his/her designee.

(oo) *Label.* A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(pp) *Labeling.* All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

(qq) *Livestock.* Cattle, sheep, swine, goat, horse, mule, or other equine.

(rr) *Meat.* The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(ss) *Meat broker.* Any person engaged in the business of buying or selling carcasses, parts of carcasses, meat or meat food products of livestock on commission, or otherwise negotiating purchases or sales of such articles other than for his/her own account or as an employee of another person.

(tt) *Meat byproduct.* Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(uu) *Meat food product.* Any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the Administrator in specific cases or by the regulations in Part 317 of this subchapter, upon a determination that they contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. This term, as applied to food products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(vv) *Misbranded.* This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

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

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

(3) 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;

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

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

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

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in Part 317 of this subchapter with respect to the quantity of contents;

(6) 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;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in Part 319 of this subchapter unless:

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

(ii) 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;

(8) 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 the regulations in Part 319 of this subchapter, and it 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;

(9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:

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

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in Part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in Part 317 of this subchapter.

(11) 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 by the regulations in Part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in Part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such 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.

(ww) *Nonfood compound.* 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 meat food and meat products, excluding labeling and packaging materials as covered in Part 317 of the subchapter.

(xx) *Official certificate.* Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

(yy) *Official device.* Any device prescribed by the regulations in Part 312 of this subchapter for use in applying any official mark.

(zz) *Official establishment.* Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

(aaa) *Official import inspection establishment.* This term means any establishment, other than an official establishment as defined in paragraph (zz) of this section, where inspections are authorized to be conducted as prescribed in § 327.6 of this subchapter.

(bbb) *Official inspection legend.* Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

(ccc) *Official mark.* The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act.

(ddd) *Packaging material.* Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for meat products.

(eee) *Person.* Any individual, firm, or corporation.

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

(ggg) *Prepared.* Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(hhh) *Product.* Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

(iii) *Program.* The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

(jjj) *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.

(kkk) *Regional Director.* The official [1] in charge of the program within each of the following regions:

Northeastern Region—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Virginia (except for Northwestern part).

Southeastern Region—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia (Northwestern), West Virginia, Puerto Rico, and the Virgin Islands.

North Central Region—Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, and Wisconsin.

Southwestern Region—Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas.

Western Region—Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming, American Samoa, Guam, and the Northern Mariana Islands.

(lll) *Renderer.* Any person engaged in the business of rendering carcasses or parts or products of the carcasses of any livestock except rendering conducted under inspection or exemption under Title I of the Act.

(mmm) *Secretary.* The Secretary of Agriculture of the United States or his/her delegate.

(nnn) *Shipping container.* The outside container (box, bag, barrel, crate, or other receptacle or covering) containing or wholly or partly enclosing any product packed in one or more immediate containers.

(ooo) *State.* Any State of the United States or the Commonwealth of Puerto Rico.

(ppp) *Supervision.* The controls, as prescribed in instructions to Program 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 subchapter.

(qqq) *Surgical anesthesia.* A state of unconsciousness measured in conformity with accepted surgical practices.

(rrr) *Territory.* Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(sss) *U.S. Condemned.* This term means that the livestock so identified has been inspected and found to be in a dying condition, or to be affected with any other condition or disease that would require condemnation of its carcass.

(ttt) *U.S. Inspected and Condemned (or any authorized abbreviation thereof).* This term means that the carcass, viscera, other part of carcass, or other product so identified has been inspected, found to be adulterated, and condemned under the regulations in this subchapter.

(uuu) *U.S. Passed for Cooking.* This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be cooked or rendered as prescribed

---

[1] The addresses of the Regional Directors are as follows:

Northeastern Region—Seventh Floor, 1421 Cherry Street, Philadelphia, PA 19102.

Southeastern Region—Room 299 South, 1718 Peachtree Street, NW., Atlanta, GA 30309.

North Central Region—607 East Second Street, Des Moines, IA 50309.

Southwestern Region—Room 5–F41, 1100 Commerce Street, Dallas, TX 75201.

Western Region—Room 620 Central Avenue, Building 2C, Alameda, CA 94501.

by the regulations in Part 315 of this chapter.

(vvv) *U.S. Passed for Refrigeration.* This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be refrigerated or otherwise handled as prescribed by the regulations in Part 311 of this subchapter.

(www) *U.S. Retained.* This term means that the carcass, viscera, other part of carcass, or other product, or article so identified is held for further examination by an inspector to determine its disposal.

(xxx) *U.S. Suspect.* This term means that the livestock so identified is suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, when slaughtered, and is subject to further examination by an inspector to determine its disposal.

(yyy) *United States.* The States, the District of Columbia, and the Territories of the United States.

PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

2. The authority citation for Part 304 continues to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 466–466k.

§ 304.1 [Amended]

3. Section 304.1(b) is amended by removing "§ 301.2(iii)" and inserting in its place "§ 301.2(kkk)".

PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

4. The authority citation for Part 305 continues to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 466–466k.

§ 305.5 [Amended]

5. Section 305.5(c) is amended by removing "§ 301.2(ooo) (9 CFR 301.2(ooo))" and inserting in its place "§ 301.2(kk) (9 CFR 301.2(kk)."

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

6. The authority citation for Part 313 continues to read as follows:

Authority: 92 Stat. 1069, 72 Stat. 862, 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 91, 438; 21 U.S.C. 71 *et seq.*; 601 *et seq.*; 7 U.S.C. 1901–1906.

§ 313.1 [Amended]

7. Section 313.1(c) is amended by removing "§ 301.2(gg)" and "§ 301.2(ccc)" and replacing with "§ 301.2(xxx)" and "§ 301.2(y)", respectively.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

8. The authority citation for Part 318 continues to read as follows:

Authority: 34 Stat. 1260 as amended, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*), 72 Stat. 862, 92 Stat. 1069, as amended (7 U.S.C. 1901 *et seq.*), 76 Stat. 663 (7 U.S.C. 450 *et seq.*).

Subpart G—Canning and Canned Products

§ 318.308 [Amended]

9. Section 318.308(d)(vi)(*a*(*1*) is amended by removing "§ 301.2(ee)" and inserting in its place "§ 301.2(ttt)".

PART 327—IMPORTED PRODUCTS

10. The authority citation for Part 327 continues to read as follows:

Authority: 38 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*

§ 327.5 [Amended]

11. Section 327.5(a) is amended by removing "§ 301.2(yyy)" and inserting in its place "§ 301.2(hh).".

The amendments are not substantive changes and do not affect any member of the public. Therefore, under the administrative procedures provisions in 5 U.S.C. 553, it is found upon good cause that public participation in this rulemaking procedure is impracticable and unnecessary, and good cause is found for making the amendments effective less than 30 days after publication in the **Federal Register.**

Done at Washington, DC, on: November 16, 1988.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

[FR Doc. 88–28321 Filed 12–9–88; 8:45 am]

BILLING CODE 3410-DM-M

---

9 CFR Parts 317 and 318

[Docket No. 85–030F]

Ascorbic Acid, Erythorbic Acid, Citric Acid, Sodium Ascorbate, and Sodium Citrate in Fresh Pork Cuts

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule; confirmation of interim rule.

SUMMARY: On August 22, 1986, FSIS published an interim final rule (51 FR 30052) (corrected on September 22, 1986, at 51 FR 33565) amending the Federal meat inspection regulations to permit the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate, singly or in combination, to maintain the color of fresh pork cuts. Fresh pork cuts which have been treated to maintain color by the addition of these substances are required to be labeled with a qualifying phrase, contiguous to the product name, which indicates that they have been treated to maintain color. The Administrator of FSIS determined that the Agency had sufficient information and data to satisfy the requirements for amending the regulations. However, an interim rule was published to permit public comments because of the novelty of the new use of these substances, and to allow additional time for the Agency to assess data under actual market conditions before confirming the interim rule. FSIS has determined the interim rule should be made final.

EFFECTIVE DATE: January 11, 1989.

FOR FURTHER INFORMATION CONTACT: Ashland L. Clemons, Acting Director, Standards and Labeling Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Area Code (202) 447–6042.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined that this final rule is not a "major rule" within the scope of E.O. 12291. It will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This final rule affirms the discretionary use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate, singly or in combination, to maintain the color of fresh pork cuts.

Effect on Small Entities

The Administrator certifies that this final rule will not have a significant economic impact on a substantial

number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601 through 612).

This final rule will impose no new requirements on industry. This rule affirms FSIS approval for the meat industry to use a new method of color preservation to help maintain the fresh appearance of fresh pork cuts. Costs should be incidental and would be offset by distribution efficiencies and reduction of losses due to color deterioration of fresh pork cuts.

Background

FSIS was petitioned [1] by Wilson Foods Corporation to permit the addition of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate, in conjunction with phosphates, to fresh port cuts packaged in a controlled atmosphere of carbon dioxide, oxygen and nitrogen in order to maintain the fresh appearance of such meat. This treatment was claimed to result in the extension of a fresh color and appearance during the product's microbiological shelf life.

Fresh pork which is packaged and stored at low temperatures will remain safe and wholesome for 30 days or more. During storage, however, pork color changes and the product loses its appeal and marketability while still safe and wholesome. These color changes detract from the appearance of the product.

The petitioner presented data demonstrating that the addition of the above mentioned substances resulted in extension of the color and appearance of fresh pork cuts for a period of time less than or equal to the microbiological shelf life of fresh port cuts.

The Administrator of FSIS found that information provided by the petitioner and other data available to the Agency disclosed that (1) the use of these substances is functional and suitable for the product, (2) the substances would be used at the lowest level necessary to accomplish their intended technical effect, and (3) the use of these substances will not render the product on which they are used, adulterated, misbranded, or otherwise not in accordance with the requirements of the Act provided treatment occurs only under an approved partial quality control (PQC) program monitored by FSIS. The Agency published an interim final rule (51 FR 30052) amending the Federal meat inspection regulations to permit the use of ascorbic acid, citric acid, erythorbic acid, sodium ascorbate and sodium citrate, singly or in combination, to maintain the color of fresh pork cuts. However, public comments were solicited so that commercial experience could be obtained and considered prior to confirmation of the rule as final.

The petitioner provided further data on consumer tests to determine the habits of consumers when purchasing fresh pork, as well as methods used by consumers to evaluate freshness and wholesomeness. Additionally, data were evaluated on typical duration of refrigerated and frozen storage by consumers. These data indicated that product color was the first test for wholesomeness, but that consumers also used odor and flavor as indicators. It was determined that consumers typically prepare or freeze fresh meat within the first three days of refrigerated storage.

Webb Foodlab, Inc., conducted an independent study for FSIS, which corroborated data provided by the petitioner. The study evaluated the treatment under commercial and retail conditions rather than laboratory conditions and included sensory analysis, microbiological evaluation and chemical analysis. Samples of treated pork were obtained from retail stores in two cities. Retail storage conditions were maintained throughout the study. Analyses were performed on samples which were fresh, three days old and seven days old.

For the sensory analysis, samples were evaluated by ten panelists trained to focus on color as the sole criterion of freshness. The samples were rated as to whether the panelist would purchase the pork chops. The samples were then rated in categories of color, odor, cooked odor, flavor and off flavor.

The microbiological evaluation involved several tests including aerobic plate count, *Salmonella, Listeria,* and the Mugg test (PTG agar plate) for total Enterobacteriaceae and *E. Coli.* The chemical tests included analysis of rancidity (thiobarbituric acid (TBA) content), ascorbic acid content, and pH.

Following the sensory, microbiological, and chemical analyses, the study concluded that if pork chops treated with ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate are handled in the same manner as untreated fresh pork cuts regarding both retail storage and domestic usage, the appearance of a spoiled or unwholesome product would not be enhanced to the extent that it might be purchased and eaten by the consumer who relied on the appearance of the product.

Comments Received on Interim Rule

A total of 88 comments was received in response to the interim final rule. There were 65 from consumers, 9 from university professors, 7 from trade associations, 2 from meat processors, 2 from chemical manufacturers, 2 from supermarket chains and 1 from a consultant to the meat industry. Thirty-nine of the comments supported the rule, and 49 of the comments opposed the rule. Three of those comments in opposition were signed by 41 additional people for a total of 90 who opposed the rule.

All of the 18 consumers supporting the rule believed this would enable consumers to have a wider variety of products available, with better quality and longer shelf life.

The consultant, supermarket chains, chemical manufacturers, meat processors, trade associations and 7 of the 9 university professors supported the rule. Many of the comments from these groups stressed the need for controls to ensure that proper amounts of the color maintenance additives are utilized and excessive amounts are not added.

The Agency agrees that controls are necessary to assure proper use of these substances. Therefore, when processors request to apply the above mentioned substances to fresh pork cuts, they will be required to apply for an approved Partial Quality Control (PQC) program pursuant to 9 CFR 318.4(d) and, if approved, to follow that program. Processing will not be permitted, nor will labeled products be permitted to be distributed in commerce until such PQC programs are evaluated and approved according to the requirements set forth in 9 CFR 318.4(e). This will ensure that the substances will not be applied in excessive amounts and that color maintenance will not exceed microbiological shelf life. All such PQC programs must cover certain critical control points, including but not necessarily limited to:

(1) Condition of meat before treatment (must be fresh or previously frozen meat maintained in a wholesome conditions as evidenced by time and temperature records from the point of slaughter),

(2) Solution formulation control,

(3) Single application control,

(4) Finished product ingredient analysis monitoring,

(5) Integrity of packaging during storage, transportation, and distribution, and

(6) Further processing control (ascorbate treated cuts may not be further processed into fresh, ground pork products).

[1] Petition submitted on April 22, 1985, by Wilson Foods Corporation.

The chemical manufacturers and 1 meat processor commented that the list of acceptable substances should be expanded to include sodium erythorbate. This would not comply with the procedures stipulated in 9 CFR 318.7(a)(2) for the approval of food additives and therefore cannot be included in this final rulemaking.

Two of the university professors expressed concern that treatment of fresh pork cuts at the permitted levels would result in color maintenance exceeding the microbiological shelf life. They suggested that further studies be conducted to ensure that this would not occur at the permitted levels. These studies have been conducted, as described above, and it was found that the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate does not mask unwholesomeness. These results support issuance of a final rule.

The consumer comments opposing the rule were generally based on the objection to meat additives. Many felt that such additives were unnecessary and deceptive in nature. Six of the commenters strongly objected to use of these substances because of allergic reactions to them. The Agency permits an additive only if "its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases" (9 CFR 318.7(a)(2). Data show that the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate on fresh pork cuts does provide the useful function of maintaining product color and that the additive levels permitted by this final rule are the lowest levels that will achieve this function. Further, a label declaration regarding the use of these substances and a listing of the substances in the ingredient statement is required. Consumers can readily avoid buying these products. The requirement to prominently disclose the presence and purpose of the additives, by use of a qualifying statement adjacent to the product name, was endorsed by many commenters.

One commenter objected to use of the term "fresh" when labeling pork cuts that had been treated with a preservative. The Agency believes consumers understand the word "fresh" to indicate a meat product has not been cured (9 CFR 317.8(b)(6)). Although the product for which these substances have been approved is "fresh pork cuts," from the time of application, the product is no longer "fresh" as defined in the regulations. As such, the Agency will not permit use of the term "fresh" to be included as part of the name of pork cuts that have been treated with these substances.

Several commenters suggested that the use of color maintainers be extended to fresh meat cuts of other species. The Agency will consider the use of these substances on meat from other species at such time that data is submitted to FSIS to demonstrate efficacy and the lowest use levels necessary to achieve the intended technical effect.

Provisions of the Final Rule

Pork cuts treated with ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate that were used to provide data supporting the petition were packaged in a controlled atmosphere of carbon dioxide, oxygen and nitrogen. Packing gases are already permitted for use and are not a part of this rule.

The intended technical effect of the ascorbic acid, erythorbic acid and sodium ascorbate is to serve as antioxidants. The amount of these substances required to achieve the intended technical effect is between 250 and 500 parts per million (ppm), or up to 1.8 milligrams per square inch of surface area collectively. This rule provides for use of these substances at levels not to exceed either 500 ppm or 1.8 milligrams per square inch of surface, singly or in combination. Neither of these levels may be exceeded.

The intended technical effect of the citric acid and sodium citrate is to serve as sequestrants. Sequestrants are "substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products" (21 CFR 170.3 (o)(26)). The amount of these substances required to achieve the intended technical effect is 250 ppm or 0.9 milligrams per square inch of surface area collectively. This rule provides for use of these substances at levels not to exceed either 250 ppm or 0.9 milligrams per square inch of surface, singly or in combination. Neither of these levels may be exceeded.

Fresh pork cuts which are treated with these substances to maintain the color during distribution will be required to be labeled with a statement identifying each specific approved substance by its common or usual name and the purpose for which it is added, such as "sprayed with a solution of water, ascorbic acid and citric acid to maintain color." This phrase must be contiguous to the product name and must be in the same style of print no smaller than one fourth the size of the print in the product name. The requirement of the presence of the qualifying statement is consistent with established regulatory standards when other preservatives, such as antioxidants or mold inhibitors, are added to meat food product (9 CFR 317.2(j)(10) and 317.8(b) (27) and (28)).

The substances addressed in this rulemaking are generally recognized as safe (GRAS) as direct human food ingredients by the Food and Drug Administration, when used in accordance with good manufacturing practice. Ascorbic acid is listed as a chemical preservative in 21 CFR 182.3013, erythorbic acid is listed as a chemical preservative in 21 CFR 182.3041, citric acid is listed as a sequestrant in 21 CFR 182.6033, sodium ascorbate is listed as a chemical preservative in 21 CFR 182.3731, and sodium citrate is listed as a sequestrant in 21 CFR 182.6751.

Based on all of the information and data available to the Agency, the Administrator reaffirms his findings that (1) the use of these substances is functional and suitable for the product, (2) the substances would be used at the lowest level necessary to accomplish their intended technical effect, and (3) the use of these substances will not render the product on which they are used adulterated, misbranded, or otherwise not in accordance with the requirements of the Act provided treatment occurs only under an approved partial quality control (PQC) program monitored by FSIS, as indicated above.

Therefore, FSIS is confirming the interim rule published on August 22, 1986, (51 FR 30052) which (1) amended the table of approved substances in 9 CFR 318.7(c)(4) to include the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination, as color maintainers for fresh pork cuts and (2) required descriptive labeling of fresh pork products to which ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination, are added to maintain color.

List of Subjects in 9 CFR Parts 317 and 318

Food labeling, Food additives, Meat inspection.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for Part 317 continues to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 1254.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

2. The authority citation for Part 318 continues to read as follows:

Authority: 34 Stat. 1260, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*), 72 Stat. 862, 92 Stat. 1069, as amended (7 U.S.C. 1901 *et seq.*), 76 Stat. 663 (7 U.S.C. 450 *et seq.*).

§§ 317.8 and 318.7 [Amended]

Accordingly, FSIS is adopting as a final rule, without change, the interim rule that amended §§ 317.8(b)(37) and 318.7(c)(4), that was published on August 22, 1986, at 51 FR 30052.

Done at Washington, DC, on November 17, 1988.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

[FR Doc. 88-28584 Filed 12-9-88; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 23

[Docket No. 057CE, Special Condition No. 23-ACE-42]

Special Conditions; Gyroflug Model SC-01 Speed Canard

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued to Gyroflug Ingenieurgesellschaft mbH to become part of the type certification basis for the Model SC-01 Speed Canard airplane. The airplane will have novel or unusual design features related to the aerodynamic configuration of the airplane, the location of the engine and propeller, and the use of composite materials for primary flight structure, which were not envisaged in the applicable airworthiness standards and for which the regulations do not contain adequate or appropriate airworthiness standards. These special conditions contain the additional safety standards which the Administrator considers necessary to establish a level of safety equivalent to that provided by the applicable airworthiness standards.

EFFECTIVE DATE: January 11, 1989.

FOR FURTHER INFORMATION CONTACT: Bobby W. Sexton, Aerospace Engineer, Standards Office (ACE-110), Small Airplane Directorate, Aircraft Certification Service, Central Region, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone (816) 426-5688.

SUPPLEMENTARY INFORMATION:

Type Certification Basis

The type certification basis for the Gyroflug Model SC-01 airplane is as follows: Part 21 of the Federal Aviation Regulations (FAR), § 21.29; Part 23 of the FAR, effective January 9, 1965, including amendments 23-1 through 23-25; Part 36 of the FAR, effective December 1, 1969, as amended by amendments 36-1 through the amendment effective on the date of type certification; exemptions, if any; and the special conditions adopted by this rulemaking.

Background

On January 27, 1984, Gyroflug Ingenieurgesellschaft mbH, Flughafen, 7570 Baden-Baden Oos, West Germany, filed an application to the FAA Brussel's Office for U.S. type certification for its Model SC-01 Speed Canard airplane. The Gyroflug Model SC-01 is a small, two-place, composite structure, canard configuration airplane with a pusher propulsion system. It is powered by a 116-horsepower Avco Lycoming 0-235-P2A reciprocating engine and the airplane has a maxium takeoff weight of 1,500 pounds. The airplane received German type certification on September 30, 1983.

Special conditions may be issued and amended, as necessary, as part of the type certification basis if the Administrator finds that the airworthiness standards designated in accordance with § 21.17(a)(1) do not contain adequate or appropriate safety standards because of novel or unusual design features of an airplane. Special conditions, as appropriate, are issued in accordance with § 11.49, after public notice as required by §§ 11.28 and 11.29(b), effective October 14, 1980, and will become part of the type certification basis, as provided by § 21.17(a)(2).

The proposed type design of the Model SC-01 airplane contains a number of novel or unusual design features not envisaged by the applicable Part 23 airworthiness standards. Special conditions are considered necessary because the airworthiness standards of Part 23 do not contain adequate or appropriate safety standards for the novel or unusual design features of the Model SC-01 airplane.

A Notice of Proposed Special Conditions, Notice No. 23-ACE-42, was published in the **Federal Register** on June 7, 1988 (53 FR 20860). No comments were received.

Federalism Implications

The regulations adopted herein will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 14 CFR Parts 21 and 23

Aircraft, Air transportation, Aviation safety, Safety.

PARTS 21 AND 23—[AMENDED]

The authority citation for these special conditions is as follows:

Authority: Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958; as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 21.16 and 21.17; and 14 CFR 11.28 and 11.29(b).

Adoption of the Special Conditions

In consideration of the foregoing, the following special conditions are issued as a part of the type certification basis for the Gyroflug Model SC-01 series airplanes:

1. Evaluation of Composite Structure.

In lieu of complying with § 23.572, and in addition to the requirements of §§ 23.603 and 23.613, airframe structure, the failure of which would result in catastrophic loss of the airplane, in each wing, wing carry-through, wing attaching structure, fuselage, wing mounted vertical stabilizer, wing flap, and moveable control surfaces must be evaluated to damage tolerance criteria prescribed in paragraphs (a) through (i) of this special condition, unless shown to be impractical. In cases shown to be impractical, the aforementioned structure must be evaluated in accordance with the criteria of paragraphs (a) and (j) of this special condition. Where bonded joints are used, the structure must also be evaluated in accordance with the residual strength criteria in paragraph (g) of this special condition.

(a) It must be demonstrated by tests, or by analysis supported by tests, that the structure is capable of carrying ultimate load with impact damage. The level of impact damage considered need not be more than the established