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TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, MEAT AND POULTRY INSPECTION, DEPARTMENT OF AGRICULTURE

PART 381--POULTRY PRODUCTS INSPECTION REGULATIONS--Table of Contents

Subpart N--Labeling and Containers

Sec. 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.

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Sec. 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 Sec. 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 Secs. 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 Sec. 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]

Sec. 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 Sec. 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 Sec. 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:

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	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 Sec. 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]

Sec. 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 Sec. 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,

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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.

[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]

Sec. 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.

Sec. 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 Sec. 381.147 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 Sec. 381.147 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]

Sec. 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 Sec. 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 1\1/2\ pounds avoirdupois weight shall be expressed as ``Net Wt. 24 oz. (1 lb. 8 oz.),'' ``Net Wt. 24 oz. (1\1/2\ 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 \1/2\ ounce), respectively.

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

(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

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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 \1/2\ 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 \1/2\ 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]

Sec. 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 Sec. 381.121 of this part.

[55 FR 49835, Nov. 30, 1990]

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

(a) For the purpose of Sec. 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,

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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]

Sec. 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

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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,'' 1994 Edition, October 1993, 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]

Sec. 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, or shall have an FSIS approval net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with Sec. 381.145 of this subchapter.

[55 FR 49836, Nov. 30, 1990]

Sec. 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 Sec. 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]

Sec. 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,''

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``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]

Sec. 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]

Sec. 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).

Sec. 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 heat processed in accordance with the provisions of Sec. 381.150(b) or that have not undergone other further 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 Sec. 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]

Sec. 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 Sec. 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 Sec. 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]

Sec. 381.127 Wording on labels of shipping containers.

(a) Each label for use on a shipping container for inspected and passed

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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.

Sec. 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 Secs. 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.

Sec. 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 Sec. 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 Sec. 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 Sec. 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 deg.F, but above 0 deg.F, may not bear a label declaration of ``fresh'' and must be labeled with the descriptive term ``hard chilled.'' The word ``previously'' may be used contiguous to the term ``hard chilled'' on an optional basis. The descriptive term shall be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it shall be

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prominently affixed thereon 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. Product as described in this paragraph is not subject to the freezing procedures required in Sec. 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0 deg.F may not bear a label declaration of ``fresh'' and must be labeled with the descriptive term ``frozen'' except when such labeling duplicates or conflicts with the labeling requirements in Sec. 381.125 of this subchapter. The word ``previously'' may be used contiguous to the term ``frozen'' on an optional basis. The descriptive term shall be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it shall be prominently affixed thereon 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. Product as described in this paragraph is subject to the freezing procedures required in Sec. 381.66(f)(2) of this subchapter.

(iii) Raw poultry product whose internal temperature has ever been below 26 deg.F, but is above 0 deg.F, is not required to bear any specific descriptive term. Raw poultry product whose internal temperature has ever been below 26 deg.F, but is above 0 deg.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 Sec. 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 Sec. 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 Sec. 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]

Effective Date Note: At 61 FR 66200, Dec. 17, 1996, Sec. 381.129 was amended by revising paragraphs (b)(6)(i) and (ii); by redesignating paragraph (b)(6)(iii) as (b)(6)(iv); and by adding a new paragraph (b)(6)(iii), effective Dec. 17, 1997. For the convenience of the user, the revised text is set forth as follows:

Sec. 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(6)(i) Raw poultry product whose internal temperature has ever been below 26 deg.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 deg.F is mislabeled. The ``fresh'' designation may be deleted from such product in accordance with Sec. 381.133(b)(9)(xxiv). The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26 deg.F standard by 1 deg. (i.e., have a temperature of 25 deg.F) and still be labeled ``fresh.'' The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26 deg.F standard by 2 deg. (i.e., have a temperature of 24 deg.F) and still be labeled ``fresh.'' The average temperature of poultry product lots of each specific product type must be 26 deg.F. Product described in this paragraph is not subject to the freezing procedures required in Sec. 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0 deg.F must be labeled with the descriptive term ``frozen,'' except when such labeling duplicates or conflicts with the labeling requirements in Sec. 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 Sec. 381.66(f)(2) of this subchapter.

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Sec. 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.

Sec. 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 Sec. 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 Sec. 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]

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Sec. 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 Sec. 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 Sec. 381.132(d), for all products, except as provided in Sec. 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 Sec. 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 Sec. 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 Sec. 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]

Sec. 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.

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(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 Sec. 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in Sec. 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 Sec. 381.127;

(5) Labeling for products not intended for human food, provided they comply with Secs. 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with Sec. 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 Sec. 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 Sec. 381.125(a);

(xvii) The addition of safe handling instructions as required by Sec. 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 Sec. 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 addition of a descriptive term as required by Sec. 381.129(b)(6).

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

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

Effective Date Note: At 61 FR 66201, Dec. 17, 1996, Sec. 381.133 was amended by revising paragraph (b)(9)(xxvi) and adding paragraph (b)(9)(xxvii), effective Dec. 17, 1997. For the convenience of the user, the revised text is set forth as follows:

Sec. 381.133 Generically approved labeling.

* * * * *

(b) * * *
(9) * * *
(xxvi) The use of the descriptive term ``fresh'' in accordance with Sec. 381.129(b)(6)(i) of this subchapter.

Sec. 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]

Sec. 381.135 Irradiated poultry product.

(a) The labeling of packages of poultry product irradiated in conformance with Sec. 381.147(f)(4) of this part must bear the following logo along with a

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statement such as, ``Treated with radiation'' or ``Treated by irradiation,'' in addition to all other labeling requirements of this subpart. The logo must be placed prominently and conspicuously in conjunction with the required statement and be colored green. The statement must appear as a qualifier contiguous to the product name and in letters of the same style, color, and type as the product name. Letters used for the qualifying statement shall be no less than one-third the size of the largest letter in the product name. Any labeling bearing the logo and any wording of explanation with respect to this logo must be approved as required by subparts M and N of this part.
[GRAPHIC] [TIFF OMITTED] TC11SE91.042

(b) The product label must bear the handling statement ``Keep Refrigerated'' or ``Keep Frozen,'' as appropriate, in conformance with Sec. 381.125 of this Subpart.
(c) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the above stated requirements. Such statements must not be false or misleading.

[57 FR 43597, Sept. 21, 1992]

Sec. 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.

Sec. 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]

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

(a) Labeling and devices approved for use pursuant to Sec. 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.

Sec. 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend

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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.

Sec. 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.

Secs. 381.141-381.143 [Reserved]

Sec. 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]