

TABLE 1.—REGULATIONS THAT ARE CANDIDATES FOR REVISION OR REMOVAL PRIOR TO HACCP IMPLEMENTATION—Continued

Regulations—FMIA, PPIA	Subject	Possible action
325, 381, Subpart S	Transportation	<p>Eliminate command-and-control type requirements for the use of nitrite and sodium ascorbate or erythorbate in bacon; convert these requirements to performance standards and clarify role of inspection program employees. (See § 318.7(b).)</p> <p>Convert requirements for the treatment of pork and pork products to destroy trichinae in to performance standards; supplement with guidelines as needed. (See § 318.10.)</p> <p>Convert requirements for preparing articles not for use as human food (e.g., dog food) to performance standards; clarify role of inspection program employees; eliminate command-and-control type requirements. (See §§ 318.12 and 381.152.)</p> <p>Eliminate redundancy with other provisions (mixtures containing product that are not classed as meat food products). (See § 318.13.)</p> <p>Convert procedure for handling product adulterated by polluted water to performance standards and decision criteria; supplement with guidelines as needed. (See §§ 318.14 and 381.151.)</p> <p>Convert requirements for tagging chemicals, preservatives, cereals, spices, etc., to performance standards; clarify role of inspection program employees. (See § 318.15.)</p> <p>Convert rules for substances such as pesticide chemical residues, food additives, and color additives to performance standards and role of inspection program employees. (See § 318.16.)</p> <p>Make requirements for handling of certain material for mechanical deboning consistent with any new time-temperature requirements. (See § 318.18.)</p> <p>Convert compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems to performance standards and clarify role of inspection program employees. (See § 318.24.)</p> <p>Convert requirements for canning and canned products to performance standards and clarify role of inspection program employees. (See §§ 318.300–318.311 and 381.300–381.311.)</p> <p>Eliminate obsolete provisions; focus on and clarify policies and performance standards.</p>

IV. Request for Comments

This ANPR is intended to elicit comments, suggestions, and information that will enable FSIS to provide more efficient and effective service and to focus its organizational resources more closely on health and safety matters, which are of vital concern to all Americans. FSIS specifically requests comment on its efforts to transform its regulations from heavy reliance on command-and-control approaches to greater reliance on performance standards, and solicits detailed suggestions concerning which existing regulations need to be changed to be consistent with HACCP, and how those regulations should be changed. The Agency notes that several individuals and groups, including at least one trade association, responded to a similar request in the February 3, 1995, proposal. FSIS would also appreciate comments on the economic burdens and the paperwork, recordkeeping, or other

information collection burdens associated with the regulations discussed in this document.

Comments supported by scientific or other data on the impacts, such as the public health effects, of changing or eliminating existing regulations, would be especially valuable.

Executive Order 12866

This advance notice of proposed rulemaking has been reviewed under Executive Order 12866. This rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

FSIS does not have data necessary to assess how the regulatory changes discussed in this document might affect various sectors of the meat and poultry industries. Therefore, the Agency invites comment on potential effects, including economic costs or benefits, of any specific changes that may be suggested.

Done, at Washington, D.C., on December 21, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR PART 319 and 381

[Docket No. 92–024P]

RIN: 0583–AB51

Food Standards: Requirements for Processed Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations to establish a general definition and standard of identity for standardized meat food and poultry food products that have been modified to qualify for use of an expressed nutrient content claim in their product name. These products would be identified by an expressed nutrient content claim, such as "Fat Free," "Low Fat," and "Light," in conjunction with an appropriate standardized product name. FSIS is taking this action to: (1) Assist consumers in maintaining healthy dietary practices by providing for substitute versions of standardized processed meat food and poultry food products that have reductions of certain constituents that are of health concern to consumers, such as fat and cholesterol, (2) increase regulatory flexibility and support product innovation in accord with Executive Orders 12861 and 12866 and with President Clinton's Memorandum to Heads of Departments and Agencies, "Regulatory Reinvention Initiative," dated March 4, 1995, and (3) provide consumers with an informative nutrition labeling system.

DATES: Comments must be received on or before February 27, 1996.

ADDRESSES: Written comments should be sent in triplicate to, Policy, Evaluation and Planning Office, Attn: FSIS Docket Clerk, DOCKET No. 92-024P, Room 4352, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to Mr. Charles R. Edwards, Director, Product Assessment Division, at (202) 254-2565. (See also "Comments" under **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: Mr. Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 254-2565.

SUPPLEMENTARY INFORMATION:

Background

I. Introduction

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) authorize the Secretary of Agriculture to establish and maintain inspection programs designed to assure consumers that meat and

poultry products distributed in commerce or within designated States are wholesome, not adulterated, and are properly marked, labeled and packaged.

Under section 7(c) of the FMIA (21 U.S.C. 607 (c)) and section 8(b) of the PPIA (21 U.S.C. 457(b)), FSIS develops and promulgates regulations that prescribe definitions and standards of identity and composition for meat and poultry products (9 CFR parts 319 and 381, subpart P). FSIS also promulgates regulations that prescribe the content and design of labels for meat and poultry products (9 CFR parts 317 and 381, subpart N). Food and Drug Administration (FDA) has responsibility for all other food products.

Food standards have existed in various forms since food was first produced for distribution in commerce to people. In fact, the U.S. Department of Agriculture, which was established in 1862, promulgated about 200 "standards of purity" by 1906, which included definitions of adulteration and misbranding. Meat and poultry standards have been developed for various reasons, including (1) to prevent nutritional and economic dilution (i.e., economic adulteration) of the expected, characterizing, or valued components of meat and poultry products, such as the amount of beef needed for a product to be considered a "beef stew," and (2) to establish standardized names for products, such as "frankfurter," "bologna," "hamburger," "chili con carne," and "corned beef hash," that consumers can understand and, in turn, to establish standardized requirements for the composition of these products to assure, in general, that the products will contain certain expected compositional components. For example, a product named "corned beef hash" is expected to contain cured beef, potatoes, and seasonings. Providing standards for meat and poultry products serves the needs of industry to produce, and the desires of consumers to purchase products that contain the characteristics and ingredients that are expected in a product represented by a particular name.

Parts 319 and 381, subpart P, of the meat and poultry inspection regulations (9 CFR parts 319 and 381, subpart P, respectively) contain standards of identity or composition for about 60 meat and poultry product categories. Standards of identity and composition can be like a recipe and may establish specific requirements for a product such as the kind of ingredients and/or the amount of ingredients allowed in it; and/or the methods by which the product must be prepared; and/or the criteria the finished product must meet,

such as a specified salt content of 4 percent that can affect the wholesomeness or shelf-life of a product, such as a dried ham.

The standard for "pizza" (9 CFR 319.600), for example, defines the product "pizza with meat" as "a bread base meat food product with tomato sauce, cheese, and meat topping," and indicates the minimum amount of the meat it must be made from, which is not less than 15 percent raw meat. The standard for corned beef hash (9 CFR 319.303) sets the minimum amount of meat (i.e., meat content) that this product must contain, and in addition, lists other required and optional ingredients for the product. The standard for "Country Ham" (9 CFR 319.106) states that this product is an uncooked, cured, dried, smoked or unsmoked meat food product made up of a single piece of meat from a pork "ham" (i.e., hind leg of a hog) or pork shoulder. This standard also states that a "Country Ham" must be prepared using a dry application of salt and curing agents in order to have a prescribed salt, brine concentration, or water activity in the finished product. The standard for "meat pies" (9 CFR 319.500), for example, a beef or pork pie, requires that the product have not less than 25 percent meat based on the amount of all the product's ingredients. Hereafter, in this document, "standards" will refer to both the meat and poultry product standards of identity or composition codified in 9 CFR parts 319 and 381, subpart P.¹

Meat and poultry products that are subject to FSIS' regulatory standards make up a substantial portion of the nation's food supply. The Agency believes that there is a desire among consumers to be able to purchase healthful, alternative standardized meat and poultry food products that have been modified to reduce the level of constituents that are of health concern to some people, such as fat, cholesterol, or sodium, below that which occurs under existing FSIS regulatory

¹ FSIS has also established policy guides in its Standards and Labeling Policy Book for many processed meat and poultry food products for which there are no specific regulatory standards, e.g., "Chinese Pepper Steak." These policy guides address the criteria, the characteristics, and/or the expected composition of a particular poultry or meat food product that is associated with a particular product name. These policy guides may identify minimum meat and/or poultry contents, maximum fat and water contents, methods of processing or cooking, expected or characterizing ingredients, and/or finished product criteria (such as salt content or cooking yield) for various meat or poultry products. A copy of the Standards and Labeling Policy Book is available for inspection in the FSIS Docket Clerk's Office, Room 4352, South Agriculture Building, Washington, DC 20250.

standards. Industry has previously petitioned FSIS for permission to market these products. The Agency's objective, through this proposal, is to help facilitate the industry's ability to produce these substitute standardized products and, in turn, to facilitate consumers' selections of a variety of alternative products that are wholesome and properly labeled, as required by the FMIA and the PPIA.

II. IOM Report

Federal regulatory agencies responsible for food safety and food labeling have been interested in modernizing labeling and food standards for some time. In 1989, FSIS and the Public Health Service, U.S. Department of Health and Human Services, which includes FDA, jointly sponsored a study by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS), to provide options for improving food labeling. The NAS in its 1990 final report, *Nutrition Labeling, Issues and Directions for the 1990's*² (IOM Report), expressed the concern that some of FDA's standards of identity impeded a manufacturer's ability to offer more nutritious foods.

Although both FSIS and FDA were encouraged to review their food standards, the IOM Report pointed out that there was a distinct difference between FDA standards and those of FSIS. FDA standards for certain products in which fat has traditionally been considered a valuable or characterizing ingredient require a minimum amount of fat to be present in a product before the product can be identified by the standardized name established in FDA regulations. On the other hand, generally speaking, FSIS standards set maximum limits on fat, water, or other added substances that can be present in a product in order to use the name established by the standards. For example, in FDA's standards, a product using the name "ice cream" is required by regulation (21 CFR 135.110) to have a minimum of 10 percent milkfat in order to bear that name. However, FSIS standards for products identified by the names "Frankfurter," "Wieners," or "Hot Dog" (9 CFR 319.180(b)), for example, limit the combination of fat and added water to no more than 40 percent of the product's formulation. The IOM Report noted that, historically, a high milkfat content was considered a desirable characteristic in dairy products, whereas, in meat and poultry products, an excess amount of fat, water, and

other added substances were considered to dilute the protein contributed by the meat or poultry portion (which was the "valued" component of a meat and poultry product).

The Agency agrees with the IOM Report, which stated, "In 1990, less skepticism exists about consumers' abilities, aided by informative labeling, to protect themselves against debased or diluted products * * * Attention is now focused on the consumption of too much fat rather than the possibility that some products will be made using less of an ingredient [less fat] than was historically considered a valuable constituent. Accordingly, it seems clear to the [IOM] Committee that any system that significantly impedes the marketing of reduced-, low-, and non- or no-fat substitutes should be examined and, presumably, changed."

Processed meat and poultry products are important sources of many nutrients, especially protein, vitamin B-6, vitamin B-12, iron, and zinc. Meat is rich in heme iron, which is more readily absorbed by the body than is iron from many other foods. Heme iron also enhances the absorption of iron from other sources. Meat and poultry products will continue to be an important part of the total American diet. FSIS believes that it is appropriate to provide consumers with the largest variety of processed meat and poultry products that can be made available to them, from which consumers can then make healthful food purchasing choices. Therefore, FSIS believes that reform of labeling for meat and poultry products and reform of regulatory standards for these products should include implementing the regulatory changes needed to provide the meat and poultry industry the flexibility necessary to create and market an increased variety of healthful processed meat and poultry products, such as those lower in fat, which have the beneficial nutrients, flavor, texture and appearance desired by consumers.

III. NLEA and Regulatory Actions

As a result of increased interest in the benefits of more healthful diets, consumer groups, Congress, the FDA, and FSIS began to actively focus on food label reform during the late 1980's and early 1990's. In November 1990, Congress passed the "Nutrition Labeling and Education Act of 1990" (NLEA). The NLEA, which applies to foods under FDA's jurisdiction, gave legislative emphasis to an already on-going effort by the FDA and FSIS to reform food labeling. It included direction for improving ingredient

labeling and addressing issues concerning standards of identity reform.

The NLEA addressed food labeling only for foods under the jurisdiction of the FDA. However, in the interest of providing consumers with uniform nutrition labeling for all foods, FSIS published an advance notice of proposed rulemaking (ANPR) in the Federal Register on April 2, 1991 (56 FR 13564), advising of its intent to publish a proposed rule for nutrition labeling of meat and poultry products. In regard to meat and poultry product standards of identity, FSIS stated that it would reassess this issue after completing its rulemaking on nutrition labeling.

Final nutrition labeling rules for food under the jurisdiction of FDA and FSIS were published in the January 6, 1993, Federal Register. The January 6, 1993 Federal Register contained final rules for nutrition labeling for most meat and poultry products under FSIS' jurisdiction (58 FR 632), and FDA final nutrition labeling rules for most food products under its jurisdiction. The nutrition labeling rules were comprehensive. They addressed both required nutrients and food components which were to be listed in the "Nutrition Facts" panel of food products, as well as optional nutrient and food components that could be listed on the panel. Rules were also issued that specified food product labeling formats and food category serving sizes, as well as defined nutrient content claims such as "Low," "Light," and "Free."

In the same Federal Register (58 FR 2431), FDA published a final rule that affected many FDA standardized foods. Section 130.10 (21 CFR 130.10), prescribes conditions under which foods that substitute for a standardized food can deviate from the standard of identity and still use the standardized name as part of the product name. Provisions in 21 CFR 130.10 prescribe a general definition and standard of identity for foods that substitute for FDA-regulated standardized foods and use the name of the standardized food in their statement of identity but do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim defined by FDA's regulations. These foods are named by use of an expressed nutrient content claim, such as "Fat Free" "Light," and "Lean," in conjunction with an applicable standardized name. Based on an informal market review conducted by FSIS, FDA's rule has resulted in the appearance in supermarkets of an array of new food products that qualify for use of an expressed nutrient content

²This report is available for public inspection in the FSIS Docket Clerk's office.

claim and standardized names, e.g., "Fat Free Ice Cream," "Low Fat Cheddar Cheese," and "Reduced Fat Egg Nog," because of allowable deviations from FDA food standards permitted by 21 CFR 130.10.

The FDA regulation requires that the performance characteristics of the substitute standardized food be similar to those of the standardized food, except as discussed below. Performance characteristics are the physical properties (e.g., the ability to freeze), flavor, functional properties (e.g., spreadability), and shelf-life (i.e., the time the product exists in a wholesome condition under acceptable handling practices) of a food. If, however, there are any significant differences in the performance characteristics of the modified version of the standardized food that materially limit the uses of the food, as compared to the uses of the standardized food, these must be disclosed on the product's labeling. For example, if a "Fat Free Cream Cheese" cannot be used in baking, that fact must be stated on the product's labeling, e.g., "not recommended for baking."

The FDA regulation also provides that the ingredients used in the substitute food product must be those ingredients provided for by the standard, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food. The FDA regulation also requires that ingredients not provided for, and ingredients used in excess of those levels provided for by the standards, must be identified by an asterisk in the ingredients statement of a product and the meaning of the asterisk must be explained immediately following the ingredients statement.

The FDA regulation facilitated new markets and new opportunities for FDA-regulated food companies to develop modified versions of standardized foods. Although 21 CFR 130.10 addressed only FDA-regulated foods, meat and poultry food manufacturers were quick to respond to the potential market for modified standardized meat and poultry products. According to the meat and poultry industries, they intensified their research and development activities in order to be able to respond to potential consumer demands for meat and poultry products with reductions in various constituents, such as fat and cholesterol, where current standards may limit the marketing of such products. Technological developments and new ingredient uses now allow the industry

to develop new meat and poultry products, including substitute standardized products with decreased amounts of fat, such as, "Fat Free Bologna."

Manufacturers of these new meat and poultry products wanted to market them without labeling them by what they considered to be pejorative terms such as "alternative," "replacement," and "substitute." The manufacturers indicated that such products were not of lesser value compared to their traditional standardized counterparts. They asserted that these products, including new lower fat products, were better and should be allowed to be identified with an appropriate nutrient content descriptor and a commonly understood standardized name that would be familiar to consumers. They requested that FSIS allow labeling for these products similar to that provided for in FDA's general standard of identity in 21 CFR 130.10 for modified standardized products.

FSIS responded to this request by issuing Policy Memo 123³ (dated January 20, 1995) as an interim policy to allow some standardized or traditional meat and poultry food products that have been formulated to reduce their fat content to enter the marketplace while appropriate regulatory actions related to the modernization of standards were developed. Policy Memo 123 allowed modified versions of cooked sausage (e.g., frankfurters), fermented sausages (e.g., pepperoni, salami) and breakfast sausage products to be identified by a nutrient content claim that reflected a reduction in fat content in conjunction with a standardized or traditional name, e.g., "Fat Free Bologna," "Low Fat Pepperoni." Policy Memo 123 included provisions for labeling which were similar to those established by FDA's general standard of identity in 21 CFR 130.10. In a prior related policy, on May 10, 1991, FSIS issued Policy Memo 121, "Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients." Policy Memo 121 allowed for such products to be named with a standardized name along with other descriptive labeling, e.g., "Low Fat Hamburger With a X% Solution of Water and Carrageenan" or "Low Fat Hamburger, Water and Carrageenan Product." Policy Memo 121 has been updated (See Policy Memo 121B, dated January 20, 1995)⁴ to reflect current

³This paper is available for public inspection in the FSIS Docket Clerk's office.

⁴This paper is available for public inspection in the FSIS Docket Clerk's office.

changes in nutrition labeling regulations.

Both Policy Memo 121B and Policy Memo 123 were issued as interim policies intended to accommodate certain lower fat substitute meat and poultry products until such time that rulemaking was completed. Both of these policy memoranda will be rescinded if provisions proposed in 9 CFR 319.10 and 381.172 become final rules.

FSIS is now, in this rulemaking, proposing to establish a general regulatory standard of identity for modified meat and poultry products which substitute for meat and poultry food products defined by a regulatory standard of identity or composition in 9 CFR parts 319 and 381, subpart P. FSIS believes that this general standard of identity will be beneficial to consumers because it will (1) assist consumers by providing for substitute versions of standardized processed meat and poultry products that have reductions of certain constituents that are of health concern to consumers, such as fat and cholesterol, and which bear accurate descriptive names that are meaningful to consumers, (2) increase regulatory flexibility and support product innovation in accord with Executive Orders 12861 and 12866 and with President Clinton's Memorandum to Heads of Departments and Agencies, entitled "Regulatory Reinvention Initiative," dated March 4, 1995, and (3) provide consumers with an informative nutrition labeling system that will parallel, to a significant extent, the nutrition food labeling initiatives of FDA. FSIS believes that this proposed general standard of identity is fully consistent with FSIS's statutory responsibilities under the FMIA and PPIA to assure that the labeling of meat and poultry products is accurate and truthful and not false or misleading. The substitute meat food and poultry food products covered by this proposal will be identified by familiar product names and will be labeled to inform consumers about their general compositional changes from standardized products by use of a nutrient content claim as part of the product's name.

IV. Discussion of Regulatory Proposal

FSIS is proposing to amend the Federal meat and poultry products inspection regulations to establish a definition and general standard of identity for modified versions of standardized meat and poultry food products, i.e., "substitute standardized products." These products will be formulated and processed with ingredients otherwise not in or in

amounts greater than that allowed by FSIS regulatory food standards in 9 CFR parts 319 and 381, subpart P, in order that the product's make-up is consistent with the nutrient content claim made about the product. The names of these products will be composed of an expressed nutrient content claim that, in general, reflects the necessary ingredient modifications made for the product to be accurately identified by such a claim, along with an established appropriate standardized term.

This proposed rule would: (1) Define "substitute processed meat or poultry food products"; (2) allow an expressed nutrient content claim to be used to identify substitute meat and poultry products, in conjunction with the name of a standardized product; (3) require substitute processed meat and poultry food products to have similar performance characteristics such as physical and functional properties to the standardized products for which they substitute, except for significant differences that materially limit the use of the product as compared to the use of the standardized food, which will be allowed if the differences are identified by special labeling statements next to the product's name; (4) require that ingredients used in substitute standardized products be those provided for use by the regulatory standard for which the product is a substitute, except that safe and suitable ingredients approved for use in meat and poultry food products will be allowed to be used at the minimum level necessary to improve texture and prevent syneresis, in order that the product does not have inferior performance characteristics to the standardized product it modifies; (5) require other ingredient requirements for the substitute product including not replacing or exchanging an ingredient specifically required by the standard with a similar ingredient from another source and requiring such required ingredients to be present in the same amounts as required by the standard; (6) prescribe nomenclature for identifying substitute standardized processed meat and poultry products; and (7) establish labeling requirements for identifying ingredients used in the substitute standardized processed meat and poultry products that are not provided for or are used in excess of the level provided for by the standard for which the product substitutes.

FSIS believes that this proposed action is needed to provide consumers with accurate, descriptive, and fully informative labeling that will promote honesty and fair dealing in the distribution of products of interest to

consumers. This proposed rule is needed to facilitate the development and availability of substitute processed meat and poultry products that have reductions in constituents that are of health concern to some people, e.g. fat, cholesterol, and sodium. The proposed rule would enable FSIS to rely more on labeling requirements, and less on recipe-type standards that are restrictive, in carrying out its mandate to assure that the labels of meat and poultry food products are accurate and not misleading to consumers. FSIS believes that today's consumer is better able to evaluate the merits of standardized processed meat and poultry food products when provided with labeling that is guided by rules that require, for most products (1) a commonly recognized product name, (2) nutritional information about what one serving of the food contains (i.e., Nutrition Facts), and (3) a listing of ingredients in the order of predominance by weight used to make the product (i.e., the ingredients statement).

Meat and poultry food products that satisfy the criteria for use of nutrient content claims defined in 9 CFR parts 317 and 381 can also make claims other than those that reflect reductions of constituents of health concern to some people, such as "high in" or "good source of." FSIS believes current meat and poultry product standards do not preclude the making and marketing of substitute products that qualify to use these claims. Therefore, FSIS is not, in this proposal, proposing regulations to provide for the production and distribution of these products, since it believes new regulations are not needed for these products to be manufactured and distributed. FSIS would, however, like comments from members of the public, including consumers, industry, and scientists as to whether or not current regulatory standards prevent the distribution of products with nutrient content claims, other than those that reflect a reduction of constituents of health concern to some people. If after a review of this issue, FSIS determines its standards impede the development of these products, FSIS will consider amending the scope of coverage in its proposal.

A. General Standard

FSIS recognizes that valuable and helpful information concerning the nutrient content of meat and poultry food products can be conveyed to consumers if defined nutrient content claims can be used in a consistent and accurate manner in the names of certain substitute meat and poultry food

products. Substitute meat and poultry products are defined in FSIS nutrition labeling regulations in 9 CFR 317.313(d) and 381.413(d), respectively. These products are defined as a product that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf-life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation." Those same regulations provide that products that have performance characteristics that materially limit the use of the product may still be considered a substitute product if the label of the product includes a disclaimer informing the consumer of such a difference, such as "not suitable for frying."

As part of its nutrition labeling regulations (9 CFR parts 317 and 381, subpart Y), the Agency defined the terms for certain expressed nutrient content claims, including terms such as "free," "low," "reduced," and "light" (9 CFR 317.313, 317.356, 317.361, 317.362, 381.413, 381.456, 381.461, and 381.462) that are associated with reductions in constituents of health concern to some people. These claims are useful in helping consumers choose a healthy diet. Manufacturers that wish to use other nutrient content claims on labels of meat and poultry products that are not currently defined by FSIS regulations can utilize the procedures set forth in 9 CFR 317.369 and 381.469, "Labeling Applications for Nutrient Content Claims," respectively to seek permission to use other nutrient content claims on labels of meat and poultry products.

Given these developments, FSIS believes that it is now appropriate to set forth general requirements governing the establishment of a general standard of identity for substitute meat and poultry food products. The proposed general requirements in 9 CFR 319.10 and 381.172 specify the conditions under which names of standardized foods set forth in 9 CFR parts 319 and 381, subpart P, and appropriate expressed nutrient content claims may be used to identify new substitute standardized meat and poultry food products.

FSIS recognizes that the establishment of individual new standards may, in some cases, be necessary for certain meat and poultry food products, but, it believes, that in general, the promulgation of a large number of individual regulations for substitute meat and poultry food products would be an unnecessarily wasteful use of the Agency's resources. FSIS believes that the development of a

general standard applicable to the vast majority of substitute meat and poultry food products offers the most reasonable and effective regulatory approach for substitute products that contain reductions of constituents of health concern for various people. Proposed provisions 9 CFR 319.10 and 381.172 describe the conditions under which a variety of substitute meat and poultry food products may use expressed nutrient content claims and standardized terms.

B. Substitute Meat and Poultry Food Products Defined by This Proposal

FSIS is proposing to define substitute processed meat and poultry products as: any processed meat and/or poultry product whose formulation has been minimally modified to enable it to be used as a substitute for another meat and/or poultry product that it resembles and which has a standard of identity in the regulations (9 CFR parts 319 and 381, subpart P). The substitute meat or poultry food product would be eligible to use an expressed nutrient content claim to identify it; would resemble the standardized product in appearance, form, taste, and texture; and, would use safe, suitable, and approved substitute ingredients at proper levels and functions, i.e., the lowest level necessary to satisfy the criteria for use of the expressed nutrient content claim provided in regulations.

The substitute meat or poultry product will substantially meet the regulatory requirements and consumer expectations of the standardized product for which it substitutes (i.e., the product will not be dissimilar in general appearance, form, taste, and texture and will be prepared with the ingredients used in the standard of identity or composition identified in 9 CFR parts 319 and 381, subpart P), unless the product is labeled in a manner that conveys allowable ingredient differences to consumers. The ingredient differences that will be allowed relate to the use of ingredients needed to make a product that complies with the specific expressed nutrient content claim related to a reduction in a constituent that has negative health implications that is used, i.e., fat, cholesterol, and sodium. The substitute meat or poultry food product will be allowed to be named using a standardized term because it either will be similar to the standardized product in its performance characteristics and the ingredients used, or it will, through appropriate labeling terminology, describe how it differs from the standardized product for which it substitutes. The Agency believes that

consumers will be protected from false or misleading labeling by requiring labeling for the substitute product that reflects its deviations from the standardized product for which it substitutes.

When a Product Will Not Be Considered a Substitute Standardized Product. There are certain aspects of the standards that are essential to the identity of the standardized product and deviations from these aspects would result in products that would not meet FSIS's definition of substitute products set forth in 9 CFR 317.313(d) and 381.413(d). In this regard, some of the standards in 9 CFR parts 319 and 381, subpart P, specify that the standardized product must be prepared using meat or poultry from a specific anatomical location and/or of a specific kind and/or amount, and must undergo specified processing procedures that are essential to the identity of the product. Deviations from these types of requirements would result in a product that does not come within the established definition for substitute products because they would result in a product that is physically dissimilar and, thus, not a substitute product. Therefore, modified versions of standardized products which purport to be substitutes of them must adhere to the original regulatory standards requirements set forth in parts 319 and 381, subpart P regarding the use of meat and poultry from specified anatomical locations, the use of a specific kind and/or amount of meat or poultry tissue to prepare the product, and the use of specified processing procedures. It is FSIS' belief that deviation from these specified meat or poultry requirements and processing procedures would result in products that do not meet the definition of substitute products. To allow such products to affirmatively represent themselves as substitute standardized products would be false and misleading labeling in violation of the provisions of the FMIA and PPIA.

For example, in 9 CFR 319.304, beef stew must contain at least 25 percent meat (i.e., beef). Since the meat or poultry content of such a product is integral to its identity, the label for a substitute of this product would be false or misleading if the substitute was named, in part, by a standardized term, but contained less than the amount of meat and/or poultry required by the standard. Consumers have come to expect certain meat and/or poultry contents of products they purchase that bear a standardized term. For example, a product identified with the standardized name "Chicken A-La-King" is required to contain a minimum

of 20% cooked chicken meat and a substitute for this product would also be required to contain the same amount of chicken meat. Furthermore, a product identified with the standardized name "Beef Stew" would continue to be required to contain not less than 25% meat computed on the weight of the fresh meat. In addition, for example, in 9 CFR 381.171, "Turkey Ham" must be made from turkey thigh meat and be cured, and in 9 CFR 319.107, "Bacon" must be made from pork bellies and be cured and substitute products would be required to be made from those same anatomical parts and by the same processing procedures.

Although this proposal would not alter the minimum meat and poultry content requirements in current FSIS standards, FSIS is considering broader reform of its standards system that would provide firms greater flexibility in product formulation while fully informing consumers regarding the meat or poultry content of the product. FSIS plans to invite comment on possible alternative regulatory approaches in this area in an ANPR to be published in the Federal Register.

C. Expressed Nutrient Content Claims

FSIS believes that an issue of importance to many consumers is the lowering of the amount of fat, cholesterol, and/or sodium in meat and poultry food products. FSIS has the responsibility, under the FMIA and PPIA to assure that meat and poultry products with reduced amounts of such constituents are accurately and truthfully labeled. FSIS is, therefore, proposing in 9 CFR 319.10 and 381.172 the conditions under which substitute meat and poultry products (as defined in 9 CFR 317.313(d) and 381.469(d)) that do not comply with a standard of identity in 9 CFR parts 319 and 381, subpart P, because of a deviation that is described by an expressed nutrient content claim, that represents reductions in constituents associated with negative health implications, i.e., fat, cholesterol, and sodium, may be named using an expressed nutrient content claim and a standardized term.

Final FSIS nutrition labeling regulations published in the January 6, 1993, Federal Register (58 FR 632) provided definitions for various nutrient content claims that can be used on the label of meat and poultry products, e.g., "Fat Free," "Low Fat," and "Low Cholesterol." Those same regulations, which were recodified in January 3, 1995, (60 FR 174), define an expressed nutrient content claim as any direct statement about the level (or range) of a nutrient in the product, e.g., "low fat"

or "reduced fat turkey ham." Since the proposed product name of a substitute standardized product is intended to distinguish it from the standardized product based on its improved nutritional attribute, a nutrient content claim along with a standardized term must be used to name the substitute products in order for consumers to understand how the modified product differs from the standardized product. FSIS is proposing that only expressed nutrient content claims, i.e., claims that have been defined and are related to reductions in constituents having negative health implications, be permitted in conjunction with the standardized name, in the name of the substitute meat and poultry products provided for in this proposal. Because such products cannot be formulated under some existing regulatory standards, FSIS is proposing to allow additional flexibility for industry to manufacture meat and poultry products whose compositions has been modified to qualify for use of an expressed nutrient content claim that asserts that a constituent of a product, of health concern to some people, has been reduced in amount. Examples of the applicable nutrient content claims are: "low," "lower," "lite," "reduced," "lean," "extra lean," and "free," as defined in 9 CFR 317.313, 317.356, 317.361, 317.362, 381.413, 381.456, 381.461, and 381.462.

D. Performance Characteristics of Substitute Foods

FSIS believes that in order for a product that bears a standardized name to be considered to be accurately labeled it must not only resemble the traditional standardized meat and poultry food product but also must perform similarly to the traditional standardized products unless, the product is specifically labeled to show any significant performance usage differences it has, such as a frankfurter not being suitable for freezing. Unless this is done, consumers might assume that the substitute product could be used interchangeably with the traditional standardized food in all applications.

Therefore, in order not to mislead consumers, FSIS is proposing in 9 CFR 319.10(b) and 381.172(b) to require that a substitute standardized product that bears a standardized name have similar performance characteristics to the standardized meat and poultry food product defined in 9 CFR parts 319 and 381, subpart P for which it substitutes, except as discussed below. FSIS is proposing that the performance characteristics by which a substitute food be judged in terms of its similarity

include its physical properties (e.g., texture, cooking qualities, freezing qualities, its functional properties (e.g., body, spreadability), and shelf-life.

FSIS recognizes, however, that when a standardized product is modified so that its composition accurately supports the nutrient content claim intended to be made, it may not be possible, in all cases, to produce a substitute product that performs similarly in regard to all uses of the regulated standardized meat or poultry food product of which it is a modification. The product would be considered a substitute product allowed under this proposal if the limitation on use does not affect the fundamental nature of the product and is disclosed in labeling.

The FMIA and PPIA require that the label or labeling of a meat or poultry food product must be accurate and not misleading and that such labels and labeling must accurately disclose to consumers what they are buying when they purchase any meat and poultry food product. Information disclosing differences in use performance characteristics (e.g., cooking quality, freezing quality, spreadability of product, and shelf-life) of substitute standardized products is a fact FSIS believes should be specifically disclosed on labels of substitute products identified partially by a standardized term because without such labeling consumers would be misled about the uses the product has in comparison to the standardized product for which it substitutes. Accordingly, this information must be communicated to consumers on the product's label, or the label would be misleading, and the product would be misbranded under the FMIA and PPIA.

Therefore, the provision in proposed 9 CFR 319.10(d) and 381.172(d) that requires disclosure of material differences in uses in regard to the performance characteristics between the substitute product and the standardized product for which it is a substitute is fully consistent with FSIS statutory responsibility under the FMIA and PPIA to prevent false or misleading labeling. If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim in accordance with 9 CFR 317.313(d) (1) and (2) and 381.413(d) (1) and (2), informing the consumer of such difference. The statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and

use, in accordance with requirements of 9 CFR 317.313(d) (1) and (2) and 381.413(d) (1) and (2).

For example, according to the provisions of this proposal, a product identified as a "fat free frankfurter" would have to meet the criteria for using the nutrient content claim "fat free" and would have to have similar performance characteristics to a "frankfurter," unless a statement of any difference(s) in uses appears on the label of the substitute frankfurter product; and if it does not, the product would be considered to be misbranded. A "frankfurter" produced according to the standard for frankfurters would be expected by consumers to have certain physical and functional characteristics, such as a "link" form, a cured pink color, a spongy texture, and the ability for refrigeration or freezing for an appropriate time period to keep the product wholesome. It would also be expected that it could be prepared in a variety of ways, i.e., by boiling, broiling, grilling, and frying.

When fat, however, in a frankfurter or another standardized product is replaced by one or more other ingredients, it may not be possible, in all cases, to produce substitute products that perform identically to the traditional standardized meat and poultry products. Successful fat reduction in meat and/or poultry products requires a firm understanding of the functions of fat in a product, i.e., to provide texture, flavor, and palatability, and how those functions can be replicated with nonfat ingredients. Fats exhibit unique physical properties in meat and poultry products, e.g., their ability to combine with protein to form emulsions and their ability to enhance tenderness. In order to make a substitute product that qualifies for a "fat free" nutrient content claim, it may be necessary to replace fat with water and binders (i.e., additives that hold water and protein) which may result in a substitute meat or poultry food product with limitations in performance related to product uses because water and binders may not provide all of the physical and functional properties related to product use that are associated with fat, e.g., ability to be stored frozen. In products such as frankfurters, the increase in moisture which may be a direct result of fat replacement, and the way water is held by binders and dispersed in the product, can lead to the formation of large ice crystals because a higher level of available moisture makes the product less stable when thawed from the frozen state, i.e., water leaks from the product. Therefore, if a "fat free frankfurter" does

not tolerate frozen storage for long periods of time, because the ingredients needed to make the substitute product do not withstand the same conditions of storage as the standardized product for which it is a substitute, a non-performance statement would inform the consumer of that fact, e.g., "Do Not Freeze."

E. Ingredients Used in Substitute Products

1. *Ingredients Provided for by Proposed Regulation.* FSIS believes that the ingredients used in a substitute version of a standardized product should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable substitute product that meets the requirements of the expressed nutrient content claim that is intended to be used to reflect a reduction in a constituent that has negative health implication, e.g. fat, cholesterol, and sodium. Therefore, FSIS is proposing in 9 CFR 319.10(c) and 381.172(c) that ingredients used in a substitute product be those ingredients provided for by the traditional standard except that, in addition, "safe and suitable" ingredients, as defined in 9 CFR 318.7 and 381.147, may be used to improve texture and prevent syneresis so that the product has similar characteristics to the traditional standardized meat or poultry food product, e.g., taste and appearance.

This proposed rule would have the most significant impact on the use of water and binders as a "fat replacement system" for substitute products intending to use nutrient content claims related to reductions in fat and cholesterol. FSIS is providing the following list as examples of "fat replacing" binders, i.e., ingredients or additives historically classified as binders by food scientists, to aid commenters in understanding the types of ingredients the Agency believes are applicable to making substitute products that have reductions in fat and associated cholesterol. These ingredients have typically been restricted in standardized meat and poultry food product formulations, but will now be allowed in substitute products under the conditions described in this proposal. Examples of these substances are: Agar-agar; Algin; Sodium alginate; calcium carbonate, lactic acid, and calcium lactate (or glucono delta-lactone); Calcium reduced dried skim milk; Carrageenan; Carboxymethyl cellulose (Cellulose gum); Dried milk; Enzyme (rennet)-treated calcium reduced dried skim milk and calcium lactate; Food starch

modified; Gelatin; Guar gum; Methyl cellulose; Isolated soy protein; Sodium caseinate; Dry or dried whey; Reduced lactose whey; Reduced minerals whey; Whey protein concentrate; Starchy vegetable flour (e.g., potato flour, rice flour, and pea flour); Vegetable starch (e.g., corn starch, potato starch, and wheat starch); Wheat gluten; Tapioca dextrin; Soy flour; Soy protein concentrate; and Xanthan gum.

Emulsifying agents also aid water and binders in replacing fat and associated cholesterol by holding water, binders, and muscle tissue together. Therefore, they will be permitted in combination with water and binders as part of a fat-replacement system. Emulsifying agents identified in 9 CFR 318.7(c)(4) and 381.147(f)(4), e.g., lecithin, mono and diglycerides, and polyglycerol esters of fatty acids, commonly used as emulsifying agents in shortenings and margarines, can be used as part of the fat-replacement system in combination with approved binders and water, but are not considered to be "fat replacing" ingredients when used alone. This is because such substances are derived from fat and do not, themselves, mimic fat. However, emulsifying agents approved for use in meat and poultry products can be used in amounts consistent with the regulations, in combination with approved binders and water, and functioning as part of the "fat replacing system."

Humectants are another class of substances that assist water and binders to mimic fat. They are substances that attract and hold water, e.g., glycerine and corn syrup solids. Humectants would not be considered by themselves to be fat replacers, but would be allowed as part of a "fat-replacement system." Humectants do not by themselves mimic the functions of fat, but assist in fat-replacement systems by enhancing water binding.

2. *Use of Similar Ingredients.* The provision for the use of safe and suitable ingredients in substitute standardized meat and poultry products, which is proposed in 9 CFR 319.10(c)(1) and 381.172(c)(1), is not intended to allow for replacement or exchange of any required ingredients or component of a required ingredient in the standardized product with functionally similar ingredients from other sources not provided for by the standard. This intent is reflected in the provisions proposed in 9 CFR 319.10(c)(2) and 381.172(c)(2).

For example, FSIS believes that replacing the expected meat or poultry ingredient(s) of a standardized product with textured vegetable protein (TVP) to meet the requirements of a lower fat

nutrient content claim of a substitute standardized product should not be allowed because it would be misleading since such food ingredients are meat analogues. FSIS believes that consumers expect the meat or poultry in a meat or poultry product to be its primary source of protein and they view the meat as the valued component in a meat or poultry product. The Agency views textured vegetable protein as a "meat or poultry replacer." A multitude of "meat substitute" or "meat alternative" foods are currently marketed, e.g., "Veggie Burgers," "Veggie Patties," "Garden Links," and "Vegetarian Meat Loaf," and are primarily composed of textured vegetable protein. Textured vegetable protein is used as a meat or poultry alternative because it looks like and has texture like meat or poultry, and is virtually indistinguishable from meat or poultry in mixtures. FSIS believes that the use of textured vegetable protein as a "fat replacing" ingredient in a substitute product would be inappropriate because its use in such a product would change the nature of the product to such an extent that it would no longer be a substitute product within the parameters of this regulatory proposal.

In a similar manner, FSIS also considers foods, such as bread, rice, potatoes, cheese, fruits, and vegetables, to be characterizing ingredients that replace or exchange meat or poultry ingredients in meat or poultry food products. The Agency is aware that products currently exist that use such food ingredients because they blend in with the meat or poultry component of the product and "look like" the meat or poultry component. For example, cherries or beets used in a fresh ground beef mixture would have the appearance of lean beef. Rice or grits used in a ground sausage product would give the appearance of fat. Because these food ingredients have virtually no fat, their presence in products would result in a finished product with a lowered fat content. However, the lowered fat content would be a result of the food "filling" or "extending" the product rather than as a result of the food merely functioning as a fat replacer.

3. *Ingredients Prohibited by the Standard.* Ingredients that are prohibited from use in standardized products identified in 9 CFR parts 319 and 381, subpart P, would also be prohibited from use in substitute meat and poultry food products, e.g., poultry kidneys or sex glands are prohibited from use in certain cooked sausages (9 CFR 319.180(b)) and would likewise be prohibited for modified versions of traditional standardized products.

Ingredients that are restricted from use in formulating *any* meat or poultry food product, as addressed in 9 CFR 318.7 and 381.147, would continue to be prohibited in substitute meat and poultry food products because they are not approved as safe or suitable for use in meat and poultry. For example, 9 CFR 318.7(d)(2) prohibits sorbic acid and its salts from use in formulating meat products and, thus, would continue to be prohibited in substitute products.

F. Nomenclature

How Substitute Meat and Poultry Food Products are Named. FSIS is proposing in 9 CFR 319.10(d) and 381.172(d) that the name of a substitute meat or poultry food product that complies with 9 CFR 319.10 and 381.172 will be an appropriate expressed nutrient content claim, in conjunction with (i.e., next to) the respective appropriate standardized term (e.g., fat free bologna). If a food meets the requirements of 9 CFR 319.10 and 381.172, it is itself a standardized food. Therefore, even though it does not meet all of the requirements of the standard underlying the term included in its name, its name will not be required to contain the term "substitute" or "alternate." These meat and poultry food products will not purport to be the traditional standardized meat or poultry food product currently defined in 9 CFR parts 319 and 381, subpart P. Rather, these products will purport to be a food that satisfies the requirement of the standard in 9 CFR 319.10 and 381.172. Thus, these products will be appropriately named by use of an expressed nutrient content claim and the appropriate standardized term.

FSIS believes that the labeling for substitute meat and poultry food products should distinguish them from traditional standardized products for which they are substitutes in order to provide consumers with accurate and nonmisleading information, as required by the FMIA and PPIA, with which to make a purchase decision. Because the substitute product's identity is the expressed nutrient content claim adjacent to the standardized term, these words must be presented in the same style, color, and size of type, to further distinguish the substitute meat and poultry food product from other products that bear nutrient content claims, but that are not substitute meat and poultry products meeting the requirements presented in this proposal. Furthermore, the substitute product must comply with general labeling provisions established by regulations in 9 CFR 317 and 381, subpart N in order to assure that its labeling is not false or misleading.

G. Ingredient Labeling

FSIS is proposing in 9 CFR 319.10(e) and 381.172(e) that each of the ingredients used in the substitute meat and poultry food product shall be declared on the label as required by applicable regulations in 9 CFR parts 317 and 381, subpart N. Under 9 CFR parts 317 and 381, subpart N, in general, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

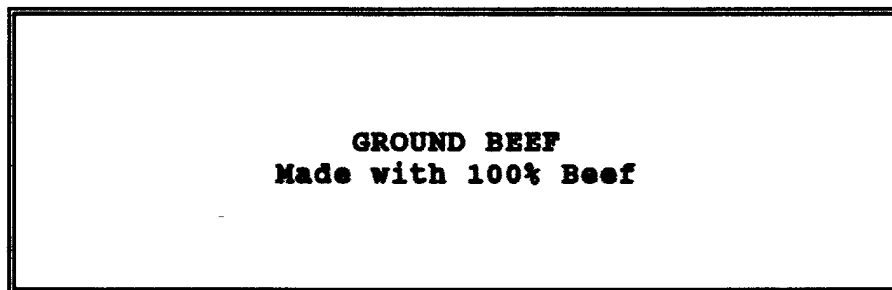
To assist the consumer in differentiating between the traditional standardized meat or poultry food product and the substitute version of the traditional standardized product, FSIS

is proposing in 9 CFR 319.10(e) and 381.172(e) that all "safe and suitable" ingredients not provided for by the traditional standard, as well as permitted ingredients added at levels in excess of those allowed by the traditional standard, must be appropriately identified as such with an asterisk in the ingredients statement to assure that the labeling of the substitute product will not be false or misleading. Therefore, the statement "Ingredients not in regular (name of the traditional standardized food)," or "Ingredients in excess of amount permitted in regular (name of the traditional standardized food)," or both statements as appropriate, shall immediately follow the ingredients statement in the same type size. The asterisk statements must clearly distinguish between "those ingredients not permitted in" and "those ingredients used in excess of amounts permitted" in a standardized product.

FSIS believes that the product name on the principal display panel of the substitute meat and poultry food product, as well as its ingredients statement, are the pertinent labeling features that identify the difference between the traditional standardized product and the modified version bearing the standardized name. The following simplified label sketches illustrate how labeling of a standardized product (Figure 1, GROUND BEEF) would differ from labeling of a substitute version (Figure 2, LOW FAT GROUND BEEF) and how labeling of a standardized product (Figure 3, BEEF FRANKS) would differ from a substitute version (Figure 4, REDUCED FAT BEEF FRANKS) according to provisions proposed by this rule.

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Figure 1.—Illustration of a Label for a Standardized Product—GROUND BEEF, according to 9 CFR 319.15



(Voluntary Nutrition Labeling)

Figure 2.—Illustration of Label for Substitute Product—LOW FAT GROUND BEEF, according to Proposed 9 CFR 319.10

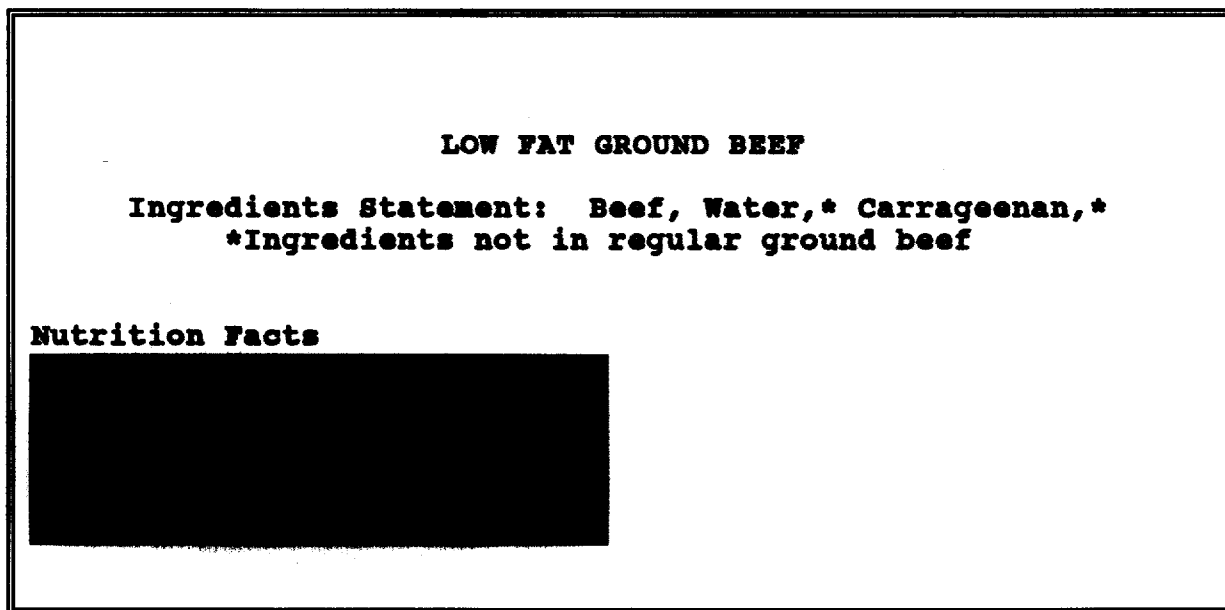


Figure 3.—Illustration of Label for a Standardized Product—BEEF FRANKS, according to 9 CFR 319.180

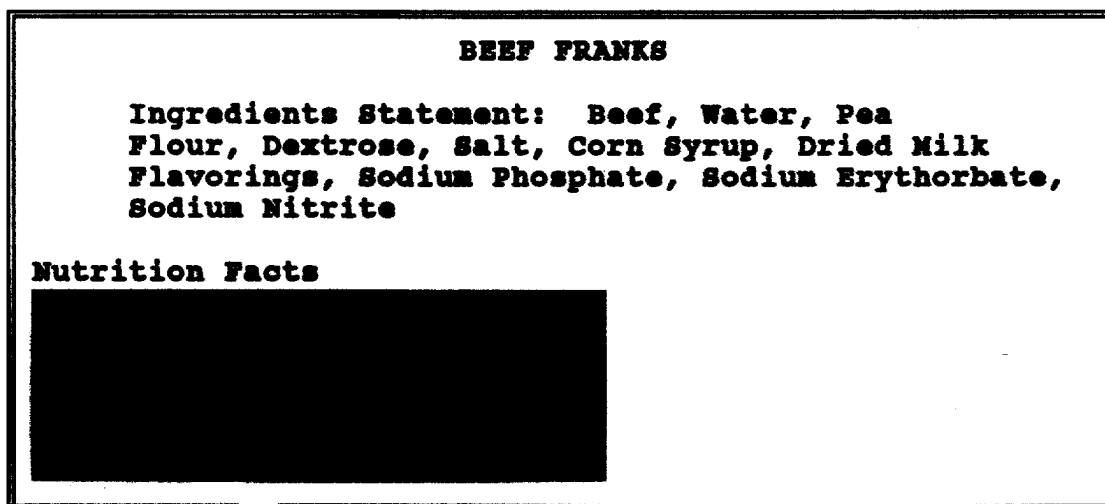
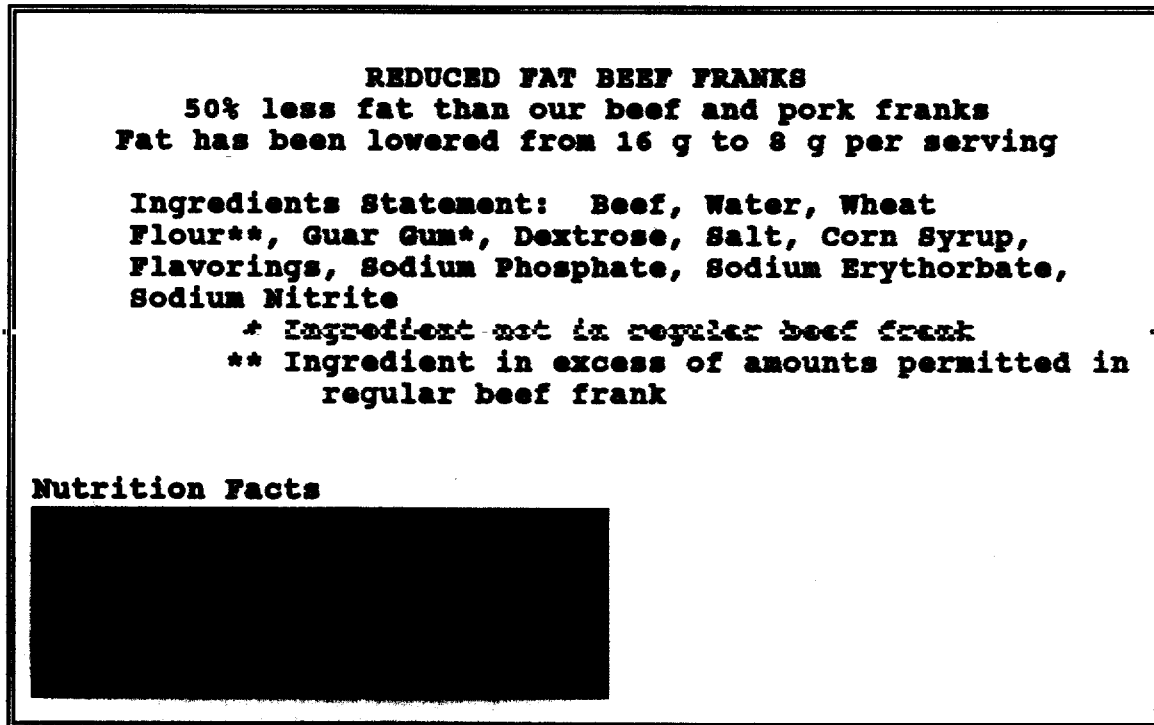


Figure 4.—Illustration of Label for Substitute Product—REDUCED FAT BEEF FRANKS, according to Proposed 9 CFR 319.10



BILLING CODE 3410-DM-C

Nutrition labeling and the listing of ingredients in order of predominance for substitute products, along with its product name and special ingredient labeling for certain differences between it and a traditional standardized product will allow consumers to be able to evaluate the merits of substitute meat and poultry food products using an expressed nutrient content claim and a standardized name. As discussed, this labeling approach for establishing a general standard of identity is similar to the labeling scheme established by FDA in final rules (21 CFR 130.10) published January 6, 1993 (58 FR 2431).

V. Advance Notice of Proposed Rulemaking on Standards Reform

The Agency is planning to publish an ANPR that explores alternative approaches to defining and standardizing meat and poultry products to assure that they bear truthful and accurate names, are labeled in a manner that is not false or misleading, and contain only safe and suitable ingredients. The ANPR will consider the broader issues concerning the role regulatory standards of identity and composition should play in today's market.

Executive Order 12866

This proposed rule has been determined to be significant for purposes of Executive Order 12866. This proposed rule would allow for substitute meat and poultry food products to deviate from current standards, provided certain conditions are met.

FSIS issued Policy Memo 121B and Policy Memo 123 as interim policies to accommodate development and distribution of certain lower fat substitute meat and poultry products while undergoing this rulemaking process. To date, industry already has taken advantage of this policy by introducing new products. This rule is necessary to encourage and continue the development of more meat and poultry products with reductions in food constituents having health implications, e.g., lower in fat and cholesterol.

Today's consumers are looking for versions of popular standardized processed meat and poultry food products that have reductions in fat and cholesterol. To take advantage of advances in ingredient and processing technologies, meat and poultry food processors would be provided with the flexibility to formulate and market new meat and poultry products with reductions in fat content, cholesterol,

and sodium—constituents which are of concern to today's health conscious consumers—and identify them by an expressed nutrient content claim and by names that are familiar to consumers.

If the proposed rule encourages firms to market a greater variety of nutritious meat and poultry products, then consumers will enjoy the benefit of greater product choices. Consumers will also benefit from a healthier diet by the availability of products with lower fat and cholesterol contents if the market is sufficiently strong to sustain increased sales of these products. Research conducted by the Economic Research Service of the U.S. Department of Agriculture has shown that when healthier diets lead to reductions in incidence of heart disease, cancer, stroke, diabetes, or other health problems, then economic benefits accrue in the form of reduced medical costs and productivity losses due to medical infirmity and premature death. While it is not yet possible to determine the extent to which the rule would lead to healthier diets and lower medical costs, there could be a benefit to society.

This proposed rule would not mandate any changes to the way meat and poultry products must be labeled, but would provide the meat and poultry industry with the option of producing

substitute meat and poultry food products. Therefore, any cost incurred would be voluntary.

If firms chose to make ingredient substitutions to bring newer, healthful products to market, they may incur some short run costs. However, these are the normal costs of marketing and production. If they are incurred, they arise because a firm expects the new product to be profitable. The costs of bringing these new products to market would, in the long run, be less than the benefits to firms of increased sales and profits. If the market for substitute foods is substantial enough for firms to successfully market these new products, then there may be a net economic benefit to the industry.

The net effect of the proposed rule would be beneficial to the meat and poultry industry as a whole and would provide consumers with a greater diversity of meat and poultry products. Consumers would benefit from the proposed rule because it is expected to increase the variety of processed meat and poultry products that would be available from which to make the most healthful dietary choices for each individual. At the same time, the proposed rule would safeguard the integrity of traditional standardized meat and poultry food products that have served the market well and for which there is expected to continue to be a strong demand. Consumers would be informed by the product labeling of the differences between the traditional standardized product and the modified version.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirement on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements

that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this proposed rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this proposed rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR parts 335 and 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provisions of this proposed rule with respect to labeling decisions.

Effect on Small Entities

The Administrator, FSIS, has made an initial determination that this proposed rule would 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). Small manufacturers would be provided the flexibility to create more meat and poultry products that have reductions in certain food constituents that have health implications. Small businesses who choose to market the new substitute meat and poultry food products would be required to design new labels or make certain revisions to their existing product labels, thereby, incurring some costs. These costs could be outweighed by the potential revenue increases from sales of the new substitute products.

Paperwork Requirements

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. This proposed rule would require manufacturers producing new meat and poultry products in accordance with the definition and general standard of identity for modified processed meat and poultry products to design their new product labels and submit such labeling to FSIS for approval.

Estimate of Burden: Meat and poultry establishments must develop product labels in accordance with the regulations. To receive approval of the labels, establishments must complete FSIS Form 7234-1. FSIS program employees review FSIS Form 7234-1 to ensure that information on the labels complies with the regulations. FSIS estimates that it will take 60 minutes to design and develop modified product labels in accordance with the proposed

regulations and 15 minutes to prepare FSIS Form 7234-1 and submit it, along with the label, to FSIS or to a label expeditor who will deliver the form and label to FSIS.

Respondents: Meat and poultry product establishments.

Estimated Number of Respondents: FSIS estimates that at this time 100 establishments would have to develop new labels.

Estimated Number of Responses per Respondent: FSIS estimates that each establishment would modify about 5 product labels.

Estimated Total Annual Burden on Respondents: 625 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, South Agriculture Building, Room 3812, Washington, DC 20250.

Comments regarding the need for and usefulness of the proposed requirements, the accuracy of FSIS's burden hour estimate, ways to minimize the estimated burden, including through the use of automated collection techniques or other forms of information collection technology, or any other aspect of this collection of information discussion, to Lee Puricelli, Paperwork Specialist, at the address above.

All responses to this notice will be summarized and included in FSIS's request for the Office Management and Budget (OMB) approval of the proposed regulation's paperwork requirements. All comments submitted will also become a matter of public record.

Comments

Interested persons may submit an original and two copies of written comments concerning this proposed rule to: FSIS Docket Clerk, DOCKET #92-024P, Room 4352, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Any person desiring an opportunity for an oral presentation of views should make such a request to Mr. Charles R. Edwards so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to this proposal will be available for public inspection in the FSIS Docket Room, Room 4352, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, 8:30 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday.

List of Subjects

9 CFR Part 319

Food grades and standards, Meat inspection.

9 CFR Part 381

Food grades and standards, Meat inspection, Poultry and poultry products.

Proposed Rule

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR parts 319 and 381 as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. Part 319, Subpart A would be amended by adding a new § 319.10 to read as follows:

§ 319.10 Requirements for substitute processed meat food products named by use of an expressed nutrient content claim and a standardized term.

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 317.313(d) for a standardized food defined in this part and use the name of that standardized food in their statement of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 317, subpart B of this subchapter. The expressed nutrient content claim shall comply with the requirements of § 317.313 of this subchapter and with the requirements of part 317, subpart B of this subchapter that define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties and shelf-life, of the meat food product shall be similar to those of the standardized meat food product produced under this part. If there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food defined in this

part, the label shall include, adjacent to the product name, a statement in accordance with § 317.313(d) (1) and (2) of this subchapter, informing the consumer of such differences (e.g., if appropriate, “not recommended for frozen storage” or “not suitable for roller grilling”). Deviations from ingredient provisions of the standard that must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients Used in Substitute Foods.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in this part, except that safe and suitable ingredients approved for use in meat food products as described in § 318.7 of this subchapter may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in this part for which it is a substitute.

(2) An ingredient or component of an ingredient that is specifically required by the standard prescribed in this part shall not be replaced or exchanged with a similar ingredient from another source, for example, textured vegetable protein shall not replace meat, and turnips shall not replace potatoes in corned beef hash.

(3) An ingredient or component of an ingredient that is specifically prohibited from use in any meat food product by this part shall not be added to the substitute meat food product under this section.

(4) All ingredients that are specifically required by a standard of identity or composition as defined in this part shall be present in the substitute product in the same amounts as required by the standard for which the product is a substitute. The meat portion of the substitute product must come from the same anatomical location, be of the same kind and amount, and undergo the same basic processing procedures as the standardized product in this part for which it substitutes.

(5) Water and fat-replacers (i.e., binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute meat food product that complies with this section is the appropriate expressed nutrient content claim and the applicable standardized term, which shall be in the same style, color, and size of type.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute meat food product shall be declared on the

label as required by this section and part 317 of this subchapter.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in this part, shall be identified as such with an asterisk in the ingredients statement. The statement “*Ingredient(s) not in regular _____” (The blank shall be filled in with the name of the traditional standardized product) or “**Ingredient(s) in excess of amounts permitted in regular _____” (The blank shall be filled in with the name of the traditional standardized product), or both as appropriate shall immediately follow the ingredients statement in the same type and size.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

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

4. Part 381, subpart P would be amended by adding a new § 381.172 to read as follows:

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

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

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties and shelf-life, of the poultry food product shall be similar, except in regard to uses, to those of the standardized poultry food product produced under subpart P of this part. If there is a significant difference in performance characteristics that

materially limits the use of the food compared to the use of the standardized food defined in subpart P of this part, the label shall include, adjacent to the product name, a statement in accordance with § 317.313(d) (1) and (2) of this part, informing the consumer of such differences (e.g., if appropriate, "not recommended for frozen storage" or "not suitable for roller grilling"). Deviations from ingredient provisions of the standard that must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients Used in Substitute Foods.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in subpart P of this part, except that safe and suitable ingredients approved for use in poultry food products as described in § 381.147 of this part may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in subpart P of this part, for which it is a substitute.

(2) An ingredient or component of an ingredient that is specifically required by the standard prescribed in subpart P

of this part shall not be replaced or exchanged with a similar ingredient from another source, for example, textured vegetable protein shall not replace poultry, and turnips shall not replace potatoes in corned beef hash.

(3) An ingredient or component of an ingredient that is specifically prohibited from use in any poultry food product by subpart P of this part shall not be added to the substitute poultry food product under this section.

(4) All ingredients that are specifically required by a standard of identity or composition as defined in subpart P of this part shall be present in the substitute product in the same amounts as required by the standard for which the product is a substitute. The poultry portion of the substitute product must come from the same anatomical location, be of the same kind and amount, and undergo the same basic processing procedures as the standardized in subpart P of this part product for which it substitutes.

(5) Water and fat-replacers (i.e., binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute poultry food product that complies with this section is the

appropriate expressed nutrient content claim and the applicable standardized term, which shall be in the same style, color, and size of type.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute poultry food product shall be declared on the label as required by this section and subpart N of this part.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in subpart P of this part, shall be identified as such with an asterisk in the ingredients statement. The statement "***Ingredient(s) not in regular _____" (The blank shall be filled in with the name of the traditional standardized product) or "***Ingredient(s) in excess of amounts permitted in regular _____" (The blank shall be filled in with the name of the traditional standardized product), or both as appropriate shall immediately follow the ingredients statement in the same type and size.

Done at Washington, DC, on: December 21, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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