

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Parts 317 and 381**

[Docket No. 98-005P]

RIN 0583-AC60

Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products**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 require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. For these products, FSIS is proposing to make the guidelines currently in place for the voluntary nutrition labeling program mandatory. Thus, the Agency is proposing to require that nutrition information be provided for these products either on their label or at their point-of-purchase. During the most recent surveys of retail stores, the Agency did not find significant participation in its voluntary nutrition labeling program, which covers the major cuts of single-ingredient, raw products. Without nutrition information for these products, the Agency has tentatively concluded that the major cuts of single-ingredient, raw meat and poultry products would be misbranded under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

FSIS is also proposing to amend its regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. Under existing regulations, multi-ingredient ground or chopped products, (e.g., ground pork with seasonings), and heat processed ground or chopped products (e.g., fully cooked or partially cooked patties) are required to be nutritionally labeled, unless they qualify for an exemption, but single-ingredient, raw ground or chopped products are not required to be so labeled. Without nutrition information for single-ingredient, raw ground or chopped products, the Agency has tentatively concluded that these products would be misbranded under the Federal Meat Inspection Act and the Poultry Products Inspection Act. The Agency has also tentatively determined that single-ingredient, raw ground or

chopped meat and poultry products are different from other single-ingredient, raw meat and poultry products in several important respects. Thus, FSIS is proposing to make nutrition labeling requirements for all ground or chopped meat and poultry products consistent with those currently required for products in the mandatory nutrition labeling program (multi-ingredient and heat processed products).

FSIS is proposing to require nutrition labels on packages of single-ingredient, raw ground or chopped products, rather than at their point-of-purchase, largely because these products are similar to products in the mandatory nutrition labeling program (which requires nutrition information to be on the label of individual packages), in that certain parameters, such as their fat content, can be controlled precisely to obtain the desired product. Although FSIS believes that nutrition information on labels of individual packages of single-ingredient, raw products is useful, FSIS is proposing that nutrition information for the major cuts of single-ingredient, raw products may also be provided on point-of-purchase materials because FSIS believes that consumers have reasonable expectations as to the nutrient content of these products, the nutrient content of a specific major cut is relatively uniform across the market, and because these products are not formulated in the manner of ground or chopped products. For single-ingredient, raw products that are not major cuts and that are not ground or chopped, FSIS is not proposing to require nutrition information on their labels or at their point-of-purchase because FSIS has not yet assessed whether adequate nutrition information is being provided for these products and, therefore, has not determined whether it would be beneficial to require nutrition labeling for these products.

Finally, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the criteria to be labeled "low fat," a lean percentage claim may be included on the label or in labeling as long as a statement of the fat percentage also is displayed on the label or in labeling.

DATES: Comments must be received on or before April 18, 2001.

ADDRESSES: Submit one original and two copies of comments to FSIS Docket Clerk, Docket #98-005P, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. Reference material cited in the document and any

comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Post, Director, Labeling and Additives Policy Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0279.

SUPPLEMENTARY INFORMATION:**Background***The Current Mandatory and Voluntary Nutrition Labeling Programs*

Mandatory nutrition labeling program. The Nutrition Labeling and Education Act (NLEA) of 1990 required nutrition labeling of most foods regulated by the Food and Drug Administration (FDA). FSIS published regulations establishing comparable nutrition labeling requirements for meat and poultry products. As explained in its proposed and final rules, FSIS determined that it had statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information, under section 1(n) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(n)(1)) and section 4(h)(1) of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(h)(1)) (56 FR 60305 and 58 FR 637). These statutory provisions state that a product is misbranded if it is false or misleading in any particular. FSIS published an advance notice of proposed rulemaking on nutrition labeling of meat and poultry products on April 2, 1991 (56 FR 13564), a proposed rule on November 27, 1991 (56 FR 60302), a final rule on January 6, 1993 (58 FR 632), and subsequently other amendments to the rule.

FSIS' regulations require nutrition labels on the packages of all multi-ingredient and heat processed meat and poultry products, unless an exemption applies. The required nutrition labeling provisions are referred to as "the mandatory nutrition labeling program." The regulations include exemptions from nutrition labeling requirements for food products produced by small businesses, products intended for further processing, products not offered for sale to consumers, products in small packages that are individually wrapped packages of less than 1/2 ounce net weight, custom slaughtered or prepared products, products intended for export, ready-to-eat products that are packaged

or portioned at a retail store or similar retail-type establishment, and multi-ingredient products processed at a retail store or similar retail-type establishment. The regulations also provide that nutrition labeling may be provided by alternate means for packages that have a total surface area available to bear labeling of less than 12 square inches; for these products, the regulations permit manufacturers to provide an address or telephone number on the package for consumers to write or call for nutrition information. Except for the nutrition labeling exemptions for custom slaughtered or prepared products and products intended for export, the exemptions from nutrition labeling requirements and the provision for alternate means of providing nutrition labeling on packages that have a limited surface area to bear labeling apply only when a product's labeling includes no nutrition claims or nutrition information. The regulations also state that restaurant menus generally do not constitute nutrition labeling or fall within the scope of the nutrition labeling regulations, and that foods represented or purported to be specifically for infants and children less than 4 years of age shall not include certain nutrient content declarations (see §§ 317.400 and 381.500).

The regulations specify the information that must be included on the labels of products in the mandatory nutrition labeling program. The required information includes the levels of total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, and certain vitamins and minerals in the product. In certain situations, information concerning some of these nutrients is not required. For example, the label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat per serving. The regulations also provide that information concerning stearic acid, polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, insoluble fiber, sugar alcohol, other carbohydrates, and calories from saturated fat may be included voluntarily. When claims related to these nutrients are made, or when certain related nutrients are declared, information concerning these nutrients is required.

The regulations require that the nutrient and food component quantities on the label of products in the mandatory nutrition labeling program be declared in relation to a serving. The regulations also require that the declaration of nutrient and food component content be on the basis of

the product "as packaged"; in addition, the declaration of nutrient and food component content may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated. The regulations also prescribe format requirements for nutrient information, which include specified headings that must be used in the presentation of nutrition labeling information.

The regulations include provisions for Agency monitoring of compliance with the mandatory nutrition labeling requirements. FSIS conducts a continuous product sampling program to ensure compliance with nutrition labeling requirements (see §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8)).

Voluntary nutrition labeling program. In the preamble to the January 6, 1993, final rule, FSIS stated that it would not require nutrition labeling for single-ingredient, raw meat and poultry products because the nutrient values of these products are not modified through various stages of preparation, such as cooking and heat processing. Therefore, the Agency believed that consumers had reasonable expectations as to the nutritional qualities of these products (58 FR 637). In the preamble to the proposed rule, FSIS also stated that nutrition information for single-ingredient, raw products was available to consumers through other means such as the extension service, grocery stores, and trade associations (56 FR 60306). For these reasons, although the Agency adopted a mandatory nutrition labeling program for multi-ingredient products and heat processed products, it chose not to do so for single-ingredient, raw meat and poultry products, including single-ingredient, raw ground or chopped products. Instead, it established guidelines for voluntary nutrition labeling of these products (see §§ 317.345 and 381.445).

Under the voluntary nutrition labeling program, retailers and manufacturers are not required to provide nutrition information for single-ingredient, raw meat or poultry products. Instead, retailers and manufacturers voluntarily may provide nutrition information on the label of these products, or at their point-of-purchase by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. However, if a nutrition claim is made on these materials, all of the requirements of the mandatory nutrition labeling program apply.

If only nutrition information, and not a nutrition claim, is supplied on the point-of-purchase materials of single-

ingredient, raw products, the requirements of the mandatory program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed basis"; the listing of percent of Daily Value for certain nutrients and the footnote explaining that the Daily Values are based on a 2,000 calorie diet and that daily values may differ depending on calorie needs (see §§ 317.309(d)(9) and 381.409 (d)(9)) may be omitted; and the point-of-purchase materials are not subject to any format requirements.

If, however, a retailer or manufacturer provides nutrition information on the label of single-ingredient, raw products, this information must be presented in the same format as that prescribed for mandatory nutrition labeling of various products. However, for these products, unlike products in the mandatory nutrition labeling program, the nutrition information may be declared on the basis of either "as consumed" or "as packaged." If the information is presented on the basis of "as consumed," the regulations provide that the methods used to cook the product must be specified and should be those which do not add nutrients from other ingredients (see §§ 317.345(d) and 381.445(d)). Also, unlike products in the mandatory program, the declaration of the number of servings per container need not be included on the nutrition label.

The regulations provide that the Agency will not conduct compliance sampling and testing of a product subject to the voluntary nutrition labeling program that contains nutrition labeling if the nutrition labeling is based upon the most current representative data base values contained in USDA's National Nutrient Data Bank or in its published form, the Agriculture Handbook No. 8 series, and if there are no nutrition claims made on the basis of the representative database values on the labeling of these products (§§ 317.309(h)(9), 317.345(e), 317.345(f), 381.409(h)(9), 381.445(e), and 381.445(f)).

The Agriculture Handbook No. 8 series is now out of print. The current released form of the USDA's National Nutrient Data Bank is the USDA Nutrient Database for Standard Reference. USDA's Nutrient Data Bank is the Agricultural Research Service's internal system that stores information and has features necessary to produce the released database. The USDA Nutrient Database for Standard Reference is developed and maintained by the Agricultural Research Service and can be found on the internet at the

following address: <http://www.nal.usda.gov/fnic/foodcomp>.

The Agency may conduct sampling and testing for compliance with nutrition labeling requirements for single-ingredient, raw meat and poultry products if the nutrition information on their labeling is not based on the latest values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims made on the basis of the representative database values, on the labeling of these products.

Compliance with voluntary nutrition labeling guidelines. FSIS' regulations provide that the Agency monitor compliance with its voluntary nutrition labeling program guidelines by evaluating the participation of retailers in the voluntary program every two years, beginning in May 1995, to determine whether significant participation of at least 60 percent of all companies evaluated exists (§§ 317.343 and 381.443). FSIS stated that it would issue its first report of its survey findings on the voluntary program by May 1995, and that it would reevaluate every two years after 1995 whether significant participation existed in the voluntary nutrition labeling program (56 FR 60306).

FSIS regulations provide that a food retailer is participating at a significant level (1) if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products it sells; and (2) if the nutrition label on these products is consistent in content and format with the mandatory program, or if nutrition information is displayed at point-of-purchase in an appropriate manner. The regulations provide that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines. The regulations provide that the voluntary nutrition labeling program will remain in effect as long as there is significant participation in the voluntary program by retail stores (§§ 317.343 and 381.443).

FSIS contracted with an independent market research contracting firm to conduct the retail surveys in 1995, 1996, and 1999. For each of these surveys, the firm surveyed a nationally representative sample of approximately 2,000 retail stores to obtain the information necessary to assess compliance with the guidelines for voluntary nutrition labeling of single-ingredient, raw meat and poultry products.

The first survey to determine participation by retail stores in the voluntary nutrition labeling program was conducted in June 1995. At that time, the National Retail Tracking Index, Inc., found that 66.5 percent of the stores surveyed were providing nutrition information on 90 percent of the major cuts of single-ingredient, raw meat and poultry products. Therefore, this survey showed that significant participation in the voluntary nutrition labeling program existed. FSIS published a notice of availability of the survey results in the January 29, 1996 *Federal Register* (61 FR 2790). In this survey, stores were counted as participating in the voluntary nutrition labeling program if they used point-of-purchase materials developed by the Food Marketing Institute (FMI) prior to the 1993 final rule on nutrition labeling of meat and poultry products. These materials did not comply entirely with the voluntary nutrition labeling program provisions in the 1993 final rule. For example, the older materials did not include the required percent daily values for certain nutrients. Therefore, the results of this survey may overestimate participation in the voluntary nutrition labeling program.

The second survey was conducted in mid-December 1996. FSIS conducted it jointly with FDA. For this survey, the two agencies contracted with the firm that conducted the 1995 FSIS survey, now named Retail Diagnostics, Incorporated (RDI). At this time, RDI found that 57.7 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. The third survey was conducted in October 1999. At this time, RDI found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. Therefore, the two most recent surveys did not show significant participation in the voluntary nutrition labeling program, according to the voluntary nutrition labeling program regulations. Reports on the 1996 and 1999 surveys are available electronically on the FSIS web page at <http://www.fsis.usda.gov>.

Nutrient Content Claims

In addition to establishing the mandatory and voluntary nutrition labeling programs, the January 6, 1993, final rule provided definitions at §§ 317.362 and 381.462 for specific nutrient content claims, including the terms "lean" and "extra lean." The

definitions of "lean" and "extra lean" provide that these terms may be used on the label or in labeling only if the product meets certain criteria (see §§ 317.362(e)(1) and (2) and 381.462(e)(1) and (2)). Meat products may be labeled "lean" if they contain less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol per 100 grams of product and per reference amount customarily consumed for individual foods. Meat products may be labeled "extra lean" if they contain less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per 100 grams of product and per reference amount customarily consumed for individual foods. Ground beef and hamburger seldom meet the criteria that would allow producers to use the terms "lean" or "extra lean" on the label or in labeling of these products.

The existing nutrition labeling regulations also provide that the term "___ percent lean" is a synonym for the term "___ percent fat free," and that, in order for either term to be used on the label or in labeling of the product, the product must meet the criteria for "low fat" (§§ 317.362(b)(6) and 381.462(b)(6)). To meet the criteria for "low fat," a product must have a reference amount customarily consumed greater than 30 grams or greater than 2 tablespoons and must contain 3 grams of fat or less per reference amount customarily consumed for individual foods, or must have a reference amount customarily consumed of 30 grams or less or 2 tablespoons or less and must contain 3 grams or less of fat per reference amount customarily consumed and per 50 grams (§§ 317.362(b)(2) and 381.462(b)(2)). Most ground beef and hamburger do not qualify as "low fat." Therefore, existing regulations preclude the use of the term "___ percent lean" on these products.

On May 24, 1994 (59 FR 26916), FSIS published a proposed rule entitled "Nutrition Labeling of Ground Beef and Hamburger." In the preamble to the proposal, FSIS explained that the Agency had determined that, although the existing regulations precluded producers of ground beef and hamburger from using the terms "lean," "extra lean," and "___ percent lean," these products should be labeled to permit consumers to readily identify and differentiate between the varying lean to fat ratios in such products. The Agency also stated that allowing such labeling would assist consumers in selecting leaner versions of these products and would provide an incentive for manufacturers to market products lower in fat. Finally, FSIS

recognized that many producers had been using lean percentages on the labeling of ground beef and hamburger products for a significant period of time (59 FR 26917).

Accordingly, FSIS proposed to amend its regulations to permit the use of percentage labeling for lean and fat on ground beef and hamburger products. Under this proposal, FSIS would have permitted a statement of the lean percentage on the labeling of ground beef and hamburger if it were contiguous to a statement of the fat percentage. The Agency would have allowed this labeling even when the ground beef or hamburger did not qualify as "low fat." The Agency proposed to allow the use of the statement of lean and fat percentages only if the product were accompanied by nutrition information presented on the label, or in point-of-purchase materials in close proximity to the product. FSIS stated that it would consider expanding the proposed percentage labeling to ground meat from other species and to ground poultry if information submitted during the comment period demonstrated the need and consumer acceptability of these terms for such products or that differential treatment of ground beef relative to other ground products would inappropriately restrict informed consumer choice (59 FR 26918).

The Agency received a total of 2,732 comments on this proposal. Fifty-five percent (1,504) of the commenters supported the proposal, 39 percent (1,063) opposed it, and 6 percent (165) addressed issues outside the scope of the proposed rule. Supporters of the proposal included trade associations representing food manufacturers and retailers, food manufacturers of both meat and poultry products, a large number of retailers, and State departments of agriculture. Supporters stated that percentage labeling provides useful information to consumers, that "lean labeling" aids consumers in selecting lower fat products, and that percentage labeling has been in use for more than 20 years. Opponents included consumer interest groups, health professionals and organizations, and consumers. They stated that the use of percent lean labeling is inherently misleading to consumers and will cause consumers to view ground beef as "lean" or "low fat."

Twenty-one of the 1,504 commenters who supported the provisions wanted them to also apply to other species or products. These commenters stated that allowing percentage labeling for lean and fat for other ground meat and poultry products, besides ground beef

and hamburger, would allow consumers to compare the fat content of beef or poultry items and to make informed dietary choices.

On August 5, 1994, FSIS published a notice of extension of the date that it would enforce compliance with the nutrition labeling requirements for ground beef and hamburger (59 FR 39941). The Agency extended the compliance enforcement date for these products indefinitely, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger. The Agency has not published a final rule concerning percentage labeling of ground beef and hamburger. Therefore, producers and retailers continue to use the term "lean" in percentage labeling on the packages of ground beef and hamburger.

Other Nutrition Activities

In addition to developing this proposed nutrition labeling rule, USDA conducts numerous other activities related to nutrition. This proposed rule on nutrition labeling is an integral part of USDA's efforts to educate consumers concerning nutrition and diets. Since 1980 USDA and the Department of Health and Human Services (HHS) have jointly published the Dietary Guidelines for Americans every five years. The Dietary Guidelines provide advice concerning food choices that promote health and prevent disease. USDA and HHS released the Dietary Guidelines for Americans, 2000, at the National Nutrition Summit on May 30, 2000, which was jointly sponsored by USDA and HHS. The Dietary Guidelines for Americans, 2000, advises consumers to aim for a total fat intake of no more than 30 percent of calories (page 30). In addition, the Dietary Guidelines for Americans, 2000, includes a chart showing the recommended upper limits for grams of saturated fat and total fat per day for a range of total calories per day (page 30). The nutrition information that FSIS is proposing to require on labels of ground or chopped products and on either labels or point-of-purchase materials for the major cuts of single-ingredient, raw products would include the number of calories and the grams of total fat and saturated fat the product contains. The information FSIS is proposing to require would, therefore, assist consumers in following the advice in the Dietary Guidelines for Americans, 2000.

Proposed Changes

Nutrition labeling of the major cuts of single-ingredient, raw products. The Agency is proposing to require nutrition labeling of the major cuts of single-

ingredient, raw meat and poultry products, except for certain exemptions. For these products, FSIS is proposing to make the guidelines currently in place for the voluntary nutrition labeling program mandatory. Thus, for all of these products, other than raw ground beef and ground pork which are currently classified as major cuts, FSIS is proposing that nutrition information be provided on the label of these products or at their point-of-purchase. As discussed below, at this time, FSIS is not proposing to require nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped products.

In the preamble to the final rule on nutrition labeling of meat and poultry products, under the discussion of its voluntary nutrition labeling program which covered all single-ingredient, raw meat and poultry products, FSIS stated that it believed that it was important to provide nutrition information to consumers (58 FR 640). FSIS also stated that it believed that by allowing for the use of point-of-purchase materials for single-ingredient, raw meat and poultry products, retailers would be able to provide consumers with the necessary nutrition information (58 FR 640). FSIS continues to believe that nutrition information for these products is important and necessary.

In the two most recent surveys, FSIS found that significant participation in the voluntary nutrition labeling program does not exist. FSIS found that less than 60 percent of the stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products. In its proposed and final rules on nutrition labeling of meat and poultry products, FSIS stated that if it determined, during any evaluation of its voluntary guidelines, that significant participation did not exist, it would initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products (56 FR 60306, 58 FR 640).

Because the most recent surveys showed that significant participation in the voluntary nutrition labeling program does not exist, FSIS now believes that this proposed rule is necessary and that it would be beneficial to require the labeling of the major cuts of single-ingredient, raw meat and poultry products to bear nutrition information. FSIS believes that without nutrition information, consumers are not able to assess the nutrient content of the major cuts and thus cannot make educated

choices about these products based on nutrition information. FSIS believes that the lack of this information on the labeling of the major cuts causes the labeling to be misleading. The FMIA and PPIA provide that product is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 601(n)(1) and 453(h)(1)). Therefore, without the nutrition information for the major cuts of single-ingredient, raw products that would be provided if significant participation in the voluntary program existed, the Agency has tentatively concluded that these products would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA. FSIS requests comments on whether consumers are currently able to assess the nutrient content of the major cuts and whether consumers are currently able to make educated choices about these products based on nutrition information.

If the guidelines currently in place for the voluntary nutrition labeling program are made mandatory, it would ensure that consumers are provided with necessary nutrition information concerning the major cuts. Therefore, the Agency is proposing to make mandatory for the major cuts of single-ingredient, raw meat and poultry products the current provisions for the voluntary nutrition labeling program for presentation of nutrition information on point-of-purchase materials.

FSIS intends to make point-of-purchase materials available over the Internet free of charge. The point-of-purchase materials reflecting the final nutrition labeling regulations that FMI developed show nutrition information in charts with columns covering multiple products. FSIS requests comments on whether the Agency should develop point-of-purchase materials that present nutrition information as a compilation of individual nutrition facts panels for each product or whether the nutrition information on the materials should be presented in charts with horizontal or vertical columns to cover multiple products.

Also, consistent with the existing provisions in the voluntary nutrition labeling program, the Agency is proposing to require that if nutrition information is provided on the label of individual packages of major cuts of single-ingredient, raw products, the current requirements of the mandatory nutrition labeling program will apply, but the nutrition information on the label may be declared either on the basis of "as consumed" or "as packaged."

FSIS is proposing to allow nutrition information on the label to be declared

on the basis of "as consumed" without also requiring that the information on the label be declared on the basis of "as packaged" for the major cuts of single-ingredient, raw products because, as discussed below, most of these products will not need FSIS compliance scrutiny. Also as noted below, nutrition information for products under the existing mandatory nutrition labeling program must be provided on an "as packaged" basis for compliance purposes. Consistent with the existing voluntary nutrition labeling program, FSIS is proposing that the declaration of the number of servings per container need not be included on the nutrition label for the major cuts of single-ingredient, raw products. FSIS is not proposing to require that the number of servings per container be declared for the major cuts of single-ingredient, raw products because all of these products are random weight products, and the number of servings is not currently required on random weight products (see §§ 317.309(b)(10)(iii) and 381.409(b)(10)(iii)).

Although FSIS believes that nutrition information on labels of individual packages of single-ingredient, raw products is useful, FSIS is proposing that the nutrition information for the major cuts of single-ingredient, raw products may also be provided on point-of-purchase materials because, as stated in the 1993 rule, consumers have reasonable expectations as to the nutrient content of these products. Also, the nutrient content of a given major cut is relatively uniform across the market, and these products are not formulated in the manner of ground or chopped products. Therefore, FSIS believes it would be relatively easy to prepare point-of-purchase materials for the major cuts and relatively easy for consumers to find the nutrition information for a particular major cut on point-of-purchase materials. Although FSIS continues to believe that consumers have reasonable expectations as to the nutrient content of these products, FSIS also continues to believe that it is important to provide nutrition information to consumers, either through labels on packages or point-of-purchase materials. FSIS requests comment on whether consumers have reasonable expectations concerning the nutrient content of the major cuts of single-ingredient, raw products and on whether point-of-purchase materials are appropriate vehicles for conveying nutrition information for these products. FSIS specifically requests comment on whether it should require that nutrition labeling should be provided for these

products on their label and, if so, on what basis it would require such labeling.

FSIS regulations provide that in evaluating whether there is significant participation in the voluntary nutrition labeling program, FSIS will consider only the major cuts of single-ingredient, raw meat and poultry products (§§ 317.343(a) and 381.443(a)). Consistent with the regulations, FSIS' voluntary nutrition labeling surveys only assessed whether nutrition labeling was provided for the major cuts of single-ingredient, raw meat and poultry products.

Examples of single-ingredient, raw products that are not major cuts (and that are not ground or chopped) include pork jowls, pigs feet, pork leg, pork shoulder picnic, and beef round rump. For single-ingredient, raw products that are not ground or chopped and are not major cuts, FSIS is not proposing that nutrition information must be provided. However, FSIS is proposing that if nutrition information is provided, it must be provided according to the existing guidelines for the current voluntary nutrition labeling program. Therefore, if nutrition information is provided for these products, it would be consistent with nutrition information for the major cuts of single-ingredient, raw products.

As the next step in the process of evaluating the need for nutrition labeling of meat and poultry products, FSIS will examine the current state of nutrition labeling for single-ingredient, raw products that are not ground or chopped and that are not major cuts. FSIS will assess whether adequate nutrition information is being provided for these products. Until this assessment is made, FSIS cannot determine whether it would be beneficial to require nutrition labeling for single-ingredient, raw products that are not ground or chopped and are not major cuts. Whether the labeling of these products should be required to bear nutrition information would depend on whether adequate nutrition information is being provided for them and, if it is not being provided, what the effect is of its not being available. If FSIS determines that adequate nutrition information is not being provided for these products, FSIS will consider whether to propose to require nutrition labeling for these products.

FSIS is proposing to revise the nutrition labeling regulations to clarify which provisions apply to nutrition labels on single-ingredient, raw products that are not ground or chopped, including the major cuts, and which provisions apply to point-of-

purchase materials for these products. FSIS is proposing to revise the regulations so that the provisions for nutrition labels for these products are in §§ 317.309 and 381.409, and the provisions for point-of-purchase materials for these products are in §§ 317.345 and 381.445.

Nutrition labeling of ground or chopped products. The Agency is proposing to add new provisions at §§ 317.301 and 381.401, in the Federal meat and poultry product inspection regulations. In proposed § 317.301, FSIS is proposing to require that nutrition labels be provided for all ground or chopped (livestock species) and hamburger, with or without added seasonings, unless an exemption applies. In proposed § 381.401, FSIS is proposing to require that nutrition labels be provided for all ground or chopped (kind), with or without added seasonings, unless an exemption applies. Products that will have to bear nutrition labeling if this proposal is finalized include single-ingredient, raw hamburger, ground beef, ground beef patties, ground chicken, ground turkey, ground chicken patties, ground pork, and ground lamb. In this discussion, these products will be referred to as ground or chopped products. Ground or chopped products that are multi-ingredient products or heat processed products are already required to bear nutrition labeling, unless they qualify for an exemption. This proposed provision would extend the current mandatory nutrition labeling requirements to single-ingredient, raw ground or chopped products. The proposed provisions do not address sausages or other comminuted products. These products are typically multi-ingredient or heat processed products that are already required to bear nutrition information.

As discussed under the "Background" heading above, the existing regulations include exemptions from nutrition labeling requirements, such as an exemption for products produced by small businesses, custom slaughtered or prepared products, and certain products that are packaged, portioned or processed at retail. As discussed below under the "Exemptions" heading, most of these exemptions would apply to ground or chopped products that qualify for the exemptions. However, FSIS is proposing that the current exemptions from nutrition labeling for ready-to-eat products packaged or portioned at retail stores and similar retail-type establishments and for multi-ingredient products processed at retail stores and similar retail-type establishments not apply to ground or chopped meat and ground or chopped poultry products, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption. This issue is discussed further under the "Exemptions" heading below.

The terms "ground" and "chopped" are synonymous (see § 319.15). FSIS is proposing to use both terms because both are used in FSIS regulations and by industry. In the discussion below, any statements made regarding the nutrient values or the production of "ground" products would also apply to "chopped" products.

On June 3, 1997, the Center for Science in the Public Interest (CSPI) submitted a petition to FSIS stating that FSIS should require complete "Nutrition Facts" on ground beef labels that make nutrient content claims; should prohibit "% lean" claims on ground beef; should require ground beef to meet the same definitions of "lean" and "extra lean" that apply to other foods; and should require ground beef

labels to replace "% lean" and "% fat" claims with the same "% less fat" claims used by other foods. CSPI also submitted information illustrating the variations in ground beef labels that include information on the lean or fat percentages of the product.

Consistent with CSPI's petition, the Agency has tentatively determined that nutrition information should be required on packages of all ground or chopped meat and poultry products, unless an exemption applies. FSIS is proposing to require this information even if there are no nutrient content claims on the label.

With regard to the statements in CSPI's petition concerning the use of "% lean," "lean," "extra lean," and "% less fat" claims on ground beef labeling, FSIS is not revising the regulations as the petitioner requested. As discussed below, FSIS is proposing to permit a statement of lean percentage on the label or in labeling of all ground or chopped meat and ground or chopped poultry products that do not meet the regulatory definition for "low fat" as long as a statement of the fat percentage is also provided, because consumers have become accustomed to this information, and because FSIS believes that this information provides a quick, simple, accurate means of comparing these products.

Unlike other single-ingredient, raw products, producers are able to formulate precisely the fat content of ground or chopped products. Therefore, in this respect, these products are similar to products in the existing mandatory program. The fat content of ground beef products can be formulated to range from under 6 percent to 30 percent. Below is a table that compares the nutrient values of three ground beef products that contain different levels of fat. All values are based on raw product.

Nutrient values per 100 g	Ground beef 17% fat	Ground beef 21% fat	Ground beef 27% fat
Calories	234	264	310.
Cholesterol	69 mg	75 mg	85 mg.
Fatty acids, saturated	6.8 g	8.3 g	10.8 g.

Source: USDA Nutrient Database for Standard Reference (1985 data)

FSIS believes that consumers cannot easily see the fat in ground or chopped beef. In ground or chopped beef products, the fat is uniformly distributed throughout the product and is not clearly distinguishable on the surface of the product. Therefore, consumers cannot estimate the level of fat in these products and cannot

compare the levels of fat in these products to those in other products.

Fat is not the only factor that contributes to the nutrient variability of ground beef products. Producers sometimes use beef from advanced meat recovery (AMR) systems and low temperature rendering in ground or chopped beef products, which affect the nutrient variability of ground beef products. Product derived from low temperature rendering of beef tissue that

is not fatty tissue, such as fat reduced beef or finely textured beef, is considered beef and can be used in ground or chopped beef or hamburger and other ground or chopped meat products. The regulations currently do not address the use of fat reduced beef or finely textured beef. FSIS may address the use of such products derived from low temperature rendering in a future rulemaking.

An American Meat Institute (AMI) survey found that the use of product derived from AMR systems in ground beef was becoming more prevalent, although AMI did not obtain specific information concerning the volume of product from AMR systems (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 10). This survey also found that producers use product such as finely textured beef recovered via technology (a product derived from low temperature rendering) in ground beef products to achieve specific lean contents (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 11). It should be noted that beef from AMR systems is not used at retail, unless the retail establishment is grinding beef product produced at a Federal establishment. Ground beef produced at retail from a

single cut of meat, such as ground chuck or ground round, would not typically include beef from AMR systems. However, ground beef produced at retail from trimmings produced at a Federal establishment could include beef from AMR systems.

Typically, meat from AMR systems does not comprise more than 10 percent of ground meat products, including ground beef (R.A. Field, "Bone Marrow Measurements for Mechanically Recovered Products from Machines that Press Bones," *Meat Science* 51 (1999): 206). Similarly, meat from low temperature rendering usually does not comprise more than 10 percent of ground products, including ground beef. However, because beef from AMR systems or low temperature rendering generally has higher levels of cholesterol, iron, and calcium than other beef, the use of these types of beef in ground beef products can affect the nutrient content of these products. The

table below shows the percentage fat and the levels of iron and calcium per 100 grams of product for regular ground beef, for beef from AMR systems, and for product made from 90 percent regular ground beef and 10 percent beef from AMR systems. For regular ground beef and for beef from AMR systems, the table shows values from different studies (R.A. Field, "Bone Marrow Measurements for Mechanically Recovered Products from Machines that Press Bones," *Meat Science* 51 (1999): 206, 209). FSIS calculated the nutrient values for product comprised of 90 percent ground beef and 10 percent AMR product based on the values from the studies. FSIS calculated values for product made from 90 percent ground beef and 10 percent AMR product because, as stated above, typically meat from AMR systems does not comprise more than 10 percent of ground meat products. All values shown below are based on raw product.

Nutrient values per 100 grams	Regular ground beef (Anderson et al., 1986)	Beef from AMR (Hasiak and Marks, 1997)	Beef from AMR product (Leising, 1997)	Ground beef, 10% AMR product (Hasiak and Marks)	Ground beef, 10% AMR product (Leising)
Cholesterol	85 mg	115 mg	102 mg	88 mg	86.7 mg
Iron	1.7 mg	2.8 mg	5.6 mg	1.81 mg	2.09 mg
Calcium	8 mg	108 mg	115 mg	18.0 mg	18.7 mg

Even if producers do not use beef from AMR systems or beef derived from low temperature rendering, they are able to precisely control the amount of fat in the beef that is ground or chopped to create packages of ground or chopped beef. A study concerning testing for the fat content of ground beef found that, using two testing methods, ground beef formulated for a certain fat percentage varied by only 2 percentage points around the average fat percentage. Although this study found some problems concerning blending of ground beef and testing for the fat content in ground beef, its results show that the product can be and is precisely formulated and within the control of the producer (Robert Campbell, "Ground Beef Testing: Determining Fat Content and Distribution," *Meat and Poultry* (October, 1997): 67-69). Many ground beef producers have quality control programs to control the fat content of their product. These producers conduct regular sampling and testing for fat in ground beef products. Thus, producers are able to formulate these products to

control the amount of fat in them more precisely than the fat can be controlled in other cuts. Other single-ingredient, raw products cannot be formulated in this manner or to this degree.

Although ground beef comprises the majority of ground meat products sold at retail, products such as ground lamb and ground pork are also available. Similar to ground beef products, these products may contain varying amounts of fat and varying nutrient content, which consumers cannot visually detect. In addition, ground pork may include product from AMR systems or from low temperature rendering, which may affect the nutrient content of these products. Therefore, FSIS is proposing to require nutrition labeling on these products and other ground or chopped meat products. As noted above, meat from AMR systems or low temperature rendering typically does not comprise more than 10 percent of ground meat products, including ground pork. Product from AMR systems or low temperature rendering is generally not used in ground or chopped lamb.

Because products such as ground pork and ground lamb may contain varying amounts of fat and nutrient content, which consumers cannot visually detect, and because ground pork may include product from AMR systems or low temperature rendering, FSIS is proposing to require nutrition labeling on all ground or chopped meat products.

The fat-to-lean content of ground poultry products does not vary as greatly as that of ground beef products; however, the fat content of ground poultry can vary depending upon whether the product is ground light or dark meat, and whether the product includes poultry skin. As with the fat on ground meat products, consumers cannot readily detect the fat content of ground poultry products. The table below shows values for light and dark turkey meat, with skin and without skin. All values are based on raw product. The nutrient content of ground turkey would vary depending on which types of meat were used to produce the product.

Nutrient values per 100 grams	Turkey, dark meat and skin	Turkey, dark meat only	Turkey, light meat and skin	Turkey, light Meat only
Calories	172	130	165	116

Nutrient values per 100 grams	Turkey, dark meat and skin	Turkey, dark meat only	Turkey, light meat and skin	Turkey, light Meat only
Cholesterol	65 mg	62 mg	62 mg	58 mg
Fatty acids, saturated	2.99 g	1.64 g	2.19 g53 g

Source: USDA Nutrient Database for Standard Reference (1985 data)

Because the characteristics of ground or chopped poultry are similar to those of ground or chopped meat, FSIS is also proposing to require nutrition labeling on ground or chopped poultry products. The Agency is also proposing comparable requirements for ground or chopped meat and poultry products because it is committed to equitable treatment of meat and poultry products. FSIS has consistently taken the position that similar products should be regulated in a similar manner to facilitate consumers' ability to make comparisons among these products.

For the reasons discussed above, the Agency has tentatively concluded that ground or chopped meat and poultry products that do not bear nutrition information would be misbranded under section 1(n)(1) of the FMIA and section 4(h)(1) of the PPIA. As noted above, in the January 6, 1993 final rule, the Agency did not require nutrition labeling on packages of single-ingredient, raw meat and poultry products because FSIS believed that consumers had reasonable expectations as to the nutritional qualities of such products since they are not modified through various stages of preparation, such as cooking and heat processing (58 FR 637). FSIS now believes that the variation in the fat and nutrient content of different ground or chopped products, the formulated nature of these products, and the fact that the fat content of these products cannot be readily visually assessed makes it difficult for consumers to have a reasonable expectation as to the nutritional quality of these products. Further consideration of the issues raised in the petition from CSPI brought many of these issues to FSIS' attention. If this proposal is adopted, the existing mandatory nutrition labeling provisions in §§ 317.309 and 381.409 would apply to these products, unless they are subject to an exemption.

Although current labeling on ground beef products often includes information concerning the percentage of fat in the product, as noted in the CSPI petition, without complete nutrition labeling, consumers cannot easily determine the amount of fat per serving of ground beef. Also, without complete nutrition labeling, consumers cannot assess how much saturated fat,

cholesterol, protein, or calories the product contains. Furthermore, consumers cannot easily compare fat percentages on the labeling of ground beef products with the information concerning grams of fat per serving or with the information concerning the percent daily values that is found on the labeling of products that are currently covered by the mandatory nutrition labeling program.

The Agency tentatively concludes that information concerning the nutritional qualities of ground or chopped meat and poultry products is particularly important because these products, especially ground beef, are widely consumed. Pertinent nutrition information is integral to consumer purchase decisions because use of this information may result in prevention of health problems and reduction of health risks for some consumers. Additional information about the nutrient values of ground or chopped meat and poultry products would enable consumers to make informed decisions about including these products in their diets and, therefore, will help consumers to construct healthy diets.

FSIS is proposing to require that nutrition information for ground or chopped meat and poultry products appear on the label of these products (unless an exemption applies), as is required for other products in the current mandatory nutrition labeling program, rather than on point-of-purchase materials. Ground or chopped products are similar to products in the mandatory nutrition labeling program, which requires nutrition information to be on the label of products, in that certain parameters, such as their fat content, can be controlled precisely to obtain the desired product. In addition, because there are numerous formulations of ground or chopped products, it would be difficult for producers or retailers to develop point-of-purchase materials that would address all the different formulations that exist for these products. Furthermore, it would be difficult for consumers to find the correct information for a specific ground or chopped product on point-of-purchase materials that include information concerning numerous formulations of these products. For these reasons, FSIS tentatively concludes that nutrition information should be required on the

label of these products, consistent with the requirements in the existing mandatory nutrition labeling program. FSIS requests comments concerning whether nutrition information should be required on individual packages of ground or chopped product or whether the information should be allowed at their point-of-purchase.

In addition, consistent with requirements for products that fall under the existing mandatory nutrition labeling program, FSIS is proposing that the declaration of nutrient and food component content for ground or chopped products be required on an "as packaged" basis. The preamble to the final rule explained why products in the mandatory nutrition labeling program would be required to be labeled on an "as packaged" basis: "There are varieties of cooking methods that affect the nutrient values of food products differently. Therefore, there is no method to assure the accuracy or measure compliance of the nutrient values of food labeled on an 'as consumed' basis." (58 FR 648). These reasons for requiring nutrition information on an "as packaged" basis for products in the current mandatory nutrition labeling program also are the basis for requiring that ground or chopped products be required to be labeled on an "as packaged" basis. Whether or not the fat is drained off during the cooking of ground or chopped products would affect the nutrient values of ground or chopped products. As discussed below, ground or chopped products will be subject to FSIS compliance. Therefore, FSIS tentatively concludes that it is necessary to require that nutrition information be presented on an "as packaged" basis for ground or chopped products in order to assure the accuracy of nutrient values and to measure compliance of the nutrient values of these products. FSIS requests comment on whether it would be difficult for producers to comply with this requirement.

However, consistent with the provisions of the existing mandatory program, FSIS is proposing that nutrition information for ground or chopped products may be presented on an "as consumed" basis, in addition to the required "as packaged" basis, provided that preparation and cooking instructions are clearly stated. FSIS is proposing to allow nutrition

information on as "as consumed" basis, in addition to the required "as packaged basis," because FSIS believes this is useful information for consumers.

FSIS requests comments on whether all Federal establishments and retail stores are able to control the fat and nutrient content of ground or chopped meat and poultry products. FSIS also requests comment on the practices of retail stores that grind or chop meat and poultry. FSIS is interested in whether retail stores that grind or chop product mix trimmings from one Federal establishment with trimmings from other Federal establishments. In addition, FSIS is interested in data on the extent to which product from AMR systems or product from low temperature rendering is used in ground or chopped products.

FSIS requests comments concerning whether consumers have reasonable expectations as to the nutritional quality of ground or chopped product, whether consumers know which ground or chopped products are lowest in fat, whether consumers understand that the fat content of ground or chopped product can affect other nutrients, whether consumers can see the fat in ground or chopped meat and poultry products, and whether consumers can make comparisons among ground or chopped products and other products.

Exemptions

Under §§ 317.400(a)(1) and 381.500(a)(1), food products produced by small businesses are exempted from mandatory nutrition labeling if the product labels bear no nutrition claims or nutrition information. The regulations provide that a small business is any single-plant facility or multi-plant company or firm that employs fewer than 500 people and, as of July 1996, that produces 100,000 pounds or less annually of the product that qualifies the establishment for the exemption from mandatory nutrition labeling. The Agency stated in the preamble to the January 6, 1993, final rule, that it would exempt small businesses from mandatory nutrition labeling requirements because these requirements would create undue economic hardship for small businesses and would create disincentives for these small businesses to develop more nutritious food products (58 FR 638).

For the reasons stated in the January 6, 1993 final rule, FSIS continues to believe that small businesses should be exempt from the mandatory nutrition labeling requirements proposed for ground or chopped meat and ground or chopped poultry products. Therefore, under this proposal, ground or chopped

products produced by establishments that qualify for the small business exemption would be exempt from the proposed nutrition labeling requirements.

As discussed below, a significant amount of ground beef is processed at retail. Therefore, FSIS is proposing to revise the regulations to make clear that a single retail store or multi-retail store operation could qualify for the small business exemption. To qualify for this exemption, the retail facility must either be a single retail store that employs 500 or fewer people or a multi-retail store operation that employs 500 or fewer people. In addition, to qualify for the exemption, the retail establishment could produce no more than 100,000 pounds per year of the product that qualifies the establishment for an exemption. Consistent with existing regulations, the qualification of a multi-retail store operation for an exemption from nutrition labeling would be based upon its total annual production of the product for all of its stores that qualifies the operation for the exemption and the total number of employees for all of its stores (see 58 FR 638 for guidance on existing regulations).

As under current regulations, for the purposes of the small business exemption, a food product is a formulation, not including distinct flavors which do not significantly alter the nutritional profile of the product, sold in any size package in commerce. Therefore, ground or chopped products formulated to have different levels of fat would be considered different food products for purposes of the small business exemption. For example, if a multi-retail store operation employed 500 or fewer people in total and produced, in total among all of its stores, 70,000 pounds of ground beef that is 10 percent fat and 60,000 pounds of ground beef that is 20 percent fat annually, the multi-retail store operation would not be required to include nutrition information on the label of these specific products if the labels for these products bore no nutrition claims or nutrition information. However, for example, if a multi-retail store operation employed in total 500 or fewer employees and produced 130,000 pounds of 10 percent fat ground beef annually in total among all of its stores, it would not be exempt from nutrition labeling requirements on the basis of the "small business exemption." FSIS is interested in comments on whether the exemption proposed is appropriate for purposes of ground or chopped products produced at retail establishments.

FSIS does not believe that the reasons that necessitated the establishment of the small business exemption, as explained in the January 6, 1993 final rule, are applicable to the major cuts of single-ingredient, raw meat and poultry products produced by small businesses. For these products, FSIS is proposing that nutrition information may be provided on labels or alternatively at their point-of-purchase. FSIS intends to make point-of-purchase materials available over the Internet free of charge; therefore, the proposed nutrition labeling requirement for major cuts of single-ingredient, raw products should not impose an economic hardship for small businesses, including those that are retail stores. FSIS is proposing to revise §§ 317.400(a)(1) and 381.500(a)(1) to provide that the small business exemption would not apply to the major cuts of single-ingredient, raw products.

Under existing §§ 317.400(a)(7) and 381.500(a)(7), retail stores and similar retail-type establishments are exempted from nutrition labeling requirements for multi-ingredient products processed at retail establishments and ready-to-eat products packaged or portioned at retail establishments (which would include ready-to-eat and multi-ingredient ground or chopped products) if the products bear no nutrition claims or nutrition information. As stated in the preamble to the January 6, 1993 final rule, FSIS exempted retail establishments from mandatory nutrition labeling requirements for these products because the Agency determined that it would be impractical to enforce nutrition labeling requirements on these products prepared or served at retail, and because the Agency concluded, based on a review of National Food Consumption Survey (NFCs) data, that the average person's diet consisted of an insignificant proportion of ready-to-eat retail packaged products or retail processed products (58 FR 639).

Most ground poultry is processed and packaged outside retail establishments. However, most ground beef is ground and packaged at retail. An AMI report states that retail survey respondents reported that an average 18.5 percent of their ground beef sales was from product arriving in a finely ground state, ready to sell or ready for repackaging at retail. Retail stores or distribution centers ground or re-ground 81.3 percent of ground beef sold (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 7).

As noted above, in the preamble to the January 6, 1993, final rule, the

Agency concluded that the average person's diet consists of an insignificant portion of ready-to-eat retail packaged products or retail processed products. Consumers who purchase ground beef likely consume a significant amount of ground beef processed at retail. Therefore, there may be a significant amount of ground beef products that are ready-to-eat retail packaged products or retail processed products.

As noted above, in the January 6, 1993 final rule, FSIS also exempted retail establishments from mandatory nutrition labeling partly because the Agency determined that it would be impractical to enforce nutrition labeling requirements on products prepared or served at retail. The Agency no longer believes enforcement of nutrition labeling requirements at retail stores to be impractical because FSIS is already conducting testing for *Escherichia coli* O157:H7 at retail.

Because a significant amount of ground beef is processed at retail, the Agency believes that there may be a significant amount of multi-ingredient ground beef retail processed products or ready-to-eat retail packaged products. FSIS also believes that enforcement of nutrition labeling at retail would not be impractical. Further, FSIS has tentatively concluded that ground or chopped products that do not include nutrition information would be misbranded for the reasons stated above. Therefore, the Agency is proposing that the current exemptions from nutrition labeling for ready-to-eat products packaged or portioned at retail stores and similar retail-type establishments and multi-ingredient products processed at retail stores and similar retail-type establishments not apply to ground or chopped meat and ground or chopped poultry products, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption. FSIS requests comments and data on the volume of ground or chopped products that are multi-ingredient retail processed products or ready-to-eat retail packaged products.

FSIS is also proposing to revise the current retail exemptions discussed above to make clear that if a retail establishment qualifies for the small business exemption discussed above, ground or chopped ready-to-eat products packaged or portioned at retail and ground or chopped multi-ingredient products processed at retail would be exempt from nutrition labeling requirements. Although most ground poultry is processed and packaged outside retail establishments, FSIS believes it is important to propose

consistent requirements for all ground or chopped products. Therefore, for all ground or chopped products, including ground or chopped products, including ground or poultry, these exemptions would not apply, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption.

The exemptions for ready-to-eat products packaged and portioned at retail stores and for multi-ingredient products processed at retail stores would not apply to the major cuts of single-ingredient, raw products because they are not ready-to-eat or multi-ingredient products.

As discussed above, in addition to the small business and retail exemptions, existing §§ 317.400 and 381.500 provide other exemptions from nutrition labeling requirements. These exemptions include products intended for further processing, products not for sale to consumers, products in small packages that are individually wrapped packages of less than ½ ounce net weight, custom slaughtered or prepared products, and products intended for export. To qualify for the first three exemptions, the product's label cannot bear nutrition information or a nutrition claim. In the preamble to the January 6, 1993, final rule, FSIS explained that it was providing an exemption for products intended for further processing and products not for sale to consumers because consumers do not see the nutrition information on products used for further processing or products that are not for sale to consumers. The Agency also explained that it would exempt individually wrapped packages of less than ½ ounce net weight, provided no nutrition claim or nutrition information was made on the label, because these products are an insignificant part of the diet. With regard to the custom exemption, the Agency explained that an exemption should apply because these custom services are performed solely for individuals. Finally, the Agency explained that products intended for export should be exempt because these products are labeled according to the requirements of the country where the product is to be exported (58 FR 639). The Agency has tentatively determined that the bases for these exemptions, as explained in the January 6, 1993 final rule, are valid as applied to nutrition labeling for ground or chopped products and for major cuts of single-ingredient, raw products. Therefore, under this proposal, any ground or chopped product or major cut of single-ingredient, raw product that qualifies for any of these exemptions will continue to be exempt even if the

proposed nutrition labeling requirements are adopted.

Under current regulations, products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided the product's labeling includes no nutrition claims or nutrition information and provided that an address or telephone number that a consumer can use to obtain the required information is included on the label. FSIS allowed for nutrition information to be provided by alternative means for products of this size in order to incorporate sufficient flexibility in the regulations (58 FR 47625). For ground or chopped products, FSIS believes it is necessary to provide this flexibility for products in packages that have a total surface area available to bear labeling of less than 12 square inches, provided that the labels for these products bear no nutrition claims or nutrition information. However, because nutrition information for the major cuts of single-ingredient, raw meat and poultry products may be provided on point-of-purchase materials, FSIS is proposing that the provisions for providing nutrition labeling by alternate means for products in packages that have a total surface area available to bear labeling of less than 12 square inches would not apply to the major cuts of single-ingredient, raw meat and poultry products.

As stated in the existing regulations, restaurant menus generally do not constitute labeling or fall within the scope of these regulations. Likewise, restaurant menus that include ground or chopped products generally do not constitute nutrition labeling or fall within the scope of these regulations. Similarly, although a restaurant menu would most likely not include a major cut of single-ingredient, raw product, if it did, the menu would not fall within the scope of these regulations.

Finally, the current regulations provide that foods represented or purported to be specifically for infants and children less than 4 years of age must not include certain nutrient content declarations, because infants and children less than 4 years of age have different nutrition needs than adults and children older than 4 years of age. Under this proposal, any ground or chopped product or major cut of single-ingredient raw product represented or purported to be specifically for infants and children less than 4 years of age would be required to meet these same requirements.

FSIS requests comments on whether its proposed revisions to the nutrition labeling exemptions are appropriate and

necessary for ground or chopped products and for the major cuts of single-ingredient, raw products.

Enforcement and Compliance

Ground or chopped products. FSIS conducts a continuous sampling program of products that fall under the mandatory nutrition labeling program. If the proposal to mandate nutrition labeling of ground or chopped meat and ground or chopped poultry products is adopted, the procedures set forth for product sampling and nutrient analysis in §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8) will be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. Under this proposal, the Agency will sample and conduct nutrient analysis of ground or chopped products to verify compliance with nutrition labeling requirements, even if nutrition labeling on these products is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference and there are no claims on the labeling. Therefore, if these proposed provisions for ground or chopped meat and poultry products are adopted, the Agency will treat these products as it treats all other products for which regulations already require nutrition labels on their package.

FSIS is proposing that ground or chopped products be subject to compliance even if nutrition labeling on these products is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference because the fat content of different ground or chopped products can vary significantly, depending upon the level of fat in the product being ground and depending on whether product from advanced meat recovery systems is used. Additionally, at this time, there are a limited number of ground or chopped products in the database (e.g., ground beef, 17% fat, 21% fat, and 27% fat).

Further, FSIS program employees cannot visually assess whether nutrition information on the label of ground or chopped products accurately reflects the labeled products' contents because, in most cases, it is not possible to visually assess the level of fat in a ground product. For example, FSIS program employees cannot visually determine whether product that is labeled 17 percent fat ground beef is actually 17 percent fat ground beef as opposed to 27 percent fat (or another percentage of fat) ground beef. Therefore, even if the

retailer or other producer uses information from the USDA database to label these products, FSIS will need to conduct compliance sampling and nutrient analysis to ensure that the information on the label accurately reflects the nutrient content of the labeled products.

The Agency is also proposing to revise §§ 317.345(e) and 381.445(e) so that they refer to USDA's National Nutrient Data Bank and its released form, the USDA Nutrient Database for Standard Reference, and to remove current references to the Agriculture Handbook No. 8 series, because this handbook series is now out of print.

For the nutrition labeling of some ground or chopped meat or ground or chopped poultry, nutrient data may be immediately available through the USDA Nutrient Database for Standard Reference (e.g., ground beef with 17 percent fat, ground beef with 21 percent fat, and ground beef with 27 percent fat). Private databases may be available to assess the nutrient content of other products. In addition, producers are able to provide the nutrition information for many products produced to meet purchase specifications. Because producers know the different cuts of meat that go into ground or chopped product, they have the information necessary to determine the nutrient content of the products. FSIS believes that if they need to conduct nutrient analysis, the analysis should not impose an excessive burden. FSIS will develop a list of published sources of information concerning the nutrient content of ground or chopped products, so that industry could obtain available literature from local libraries. This information would facilitate the development of nutrition labels for ground or chopped products. FSIS requests comments and supporting data on the costs that Federal and retail establishments would incur for conducting nutrient analysis of ground or chopped products.

For ground or chopped products that are nutritionally labeled at official establishments, FSIS program employees will collect samples for nutrient analysis at official establishments, consistent with the Agency's existing sampling program of products that fall under the mandatory nutrition labeling program. For ground or chopped products that are produced and nutritionally labeled at retail, it is likely that FSIS program employees will collect samples for nutrient analysis while they are conducting other program activities at retail stores. When collecting samples for nutrient analysis, FSIS will not typically collect samples

of the same product from both Federal establishments and retail establishments, unless circumstances warrant sampling the same product at both locations. In general, if a product from a Federal establishment is further processed at retail, FSIS would only collect samples of that product at retail, where it would be packaged for sale to consumers. FSIS can distinguish between product packaged at retail versus product packaged at a Federal establishment.

Major cuts of single-ingredient, raw products. If nutrition labeling of the major cuts of single-ingredient, raw products (other than ground beef or ground pork) is based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, FSIS will not sample and conduct a nutrient analysis of these products. The Agency's sampling and testing policy for these products will be consistent with its policy under the current voluntary nutrition labeling program for these products.

For the major cuts of single-ingredient, raw products, FSIS personnel can visually identify the particular cut. If the nutrition information for these products is based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, it is not necessary for FSIS to verify the accuracy of this data because it is USDA data. If the nutrition information is based on USDA data, and there are no nutrition claims, FSIS program employees would only have to verify that the data presented accurately pertains to a particular major cut of single-ingredient, raw product. Therefore, FSIS does not need to conduct nutrient analysis for these products.

If the nutrition information on the label or at the point-of-purchase of major cuts of single-ingredient, raw products is based on databases other than the above referenced USDA ones or other data, or if there are nutrition claims on the labeling, these products would be subject to FSIS compliance analysis. Most nutrition information for the major cuts of single-ingredient, raw products is based on USDA data and, typically, no nutrition claims are made on the labeling of these products. Therefore, these products are and would generally continue to be exempt from the FSIS nutrition labeling compliance verification program.

It is likely that FSIS program employees will verify that nutrition information is provided for the major

cuts of single-ingredient, raw products, either on their labels or at their point-of-purchase, at retail stores while they are conducting other program activities at retail. If nutrition information on the point-of-purchase materials or labels for these products is not based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims on the labeling, FSIS program employees may collect samples of the major cuts from retail stores for nutrient analysis. Similarly, if major cuts are nutritionally labeled at official establishments and the nutrition information on the label is not based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims on the labeling, FSIS program employees may collect samples of these products from the official establishment for nutrient analysis.

Percentage Labeling

FSIS is withdrawing its proposed rule of May 24, 1994 (59 FR 26916), discussed above, which sought to amend the regulations by permitting percentage labeling for lean and fat on ground beef and hamburger, when the product did not meet the regulatory criteria established for "low fat," if the product had nutrition information on its labeling or in point-of-purchase materials that were in close proximity to the product. FSIS is withdrawing this proposal and proposing revised percentage labeling requirements in this rule. In this proposal, FSIS is expanding the categories of ground or chopped products that can have lean percentage labeling.

FSIS is proposing to permit a statement of lean percentage on the label or in labeling of ground or chopped meat and poultry products that do not meet the regulatory criteria for "low fat." The Agency is proposing to do so because many consumers have become accustomed to this labeling on ground beef products, and because FSIS believes this labeling provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. The proposed regulatory language requires that a statement of fat percentage be contiguous to, in lettering of the same color, size and type as, and on the same color background as, the statement of lean percentage. The Agency is proposing these requirements concerning size, type, and color to ensure that the statement of the fat percentage is as clear and readily observable as the statement of the lean percentage.

FSIS requests comments on whether percent fat/percent lean information provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. Also, FSIS is specifically requesting comments concerning whether its proposed percent fat/percent lean labeling provisions for ground or chopped meat and ground or chopped poultry products that do not meet the regulatory criteria for "low fat" would be misleading in any way. FDA's regulations do not provide for the nutrient content claim, "X percent lean." Similarly, FDA does not allow a statement of "percent fat/percent lean" on the products it regulates. FSIS requests comment on whether these discrepancies between FDA's and FSIS' regulations will cause confusion among consumers. Finally, FSIS is not requiring the statement of fat percentage to precede the statement of lean percentage but will allow the statements to appear in either order. FSIS requests comment on whether consumers are more likely to read and understand the statement of fat percentage when it precedes the statement of lean percentage than when it follows the statement of lean percentage.

Executive Order 12866—Preliminary Analysis

This action has been reviewed for compliance with Executive Order 12866. As this action is determined "significant" for purposes of Executive Order 12866, the Office of Management and Budget (OMB) has reviewed it.

Need for the Rule

During the 1996 nutrition labeling survey, RDI found 57.7 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. In the 1999 nutrition labeling survey, RDI found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. Therefore, the most recent surveys did not show significant participation in the voluntary nutrition labeling program as defined in the regulations. Without significant participation, the Agency has tentatively concluded that a lack of consistent and complete nutrition information for the major cuts of single-ingredient, raw products exists. FSIS has also tentatively concluded that producers' ability to control the formulation of single-ingredient, raw ground or

chopped products results in variations across these products that may be difficult for consumers to detect. Without nutrition information, FSIS believes that these products would be misbranded under section 1(n) of the FMA or section 4(h) of the PPIA and that further action is necessary in order to provide consumers with adequate nutrition information that is consistent with the provisions of the 1993 final nutrition labeling rule.

Baseline

In the analysis below, FSIS assumes that the level of voluntary labeling, absent any Federal action, would remain at the current level. The 1999 RDI nutrition labeling survey found that 54.8 percent of the stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. As there has been little change in the level of compliance over the last several years (see discussion of previous surveys above), FSIS believes that it is appropriate to assume that this level of participation in the voluntary nutrition labeling program would not change unless the regulations are revised.

In the analysis below, FSIS also assumes that 80 percent of the retail establishments and processors have made investments in the equipment necessary to print, stamp, or affix nutrition labels on products. This assumption is based on the results of the 1999 RDI safe handling labeling compliance survey. This survey revealed that 96.7 percent of large chains, 90.5 percent of large independent retailers, and 84.1 percent of medium/small independents had already complied with the Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products final rule. FSIS used the 80 percent assumption in order to be conservative and not overestimate the percentage of processors and retailers that have already invested in the necessary equipment. Because the equipment needed to print, stamp, or affix nutrition labels is similar to the equipment used to print, stamp, or affix labels to meet the "safe handling" rule's requirements, FSIS assumes that 80 percent of establishments would not have to install new machines for stamping, printing, or affixing nutrition labels for ground or chopped products. FSIS is assuming that the same percentage of processors have invested in this equipment as retailers. Again, this is a conservative assumption. FSIS requests comments concerning whether the 80 percent

estimate is appropriate for both processors and retailers.

To determine how many entities would be affected by this rulemaking, the Agency used a combination of FSIS developed databases and industry sources. Table 1 indicates that in 1999, 63 establishments produced ground poultry and 2,426 establishments produced ground meat. FSIS developed this data on establishments from its Enhanced Facilities Database (EFD). This source does not provide separate data for ground pork, lamb and beef. The number of establishments producing ground pork or lamb is, however, likely to be very small based on information from the AMI survey discussed below in the preliminary cost analysis. One plant that produced either meat or poultry and did not have employment size specification is excluded from Table 1.

TABLE 1.—SIZE DISTRIBUTION OF MEAT AND POULTRY HACCP PLANTS PRODUCING GROUND PRODUCTS

	Poultry	Meat	Total
Very Small	10	1,470	1,480
Small	23	843	866
Large	28	68	96
Missing Values	2	45	47
Total ..	63	2,426	2,489

Note: Very small=9 or less employees; small=10 to 499 employees; large=500 or more employees.

FSIS believes that a significant amount of ground beef is processed at retail. Table 2 shows the number of retail stores in 1999. Most of these stores grind beef. However, FSIS does not have specific data concerning the levels of ground beef ground at retail or on the size of retail stores that process ground beef. FSIS researched Census data for this information, but specific

information related to retail establishments processing ground or chopped product was unavailable. Table 2 reports data from FMI. FSIS combined the first two categories of supermarkets with sales in excess of \$2 million per year to compare their share with "other stores" with sales of less than \$2 million per year. In 1999, there were 127,000 retail grocery stores.

TABLE 2.—NUMBER OF RETAIL GROCERY STORES, 1999

	1999 number	1999 % of total
Total	127,000	100
Supermarket Chains & Independent ..	31,500	25
Other Stores	37,200	29
Convenience Stores	57,500	45
Wholesale Clubs	800	0.6

Note: "Supermarkets" are defined to have sales of \$2 million or more per year. "Other Stores" are defined to have sales of under \$2 million.

Source: FMI Information Service, *Progressive Grocer, 67th Annual Report of the Grocery Industry*. April 2000, p.20.

With respect to consumers, FSIS assumes that without further action, they would have access to the current level of labeling information and continue with their current dietary habits. The 1999 RDI survey estimated that nutrition labeling, in accordance with the program guidelines, for the major cuts of single-ingredient, raw meat and poultry products was available to 62.8 percent of shoppers. This estimate was based on the sales volume of the stores surveyed. Consistent with the Agency's assumption about compliance among retail stores, FSIS assumes that this level of available nutrition information, in accordance with program guidelines, would not change without further regulatory action.

TABLE 3.—CONSUMER USAGE OF NUTRITION INFORMATION

	Often		Sometimes		Rarely/never		Do not buy	
	Men	Women	Men	Women	Men	Women	Men	Women
Use Nutrition Facts Panel	26.7	41.7	25.6	32.6	47.7	25.6	n/a	N/A
Look for Nutrition Information on Raw Meat, Poultry, or Fish	16.9	22.1	18.2	18.0	62.7	57.9	2.2	2.0

Note: Percent of respondents, based on 3 year weighted averages, 1994–1996.

To establish a baseline of Intake of Fat, Saturated Fat, and Cholesterol, FSIS used the same data sources to estimate dietary intake of fat, saturated fat, and

cholesterol, along with the percentage of calories from fat and saturated fat. The CSFII contains information on the intake of these food components, based

FSIS used data from USDA's Continuing Survey of Food Intake by Individuals (CSFII), and the associated Diet and Health Knowledge Survey (DHKS) to establish a baseline for fat, saturated fat, and cholesterol intake. The CSFII collects data on food intakes by individuals. Most recently, USDA conducted three separate one-year surveys for 1994–96. These surveys recorded two nonconsecutive days of food consumption, and collected information on what and how much individuals ate, and where the food was obtained. This information was used to develop estimates of nutrient intake for each individual respondent. The DHKS gathered data on consumers' knowledge of issues related to diet and health, and contained several questions relating to the use of nutrition information labels and nutrition information for food products. Linking information from the two surveys allowed FSIS to correlate use of nutrition information from the DHKS with nutrient intake data from the CSFII. The Agency focused here on two key questions pertaining to nutrition information use on all food products and on meat and poultry in particular:

Q: *When you buy foods, do you use the nutrition panel that tells the amount of calories, protein, fat, and such [e.g., sodium, total carbohydrate] in the serving of a food: Often (always), sometimes, rarely, or never?* (Question 16–c, DKHS)

Q: *When you buy raw meat, poultry, or fish, do you look for nutrition information: Often (always), sometimes, rarely, or never?* (Question 17–I, DHKS).

Using data from the CSFII and the DHKS, FSIS estimated rates of nutrition information usage, based on these two questions. The results are presented in Table 3. Note that rates of label usage are uniformly higher for women than for men, and that rates of nutrition label usage are higher for food products as a whole than for raw meat, poultry and fish products.

on the food consumption reported by survey respondents.

Tables 4 and 5 present the estimated intake of fat, saturated fat, and

cholesterol from the CSFII, broken down by types of nutrition information usage reported in the DHKS.

TABLE 4.—DIETARY INTAKE OF FAT, SATURATED FAT, BY USAGE OF NUTRITION FACTS PANEL

	Often	Sometimes	Rarely/ never	Average
Men:				
Total Fat	83.13	92.52	98.14	92.51
Saturated Fat	26.93	31.43	33.67	31.12
Cholesterol	293.39	327.77	353.97	339.07
Women:				
Total Fat	55.95	62.78	63.98	60.16
Saturated Fat	18.04	20.77	21.39	19.71
Cholesterol	196.60	216.84	230.03	210.53

Note: Fat intake in grams, cholesterol in milligrams.

TABLE 5.—DIETARY INTAKE OF FAT, SATURATED FAT, BY USAGE OF NUTRITION INFORMATION ON RAW MEAT, POULTRY, OR FISH

	Often	Sometimes	Rarely/ never	Do not buy	Average
Men:					
Total Fat	81.64	92.49	96.09	74.48	92.51
Saturated Fat	27.20	31.09	32.44	24.02	31.12
Cholesterol	311.81	321.49	355.14	236.83	339.07
Women:					
Total Fat	53.90	61.70	62.18	57.23	60.16
Saturated Fat	17.39	20.60	20.41	17.27	19.71
Cholesterol	194.32	219.27	216.55	135.89	210.53

Note: Fat intake in grams, cholesterol in milligrams.

The estimated intake of fat and saturated fat can also be expressed as the percentage of calories from fat. This conversion is done with the following formula:

$$\text{Percentage Calories from Fat} = 900 * \text{fat} / \text{energy}$$

Where energy is total caloric intake (kilocalories), as measured by the

CSFII. Tables 6 and 7 show the percentage of calories from fat (and total cholesterol) broken down by label and nutrition information usage:

TABLE 6.—PERCENTAGE OF CALORIES FROM FAT AND TOTAL CHOLESTEROL, BY USAGE OF NUTRITION FACTS PANEL

	Often	Sometimes	Rarely/ never	Average
Men:				
Total Fat	31.54	33.63	35.27	33.44
Saturated Fat	10.19	11.38	12.00	11.19
Cholesterol	293.39	327.77	353.97	339.07
Women:				
Total Fat	31.14	33.40	34.49	32.49
Saturated Fat	10.00	11.38	11.59	10.64
Cholesterol	196.60	216.84	230.03	210.53

Note: Fat and Saturated Fat values are percentage of calories from fat source; cholesterol in milligrams.

TABLE 7.—PERCENTAGE OF CALORIES FROM FAT AND TOTAL CHOLESTEROL, BY USAGE OF NUTRITION INFORMATION ON RAW MEAT, POULTRY, OR FISH

	Often	Sometimes	Rarely/ never	Do not buy	Average
Men:					
Total Fat	31.67	34.03	33.88	29.69	33.44
Saturated Fat	10.53	11.36	11.37	9.52	11.19
Cholesterol	311.81	321.49	355.14	236.83	339.07
Women:					
Total Fat	31.62	32.94	32.87	26.79	32.49
Saturated Fat	10.15	10.82	10.82	9.19	10.64
Cholesterol	194.32	219.27	216.55	135.89	210.53

Note: Fat and Saturated Fat values are percentage of calories from fat source; cholesterol in milligrams.

Regulatory Options

FSIS considered several regulatory options: (1) Continuing with the existing voluntary program; (2) making the voluntary program mandatory; (3) requiring nutrition information on labels of all ground or chopped products and making the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products; (4) requiring nutrition information on labels of the major cuts of single-ingredient, raw meat and poultry products and on all ground or chopped products; and (5) requiring nutrition information on labels of all single-ingredient, raw meat and poultry products and all ground or chopped products.

Option 1: Continuing with the voluntary program. FSIS could continue with the existing voluntary program and attempt to increase participation by providing additional assistance to the nonparticipants. The 1999 nutrition labeling survey found a significant difference in participation rates according to outlet type. Chain stores showed a 65.5 percent participation rate, large independents showed a 46.5 percent participation rate, and medium and small independents showed a participation rate of 26.3 percent. Thus, FSIS could provide nutrition information or point-of-purchase materials to independent retail stores to encourage their participation in the voluntary nutrition labeling program.

Retail establishments would continue to provide, on a voluntary basis, nutrition labeling for all single-ingredient, raw meat and poultry products, including major cuts identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and cuts that are not identified as major cuts (including ground or chopped products not covered in §§ 317.344 and 381.444). This information could be provided at the point-of-purchase or on the label of the product.

Option 2: Make the voluntary program mandatory. FSIS could make the voluntary program mandatory by requiring nutrition information, either on labels or at the point-of-purchase, for all single-ingredient, raw meat and poultry products, including the major cuts of single-ingredient, raw products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and the nonmajor cuts of single-ingredient, raw meat and poultry products (including ground or chopped products not covered in §§ 317.344 and 381.444). Under this option, FSIS would assume that most retailers would

display point-of-purchase information for these products rather than nutrition labels, because this is an inexpensive means of providing nutrition information for multiple products. This approach does not allow for any distinction between ground or chopped meat and poultry products and other cuts of meat. In addition, this approach does not distinguish between the major and nonmajor cuts.

Option 3: Require nutrition information on labels of all ground or chopped meat and poultry products and make the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products (other than ground beef and ground pork). FSIS could require nutrition information on the labels of all ground or chopped products and could require nutrition information, either on their labels or at their point-of-purchase, for the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 (other than ground beef and ground pork). Retail establishments and producers could continue to voluntarily provide nutrition information for nonmajor cuts of single-ingredient, raw meat and poultry products that are not ground or chopped. This approach allows for a distinction between ground or chopped meat and poultry and other cuts of meat and poultry. It also allows for a distinction between major and nonmajor cuts. Consistent with the regulations, the voluntary nutrition labeling surveys only assessed whether nutrition labeling was provided for the major cuts of single-ingredient, raw meat and poultry products. Until some assessment is made of whether adequate information is being provided for the nonmajor cuts of single-ingredient, raw products that are not ground or chopped, FSIS cannot determine whether it would be beneficial to require nutrition information for these products.

In their June 3, 1997, petition discussed above, CSPI stated that USDA should require complete "Nutrition Facts" on ground beef labels that make nutrient content claims. This option would require complete "Nutrition Facts" on all ground beef labels. Thus, CSPI's petition supports this aspect of this option. However, the CSPI petition also stated that point-of-purchase information is generally a poor substitute for labels and that the "Nutri-Facts" posters and brochures used by many stores have severe flaws. Thus, the CSPI petition does not support providing nutrition labeling at the point-of-purchase.

Option 4: Require nutrition information on labels of the major cuts

of single-ingredient, raw meat and poultry products and on all ground or chopped products. FSIS could require nutrition information only on labels of the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and on all other ground or chopped products not covered in §§ 317.344 and 381.444. As in Option 3, establishments could voluntarily provide nutrition information, either at the point-of-purchase or on the label, for the nonmajor cuts of single-ingredient, raw meat and poultry products that are not ground or chopped. This approach allows for a distinction between major cuts and nonmajor cuts that are not ground or chopped. Until some assessment is made of whether adequate information is being provided for the nonmajor cuts of single-ingredient, raw products that are not ground or chopped, FSIS cannot determine whether it would be beneficial to require nutrition information for these products.

Option 5: Require nutrition labels on all single-ingredient, raw meat and poultry products and on all ground or chopped products. FSIS could require nutrition information on labels of all single-ingredient, raw meat and poultry products, including both the major cuts of single-ingredient, raw products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and nonmajor cuts of single-ingredient, raw products, and on all ground or chopped products not covered in §§ 317.344 and 381.444. An April 4, 2000, press release on CSPI's web page, quotes the organization's executive director as stating, "Frozen and processed meats already have nutrition labels. That same information should be on fresh meat" (http://www.cspinet.org/new/nutr_labeling.html). Thus, CSPI supports this option.

FSIS requests comments on whether any of the options not chosen would be a viable alternative to the option chosen and on the possible costs and benefits of the options presented.

Quantification of Costs and Net Benefits of Regulatory Options

FSIS' preliminary analysis does not allow for a comparison of net benefits among the regulatory options. The Agency is unable, at this time, to distinguish between the benefits that accrue from moving from a voluntary program to a mandatory program and the benefits that would accrue from requiring nutrition labels on products versus nutrition information on point-

of-purchase materials. Furthermore, although a comparison of costs of the regulatory options might be possible, FSIS has not quantified all costs. As a result, FSIS believes that it would be inappropriate to provide a comparison of net benefits of the regulatory options considered at this time.

Below, FSIS provides a preliminary analysis of the costs and benefits of the proposed rule. FSIS requests comments on this preliminary analysis and any data that would be useful in estimating the costs and benefits of the proposed rule.

The Proposed Rule

FSIS is proposing Option 3. FSIS is proposing to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies, and to make the voluntary nutrition labeling program mandatory for major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444, unless an exemption applies.

Without a mandatory labeling program for the major cuts of single-ingredient, raw products (that are not ground or chopped), FSIS believes that complete and consistent information on the nutritional attributes of these products will not be provided to every consumer. FSIS also believes that the producers' ability to control the fat and nutrient content of ground or chopped product and the consumers' inability to detect the nutritional variations in these products through observation makes it necessary to further require that labeling requirements for all ground or chopped meat and poultry products be consistent with those currently required for multi-ingredient and heat processed products. The Agency has tentatively concluded that ground or chopped products and the major cuts of single-ingredient, raw products would be misbranded without nutrition information under the FMIA and the PPIA (21 U.S.C. 601(n)(1) and 21 U.S.C. 453(h)(1)).

Many exemptions from the proposed nutrition labeling requirements would apply to ground or chopped products and to the major cuts of single-ingredient, raw products. The existing regulations provide that food products produced by small businesses are exempted from mandatory nutrition labeling if the product labels bear no nutrition claims or nutrition information. Under this rule, small businesses that qualify for the exemption would be exempt from the mandatory nutrition labeling requirements proposed for ground or chopped products. However, the small

business exemption would not apply to the major cuts of single-ingredient, raw meat and poultry products. Also, the existing regulations provide that retail stores and similar retail-type establishments are exempted from nutrition labeling requirements for multi-ingredient products processed at retail and ready-to-eat products packaged or portioned at retail if the products bear no nutrition claims or nutrition information. In this rule, FSIS is proposing that these exemptions not apply to ground meat and poultry products, unless the retail store or similar retail-type establishment meets the requirements for the small business exemption. For a full discussion of the exemptions, see the "Exemptions" heading above. FSIS is requesting comments on whether these exemptions are appropriate and necessary for retail and Federal establishments. The preliminary cost and benefits analyses below do not take the exemptions into account because FSIS does not have sufficient data concerning the establishments that would qualify for the small business exemption or the volume of product that would be exempted from nutrition labeling requirements. Therefore, FSIS requests comments on how the exemptions would affect the costs and benefits of the proposed rule.

In addition to the proposed requirements discussed above, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the regulatory criteria to be labeled "low fat," a lean percentage claim may be included on the label or in labeling as long as a statement of the fat percentage also is displayed on the label or in labeling. Under existing regulations, in order for the phrase "___ percent lean" to be used on the label or in labeling of a product, the product must meet the regulatory criteria for "low fat." Most ground beef and hamburger products do not qualify as "low fat." Therefore, existing regulations preclude the use of the term "___ percent lean" on these products. FSIS extended the compliance enforcement date for nutrition labeling requirements for ground beef and hamburger indefinitely, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger (59 FR 39941); therefore, producers and retailers continue to use the term "lean" in percentage labeling on the packages of ground beef and hamburger. FSIS is proposing to allow this information on the label or in labeling for ground or chopped products

because many consumers have become accustomed to this labeling on ground beef products, and because FSIS believes this labeling provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. Under the preliminary cost analysis below, FSIS provided a preliminary cost estimate for developing new labels that include statements of the lean percentage and the fat percentage. FSIS intends to develop a more detailed analysis of this labeling provision in the final rule.

Preliminary Estimations of the Cost of the Proposed Rule

Making the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products. FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products should not be significant. Retail establishments can choose between providing nutrition information through point-of-purchase materials or providing nutrition information on labels. Processors may also provide the information on labels or on point-of-purchase materials; however, FSIS would enforce these requirements at retail. Point-of-purchase materials are available for a nominal fee (\$12.00 for members, \$24.00 for nonmembers) through the Food Marketing Institute's web site (<http://www.fmi.org>). These materials meet the point-of-purchase requirements in this proposed rule. Also, FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site. Another factor that would mitigate the cost impact of this requirement is that, based on the nutrition labeling survey conducted in 1999, many stores are currently providing nutrition information for the major cuts of single-ingredient, raw products. As discussed above, the 1999 survey found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines.

FSIS estimates the one-time costs to retail establishments for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw meat and poultry products would be about \$0.7 million. FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw meat and poultry products, because this is an inexpensive means of providing nutrition information for multiple

products and because this rule will not require that manufacturers include nutrition labels on the major cuts of single-ingredient, raw meat and poultry products. FSIS estimates that obtaining point-of-purchase materials and making them available to consumers would take an average of 30 minutes. As shown in Table 2 above, there were 69,500 retail stores in 1999 (excluding convenience stores that do not normally sell meat products), and FSIS estimates salary and expenses costs for providing nutrition information to be \$20 per hour (69,500 * 0.5 * \$20 = 0.7 million). This estimate does not take into account the voluntary nutrition labeling survey results which show that many stores currently provide nutrition information for the major cuts of single-ingredient, raw products. Information concerning this cost is addressed in the Information Collection Request submitted to OMB and in the section on paperwork requirements below.

As discussed above, FSIS is proposing that many of the existing exemptions from nutrition labeling requirements would apply to the major cuts of single-ingredient, raw meat and poultry products. However, FSIS is proposing that the small business exemption from nutrition labeling requirements would not apply to the major cuts of single-ingredient, raw products. As explained above, FSIS does not believe that the reasons that necessitated the establishment of the small business exemption, as explained in the January 6, 1993, final rule, are applicable to the major cuts of single-ingredient products. Also, because nutrition information for the major cuts of single-ingredient, raw products may be provided on point-of-purchase materials, FSIS is proposing that the provisions for providing nutrition labeling by alternative means for products in packages that have a total surface area available to bear labeling of less than 12 square inches would not apply to the major cuts of single-ingredient, raw products.

Nutrition labeling of ground or chopped products. The costs of required labels would be incurred by ground meat or poultry processors supplying labeled products to retail stores for sale to consumers and by retail establishments who grind or chop meat and poultry products in their stores for sale to consumers. Costs would include the fixed costs of equipment, the operating costs of printing labels, including materials and labor, and the cost of nutrient analysis.

FSIS estimated the costs of nutrition labels based on the cost analysis conducted for the "Mandatory Safe Handling Statements on Labeling of

Raw Meat and Poultry Products" proposed rule published November 4, 1993 (58 FR 58922); the costs estimates were not revised in the final rule in response to comments. The rationale for using the "safe handling" cost analysis is that the costs of the labels in these two proposals would be comparable for cost estimation purposes. FSIS is not using the regulatory impact analysis developed for the nutrition labeling regulations for cost estimation purposes because much less nutrient analysis will be required at this time than was required when the 1993 nutrition labeling regulations were published (January 6, 1993). There are currently much more data available for nutrition labeling than were available when the 1993 nutrition labeling regulations were published.

Safe Handling Cost Estimates

Fixed costs. The "safe handling" rule estimated the fixed costs of installing or retrofitting labeling equipment for stamping, printing, or affixing labels. The "safe handling" rule had estimated the fixed costs of labeling fresh meat and poultry products for processors to range from \$50 to \$100 million. These costs were based on an estimate that there were somewhere between 50,000 and 100,000 labels approved for use by processors that were affected and an estimated average label modification cost of \$1,000 (58 FR 58925).

The fixed costs of compliance with the "safe handling" labeling rule for retail establishments were estimated to range from \$144 to \$216 million. These estimates assumed that larger retailers would modify their equipment to increase their label size to combine weight and price information with safe handling instructions if their existing equipment was incompatible. These estimates were based on the costs to the then (*i.e.*, 1992) existing 23,813 supermarkets (with annual sales exceeding \$2.5 million/year). Based on conversations with equipment suppliers and two to three retailers, FSIS estimated that upgrading the automated scales/wrapping systems to accommodate a larger label would cost \$6,000 to \$9,000 per store. Assuming that all 24,000 (approx.) supermarkets upgraded their equipment, the cost would range from \$144 (\$6000 x 24,000) to \$216 (\$9000 x 24,000) million. FSIS estimated these costs for large retail chains, *i.e.*, supermarkets, because they constituted three-fourths of total grocery stores sales. For example, in 1992, of the total grocery stores sales of \$360 billion (excluding sales taxes), supermarkets accounted for \$274 billion, or 76 percent. FSIS also estimated these costs

for large retail chains because FSIS assumed that small retailers would produce a second label using existing equipment to meet the "safe handling" rule requirements and, therefore, would incur mostly operating costs rather than fixed costs to meet the "safe handling" rule requirements.

Operating costs. The "safe handling" analysis assumed that all meat and poultry products already included some form of commercially prepared labels, and that the incremental cost of adding safe handling instructions to the label would increase the total per label cost by \$0.0025 to \$0.005. This estimate was also supported by the comment of one large retail chain. In their response to the an earlier interim rule that included a preliminary economic analysis (58 FR 43478), this commenter stated that including the safe handling label, as part of their price labels, would double the cost of their labels from \$0.0025 to \$0.005 per label. For firms that indicated that they would need separate labels for the safe handling statement (*e.g.*, the small retail stores), the most frequent comment in response to the preliminary analysis was that the labels for safe handling would cost \$0.01 each. In the "safe handling" rule, FSIS assumed that large retail chains would incur the lower costs (\$0.0025 to \$0.005) per label by including the safe handling statement as part of their price label. For the smaller firms requiring separate labels for the safe handling statement, FSIS assumed that their costs would be \$0.01 per package. The higher costs for small retailers can be explained by the absence of economies of scale available to these retailers.

As discussed above, in 1992, large retail chains had sales that accounted for 76 percent of total grocery store sales. In the "safe handling" rule, FSIS rounded this number and assumed that 80 percent of packages of meat and poultry products labeled and sold through retail would be sold through large retail chains. The "safe handling" rule estimated that there were 10 billion packages of meat and poultry product prepared and sold through retail. Therefore, the rule estimated that 8 billion packages would be prepared and sold by large retail chains and the remaining 2 billion packages would be prepared and sold by small retail firms. The safe handling rule estimated that the 10 billion retail packages would have recurring costs associated with the "safe handling" rule of \$50 million per year. This estimate assumed that the 8 billion packages sold through large retail chains would have recurring costs of \$0.00375 (midpoint of \$0.0025 and \$0.005) and the 2 billion packages sold

through small stores would have recurring costs of \$0.01 per package.

In the "safe handling" rule, the additional labor costs for applying the 2 billion separate safe handling labels by use of label guns for small firms were estimated. Based on the number of staff years at 160 and an average salary of \$20,000 per year, the "safe handling" rule estimated the labor costs at about \$3.2 million per year.

The "safe handling" rule did not estimate operating costs of labeling for processors because they were expected to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to labels.

Adjustments to the Costs in the Safe Handling Rule

Estimating the volume of ground or chopped products. As explained above, the "safe handling" rule estimated the cost of labeling all fresh meat products. The number and volume of products that would require nutrition labels in this proposed rule are, however, much smaller relative to the number and volume of products in the "safe handling" rule, because the proposed rule would require nutrition labels on only ground or chopped meat and poultry products. FSIS adjusted the costs of the "safe handling" rule to reflect the costs related to the volume of ground or chopped product produced.

In 1996, total U.S. annual production of ground beef was 7 billion pounds (American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 5). The American Meat Institute (AMI) report cited has not been updated. However, according to AMI staff, total U.S. annual production of ground beef was 7.2 billion in 1998, an increase of less than 3 percent. For estimation purposes, FSIS believes the 1996 data are still valid. Based on discussion with AMI staff members, approximately 50 percent (or 3.5 billion) of this output is sold through retail stores (the rest goes through restaurants and institutions). As regards other ground or chopped products such as poultry, pork, and turkey, AMI estimates that for every 100 pounds of ground beef, 12.3 pounds of these competing meats are produced (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 8). The estimate of 12.3 pounds is based on a survey sent by AMI to the top 50 retail chains and wholesalers. No attempt was made to expand the survey responses to a national level or develop estimates for the entire retail sector. In the absence of any information that

would validate the survey responses for the entire retail sector, however, FSIS employed these estimates as approximate trends. However, FSIS invites comments and requests nationally representative data for the retailers for analysis of the final rule.

To arrive at the total volume of ground or chopped meat and poultry products sold in retail stores, FSIS first assumed that 50 percent of total production, or 3.5 billion pounds, represented ground or chopped beef sold in retail stores. Second, based on the AMI survey referred to above, FSIS assumed that ground or chopped poultry and other meats represented 12.3 percent of ground beef sales. Therefore, the total annual volume of ground or chopped meat and poultry sold through retail establishments amounted to 3.9 (3.5 + .4) billion pounds [3.5 billion + (3.5 billion * 0.123 = .431 billion)].

Fixed costs. As explained above, the "safe handling" rule had estimated the fixed costs of safe handling labeling for processors to range from \$50 to \$100 million. Also explained above, the fixed costs of compliance with the "safe handling" labeling rule for retail establishments were estimated to range from \$144 to \$216 million. The estimation of these fixed costs assumed that larger retail stores would modify equipment to increase their label size to combine weight and price information with safe handling instructions if their existing equipment was incompatible. In this rule, retail stores also might modify equipment to increase their label size to combine weight and price information with nutrition information.

To calculate the fixed costs of nutrition labeling of ground or chopped products, FSIS adjusted the fixed costs in the "safe handling" rule to account for existing equipment. FSIS believes that many establishments have already incurred fixed costs required for the "safe handling" rule. For example the 1999 safe handling survey revealed that 96.7 percent of large chains, 90.5 percent of large independents, and 84.1 percent of medium/small independents had already complied with the "safe handling" rule requirements. Therefore, as explained in the "Baseline" section above, FSIS made the conservative assumption that 80 percent of the estimated fixed costs were already incurred by retailers and processors and only 20 percent of the estimated fixed costs would be required for compliance with the proposed rule. Hence the estimated fixed costs of the proposed rule would range from \$10 million to \$20 million for processors and from

\$28.8 million to \$43.2 million for retailers.

Although these costs were estimated based on 1992 prices, there has been virtually no change in their prices in the year 2000. For example, the index number for producer prices for blast furnaces and steel mills was 105.8 (1982 = 100) in 1992, and it was almost the same at 105.3 (1982 = 100) in July 2000. FSIS used this index number because these producers also manufacture equipment used for stamping and printing labels. Therefore, these costs are current and do not need any updating. These costs are shown in columns 1 and 2, Table 8.

Operating costs. As explained above, the safe handling analysis had assumed that all meat and poultry products already included some form of commercially prepared labels, and that the incremental cost of adding safe handling instructions to the labels would increase the total per label cost by \$0.0025 to \$0.005. The "safe handling" rule also estimated that the cost to firms that would need separate labels for the safe handling statement would be \$0.01 per label. As in the "safe handling" rule, in this rule, FSIS is assuming that large retail chains would incur the lower costs (\$0.0025 to \$0.005) per label, because they would include nutrition information as part of their price labels. Similarly, consistent with the "safe handling" rule, for this rule, FSIS is assuming that smaller stores would apply a separate label with nutrition information.

As explained above, in the "safe handling" rule, FSIS assumed that large retail chains would account for 80 percent of all retail packages labeled at retail and that the smaller firms would account for 20 percent of all retail packages. FSIS believes that the estimate that 80 percent of retail-labeled packages are sold through large retail chains is likely to be valid in the year 2000 (without the need to round up) because of a number of mergers, acquisitions, and consolidations in this sector in the recent years. For example, Royal Ahold bought Giant Foods, Albertson's bought American Stores, SUPERVALUE bought Richfood, and Food Lion bought Hannaford (Sean Mehegan, "Merger Mania—Consolidation Changes the Face of the North American Supermarket Sector," *Meat & Poultry* (September 1999): 22–25). FSIS requests comments and data concerning whether the estimate that 80 percent of retail-labeled packages are sold through large retail chains is accurate.

For the proposed rule, FSIS is assuming that a package of ground or chopped meat or poultry would average

two pounds. FSIS believes that most packages of ground or chopped product weigh at least a fraction over one pound; however, this product is also sold in bulk size packages that are significantly over one pound. Therefore, FSIS believes that two pounds is a reasonable estimate of the average weight of a package of ground or chopped product. If FSIS were to assume that the average size package were 1 pound, this assumption would double the estimated operating costs below. FSIS requests comments on whether two pounds is an accurate average weight estimate for packages of ground or chopped product.

Since the estimated annual volume of ground or chopped product sold through retail is about 4 billion pounds, there will be 2 billion packages (at two pounds each) requiring the labels. Because FSIS assumes that 80 percent of these packages would be accounted for by large firms, their corresponding shares of the packages would be 1.6 billion (80 percent of 2 billion) and small firms would account for the rest, *i.e.*, 0.4 billion packages (20 percent of 2 billion). Assuming a mid-point cost of \$0.00375 for the range of safe handling label costs for large retail stores (\$0.0025 to \$0.005), the compliance cost for these stores would be \$6 million (1.6 billion packages * \$0.00375). The compliance cost for separate nutrition labels required by small firms would be about \$4 million (0.4 billion packages times \$0.01 per package). These costs were estimated in 1992, and there was an increase of 20 percent in related costs in July 2000. This increase is based on the producer price index numbers for plastics, foil, and coated paper bags, the materials on which labels would be

printed (1992 = 142.9, July 2000 = 171.7). Therefore, these operating costs would increase by \$2 million to \$12 million in current prices.

As explained above, the “safe handling” rule estimated the labor costs of small firms applying separate safe handling labels by use of label guns at about \$ 3.2 million per year, based on 2 billion labels, and 160 staff years at an average salary of \$20,000 per year. According to data from the Bureau of Labor Statistics, the average hourly earnings in June of 1999 were \$7.88 per hour. Assuming at least 2,000 work hours per year, the estimated annual earnings would be \$15,760. FSIS adjusted the costs in the “safe handling” rule based on this earnings estimate. Therefore, FSIS revised the estimated “safe handling” labor costs to small firms to \$3.0 million per year (160 staff years times \$16,000 per staff totals \$2,560,000 per year, which FSIS rounded to \$3 million). Since these costs were for 2 billion packages for the safe handling rule, the prorated costs for 400 million packages for the proposed rule would be \$0.6 million (400 million times \$3 million divided by 2 billion). Therefore, estimated total operating or recurring costs associated with the proposed rule would be \$12.6 (12 + 0.6). These costs are shown in Table 8, row 2, column 3.

The “safe handling” rule did not estimate operating costs of labeling for processors because they were expected to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to labels. Therefore, Table 8, row 1, column 3, reports their operating costs as “Not Applicable” (NA). The recurring costs of

nutrition labeling for processors other than retail establishments are not estimated in this rule because, again, FSIS expects these processors to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to their existing labels.

Paperwork burden costs. FSIS estimates that the one-time development and recordkeeping costs associated with nutrition labels for ground or chopped products for Federal establishments and retailers will total \$8.8 million. As explained above, FSIS estimates the one-time costs to retail establishments for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw products will be about \$0.7 million. The paperwork burden cost estimates for the required nutrition labels for ground or chopped products are based on the time required to develop 3 nutrition labels (120 minutes each), the time required for recordkeeping for the supporting data at Federal and retail establishments (5 minutes), and the time required for Federal establishments to submit label approval applications to FSIS (15 minutes). FSIS estimates that there are 2,489 Federal establishments affected by the rule and 69,500 retail establishments and estimates salary and expenses for these activities to be \$20 per hour. Information concerning these costs is addressed in the Information Collection Request submitted to OMB and the Paperwork Requirements section below.

Table 8 shows that total operating compliance costs associated with nutrition labels for ground or chopped product are estimated at \$12.6 million.

TABLE 8.—ESTIMATED COMPLIANCE COSTS FOR GROUND OR CHOPPED PRODUCTS (\$ MILLION)

	Fixed costs		Operating costs	Paperwork burden costs
	Low	High		
Processors	10.0	20.0	NA	.3
Retailers	28.8	43.2	12.6	8.5
Total	38.8	63.2	12.6	8.8

Discounted value of compliance costs. The low and high estimates of fixed costs were added to the operating costs and paperwork burden costs estimated above. Therefore, FSIS obtained two series of costs, low and high, for a period of 20 years. The low estimate was \$60.2 million per year (\$38.8 million + 12.6 million + 8.8 million) and the high cost estimate was \$84.6 million (\$63.2 million + \$12.6 million + \$8.8 million). These series were

discounted at 7 percent to compare them with discounted benefits, which are also discounted at 7 percent. It was assumed that the costs would be incurred in the middle of each year for the next 20 years. The results revealed that the present values of compliance costs for the next 20 years (from 2001 to 2020) ranged from \$659.69 million to \$927.05 million. Other than the paperwork costs discussed above, there should not be many costs associated

with nutrition labels that would exceed the estimates in the “safe handling” rule. Nutrient content is dependent on fat levels, and there is a direct relationship between fat and other nutrients. Producers should be able to use available data or to extrapolate from existing data to develop the data for nutrition labels. In addition, FSIS will develop a list of published sources of information concerning the nutrient content of ground or chopped products,

so that industry could obtain available literature from local libraries. This information would facilitate the development of nutrition labels for ground or chopped products. FSIS requests comments and data on any additional costs associated with nutrition labels that were not included in this preliminary cost analysis.

Although nutrition labels are not currently required on single-ingredient, raw ground or chopped products, such labels are often provided voluntarily on these products. According to information submitted by CSPI, a number of major supermarket chains, including Dominick's, Fred Meyer, Jewel, Kroger, Wegman's, Winn-Dixie, Albertson's, and some Lucky and Safeway stores, now include full "Nutrition Facts" labels on their ground beef (Bonnie Liebman, "Where's the Beef Labeling," *Nutrition Action Healthletter* (June 1999): 8-11). Because FSIS does not have complete information concerning the volume of ground or chopped packages that bear nutrition labels, FSIS is estimating the costs of labels for all packages of ground or chopped product in the cost estimates above.

Impact of estimated costs. The preceding estimates of fixed, operating and paperwork burden compliance costs for the proposed requirements concerning ground or chopped product at \$60.2 to \$84.6 million are not likely to be excessive relative to the volume of output of ground or chopped meat and poultry products sold at retail. For example, as noted above, the volume of these products is estimated at 3.9 billion pounds. Therefore, these costs would range from 1.5 to 2 pennies per pound (\$60.2 million/3.9 billion pounds to \$84.6 million/3.9 billion pounds). FSIS has not conducted a thorough analysis of how the costs to Federal and retail establishments would affect the price, supply, and demand of ground or chopped products. Similarly, FSIS has not thoroughly evaluated how any changes in consumer behavior that may occur as a result of this rule would affect the price, supply, and demand of ground or chopped products.

Percentage Labeling

The proposed percentage labeling for ground or chopped products would not result in significant costs because such labeling would be optional rather than mandatory. If retailers and other producers found this labeling to be costly, they would simply not exercise this option. Because FSIS extended the compliance enforcement date for use of the term "lean" for these products, pending publication of a final rule on

percentage labeling for lean and fat on ground beef and hamburger, many of these products already bear these statements on their labels. If producers chose to develop new labels, the costs per label would be comparable to those for printing nutrition labels (\$0.0025 to \$0.05 per label if the information is included as part of their price label, and, \$0.01 per label if they developed separate labels). FSIS requests comment on the costs and benefits of percent fat/percent lean labeling on ground or chopped products.

Benefits

The benefits of nutrition labeling depend on the extent to which consumers change their food consumption in favor of products that are more nutritious. As noted earlier, the absence of nutrition labeling to indicate nutrition contents of ground or chopped meat and poultry products and the major cuts of single-ingredient, raw products does not allow consumers to get adequate information for making their purchasing decisions. Provision of nutrition labels and point-of-purchase materials would disseminate nutrition information and enhance consumers' food purchasing decision-making process.

Consumption habits vary with knowledge of nutrition and health, preference for healthful diets, and socioeconomic status of different segments of the population. For example, consumers with preferences for healthful diets are likely to select products with lower fat and cholesterol levels to assist in the reduction of risk for coronary heart problems and cancerous diseases. Some consumers might perceive that a product is of higher quality or more nutritious if it has lower fat and cholesterol contents. Availability of nutrition labels on ground or chopped meat and poultry products and nutrition information for the major cuts of single-ingredient, raw products may help purchasing decision-making by these select groups of consumers.

Literature review of impact of labeling on diet quality. Nutrition labels on products such as cereals have existed for over two decades. Research studies on the effect of nutrition labeling on diet quality for these non-meat and poultry products indicate a positive relationship between these variables. Kreuter et al. (1997) analyzed survey data of 885 adult patients from four family medical clinics in Missouri (see the "References" section below for full citations of the literature referred to in this discussion). To participate, patients completed a self-administered survey

while waiting to see their physicians. The results revealed that patients eating diets lower in fat were much more likely (51% versus 26%) than patients whose diets were higher in fat to report that nutrition labels influenced their food purchasing decisions.

Guthrie *et al.* (1995) linked USDA's 1989 Continuing Survey of Food Intakes by Individuals (one database) to Diet and Health Knowledge Survey (another database). They concluded that label use appeared to be associated with the consumption of diets that were higher in vitamin C and lower in cholesterol.

Neuhouser *et al.* (1999) analyzed data from a survey of 1,450 adult residents in Washington State. The survey assessed nutrition label use, fat-related diet habits, fruit and vegetable consumption, diet-related psychosocial factors, health behavior, and demographic characteristics. They concluded that label use was significantly associated with lower fat intake and, after controlling for all demographic, psychosocial, and behavioral variables, label use explained 6% of the variance in fat intake (their conclusion had a probability of 99.9%).

Mathios and Ippolito (1998) analyzed the effect of nutrition information in advertising and labels on consumption of food cereals with fiber content. They divided their study into two periods: First, the period, 1978-1984, when the FDA permitted printing of fiber content on cereal boxes but did not permit printing of any health claims, and the period 1985-87 when health claims were permitted. They concluded that in concert with an increase in fiber intake of cereals in their diets, the average intakes of fat, saturated fat, and cholesterol for both men and women declined during both the periods, albeit, the decline was greater during the second period relative to the first. They concluded that the increase in fiber and the decrease in fat and cholesterol consumption were associated with the consumption of labeled cereals.

Preliminary benefits analysis. FSIS consulted with ERS to develop the following empirical analysis of the benefits of nutrition labeling. The estimated benefits take the form of reductions in the incidence of coronary heart disease and three types of cancer which may accrue as consumers improve their diet quality through increased use of nutrition information generated by the regulation. FSIS used survey data on nutrient intake and label use to correlate intake of fat, saturated fat, and cholesterol to usage of existing nutrition information. The Agency estimated the value of the potential changes from intake of fat, saturated fat,

and cholesterol that could occur as consumers respond to the newly available nutrition information. FSIS applied the model developed by Zarkin, et. al. which links changes in the serum cholesterol rate to changes in the percentage of total calories from polyunsaturated fat, saturated fat, and dietary cholesterol (Gary A. Zarkin, Nancy Dean, Josephine A. Mauskopf, and Richard Williams, "Potential Health Benefits of Nutrition Label Changes," *American Journal of Public Health* 83(5) (May 1993): 717-724; Gary A. Zarkin, Nancy Dean, Josephine A. Mauskopf, and Dierdre M. Neighbors, "Estimated Benefits of Nutrition Label Changes: Final Report, Volume 1," Center for Economics Research, Research Triangle Institute, Research Triangle Park, NC, 27709. April 1991). Changes in serum cholesterol are then used to estimate the health outcomes, which are reductions in the number of cases and mortality from three cancers (breast, colorectal, and prostate) and coronary heart disease. Finally, the Agency attached economic value to the public health changes by estimating the implied value of life associated with reductions in premature mortality.

To determine how much of a behavioral response and change in dietary intake may result from providing more nutrition information on meat and poultry products, FSIS makes the following assumption: The Agency assumes that when labels and other sources of nutrition information are provided for raw meat and poultry products that nutrition information usage rates will rise to match label usage rates for food products as a whole (see Table 3). Currently, some nutrition information is provided for some single-ingredient, raw meat and poultry

products, but the information is not currently required. Mandatory nutrition labeling rules for the major cuts of single-ingredient, raw products and ground or chopped products would mean the nutrition information provided for these products would be comparable to that provided for other food products. FSIS therefore could reasonably assume that nutrition information usage rates for raw meat and poultry products would then become the same as the label usage rates for all foods taken together. For example, before mandatory nutrition information labeling, the data show that about 17 percent of men look for nutrition information on meat "Often" (Row 2 of table 3). In this analysis, then, FSIS assumed that after mandatory nutrition information labeling, 26.7 percent of men would use the nutrition fact panel or point-of-purchase materials for meat products, which is the label usage rate for all foods (Row 1 of table 3). Similarly, the Agency assumes that the percentage of women using nutrition information on meat products "Sometimes" would rise from 18 percent to 32.6 percent.

What does this mean for diet quality? Here, FSIS made another (admittedly strong) assumption: The Agency assumed that as nutrition information usage rates rise for consumers eating meat and poultry, dietary patterns will change in a manner consistent with current data. As shown above, there is strong statistical evidence that people who use nutrition information to guide their food consumption decisions have healthier diets. While other factors may be at work, and the role of information use in causing dietary changes is unclear, FSIS makes the assumption that the provision of additional

nutrition information and making that information available to more consumers will lead to behavioral shifts and increased diet quality. Thus, FSIS assumes the effect of providing new information for meat and poultry products would make consumers who NEVER used nutrition information for meat and poultry products become aware of the diet implications of their choices in meat and poultry products. These consumers would then choose to consume the same mix of products as people who are currently aware of the nutritional quality of meat and poultry products. For example, men who currently do not look for nutrition information on meat in the absence of mandatory nutrition information labeling who would begin using this information "Sometimes" after labeling is in place would see a decrease in fat intake from 98 grams to 92.5 grams.

Under these assumptions, then, FSIS could see how requirements for mandatory nutrition information labeling on raw meat and poultry products could possibly affect diet quality. To reach the values shown in table 6, FSIS multiplied each cell in table 5 by the associated percentage of label use (nutrition facts panel use) from table 3. By doing this, FSIS increased the numbers of people in the "always" and "sometimes" cells, and decreased the number of people in the "rarely" and "never" cells, so that the distribution of label usage on meat and poultry products would reflect the distribution of label usage on all products. Aggregating across categories, FSIS got a new weighted average intake, which could be seen after the imposition of mandatory labeling requirements.

TABLE 9.—CHANGE IN INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory nutrition labeling of meat & poultry	After adjusting for increased label usage	Percentage decrease in intake
Men:			
Total Fat	92.51	91.31	1.30
Saturated Fat	31.12	30.69	1.37
Cholesterol	339.07	334.95	1.21
Women:			
Total Fat	60.16	58.57	2.65
Saturated Fat	19.71	19.21	2.55
Cholesterol	210.53	208.16	1.13

Note: Fat intake in grams, cholesterol in milligrams.

TABLE 10.—CHANGE IN PERCENTAGE OF CALORIES FROM FAT AND CHOLESTEROL INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory nutrition labeling of meat & poultry	After adjusting for increased label usage	Percentage decrease in calories from fat or intake
Men:			
Total Fat	33.44	33.33	0.11
Saturated Fat	11.19	11.14	0.04
Cholesterol	339.07	334.95	4.12
Women:			
Total Fat	32.49	32.37	0.11
Saturated Fat	10.64	10.54	0.10
Cholesterol	210.53	208.16	2.37

Note: Fat and saturated fat values are percent calories from fat. Cholesterol is mg.

Evaluation of health effects. Based on epidemiological research, FSIS related the reductions estimated in Table 10 to estimated decrease in incidence of major diseases associated with consumption of fat and cholesterol. The diseases considered in this analysis include three types of cancer—breast, prostate, and colon/rectal—and coronary heart disease. Epidemiological studies of the relationships between dietary fat and cholesterol intake and incidence of cancer and coronary heart disease indicate that saturated and

polyunsaturated fat and cholesterol are converted into serum cholesterol. Serum cholesterol has an impact on the incidence rates of these diseases. FSIS used the following equation from Zarkin *et al.* (1993) to convert fat contents into the change in serum cholesterol (SC) rate, in milligram/deciliter (mg/dl):

$$(1) SC (Mg/dl) = 2.16S - 1.65P + 0.097C$$

Where SC is serum cholesterol, S is the change in percentage of total calories represented by saturated fat, P is the change in percentage of total calories

represented by polyunsaturated fat, and C is the change in dietary cholesterol measured in mg/1000 calories.

FSIS substituted the estimated values of percentage changes in saturated fat and cholesterol intake from the last column of Table 10 into this equation. Since FSIS did not have separate data for polyunsaturated (P) fat, it was assumed that P would be one-third of total fats, as was also assumed by Zarkin *et al.* The estimates of serum cholesterol for male and female consumers are as follows:

TABLE 11.—REDUCTION IN SERUM CHOLESTEROL AND CHANGE IN MORTALITY

	% Change in calories from total fat	% Change in calories from sat. fat	Change in cholesterol intake	Change in serum cholesterol	% Reduction in mortality
Men	0.11	0.04	4.12	0.399	0.0240
Women	0.11	0.10	2.37	0.231	0.0139

FSIS used the calculated values of SC presented above to estimate incidence of breast, prostate, colon/rectal cancer, and coronary heart disease. Zarkin *et al.* (1993) concluded that an increase in serum cholesterol by 20 mg/dl was

associated with a 1.2-percent increase in the incidence of each of these diseases. FSIS employed this rate to convert reductions in total fat, saturated fat, and cholesterol in Table 10 into SC. It is estimated that the reduction in mortality

associated with changing dietary pattern from mandatory nutrition information labeling are 0.024 percent for men, and about 0.014 percent for women.

TABLE 12.—REDUCTION IN MORTALITY, ANNUAL NEW CASES OF MORTALITY, AND ESTIMATED LIVES SAVED

	Reduction in mortality (%)		Annual new cases of mortality		Lives saved		
	1	2	3	4	5	6	7
	Men	Women	Men	Women	Men	Women	Total
Breast Cancer		0.0139		41,200	0	6	6
Prostate Cancer	0.0240		31,900		8	0	8
Colorectal Cancer	0.0240	0.0139	28,000	28,000	7	4	11
Coronary Heart Disease	0.0240	0.0139	231,332	228,769	55	32	87

Table 12 presents data on the annual new cases of mortality associated with the three types of cancer and coronary heart disease for men and women in the United States in 1998. Data for the

number of deaths came from the National Center for Health Statistics (coronary heart disease) and the American Cancer Society (cancer). Data on colorectal cancer were not available

by gender; FSIS assumed the estimated 56,000 cases were distributed equally between men and women.

Estimating the benefits of preventing premature death. The benefits of the

proposed nutrition information labeling rule would be the lives saved due to the estimated reductions in mortality rates associated with these diseases. However, placing reduction of the risk of premature death in an economic context is difficult and controversial (for an in-depth analysis of this issue, see Fred Kuchler and Elise Golan, "Assigning Value to Life: Comparing Methods for Valuing Health Risks," Agricultural Economic Report No. 784, U.S. Dept. Agric., Econ. Res. Service, Washington, DC, Nov. 1999). The problem is that there is no market for reducing diet-related fatal risks. If food were marketed by risk levels (say, probabilities of inducing cancer or heart disease) and consumers treated advertised risk levels like they do other objectively measurable product characteristics (e.g., weight or volume), there would be little difficulty in valuing food safety. Product prices could be statistically associated with risk levels, yielding the risk-dollar trade-off consumers make. That is, FSIS could measure, based on consumer purchases, the dollar value consumers attach to particular types of risk reduction.

There is no price that can be tabulated from commercial transactions that reflects the value of reducing diet-related fatal risks. Actions that individuals might take to reduce these risks do not leave a behavioral trail for analysts to follow. This information void makes it difficult to evaluate programs that might reduce diet-related risks. In particular, there is no obvious dollar value to assign to the major benefit of such programs, namely lives saved.

Ultimately, FSIS wanted to monetize the benefits of diet-related fatal health risk reduction. Other risks do leave a clear behavioral trail that analysts have followed, measuring the risk-dollar trade-off individuals make. The Agency's goal was to find a method of transferring market-based risk-dollar trade-off estimates to diet-related fatal cancer risks.

The most studied risk choices are those for on-the-job risks of accidental injury and death. Analysts have estimated the compensation required to induce workers to accept such risks. Many studies of labor market behavior have been carried out because the wide range of risk levels workers accept and the wide range of wages paid are amenable to statistical analysis. Available evidence suggests that workers' subjective assessments of risks they face are plausible (W.K. Viscusi, *Fatal Tradeoffs—Public & Private*

Responsibilities for Risk. New York: Oxford University Press, 1992).

Viscusi (1992) summarized the empirical work estimating the value of risk of premature death. Several studies estimate the risk-dollar trade-off in the labor market by dividing the wage premium for risky jobs by the risk of a fatal job injury. Drawing on the compiled results of these studies, he stated: "Although the estimates of the risk-dollar tradeoff vary considerably depending on the population exposed to the risk, the nature of the risk, and similar factors, most of the reasonable estimates of the value of life are clustered in the \$3 to \$7 million range" (p. 73). Thus, compensating wages indicate that, on average, industrial workers value a statistical life at \$5 million (December 1990 dollars), the midpoint of the range. ERS currently uses the \$5 million per life estimate (adjusted upwards for inflation to 2000 dollars) to measure the benefits of preventing premature death from foodborne diseases caused by microbial pathogens (such as *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*.) (Crutchfield, Roberts, Buzby, and Frenzen, "Food Safety Efforts Accelerate in the 1990's," *Food Review*, 23 (3), September-December 2001, forthcoming). This estimate has been used by other government agencies to evaluate the benefits of regulations designed to reduce the risk of premature death. For example, The Food and Drug Administration (Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products Final Rule, 60 FR 65095) and the Consumer Product Safety Commission (Miller et al., "The Consumer Product Safety Commission's Revised Injury Cost Model," *Peer Review Draft Prepared for the U.S. Consumer Product Safety Commission*, July 1, 1997) currently use Viscusi's mid-point value of \$5 million for each life saved. (Kuchler and Golan, "Assigning Value to Life: Comparing Methods for Valuing Health Risks," *Agricultural Economic Report No. 784*, U.S. Department of Agriculture, Economic Research Service, Washington, DC, November 1999, page 25). However, other agencies use lower life values in their analyses. FSIS requests comments on whether \$5 million is an appropriate value of life estimate.

FSIS used the \$5 million estimate as reflecting willingness to pay to avoid health risks. This is not the value an individual would pay to save his own life, but the aggregate value paid by many individuals to reduce a small risk of death each faces. To make this transfer, FSIS assumed that individuals

make consistent risk choices, reducing health risks as much as their budgets allow. The Agency assumed individuals focus on the likelihood of health outcomes and how bad the outcomes might be, without regard to the different physical characteristics of hazards that give rise to health risks. The assumption critical for making the transfer from valuing job risks to valuing cancer risks is that individuals value years of life, and all years are equally valuable. All individuals are assumed to value a year of life equally.

FSIS adjusted for differences between years of life lost to cancer and heart disease fatalities and years of life lost to workplace fatalities. The value of statistical life estimate is based on a worker anticipating a fatal injury and losing an average life expectancy of 36.5 years (W.K. Viscusi, W.K. *Cigarette taxation and social consequences of smoking*. In James M. Poterba (ed.), *Tax Policy and the Economy*. Volume 9. Cambridge: MIT Press for the National Bureau of Economic Research, 1995). Potential life years lost to cancer and heart disease deaths were calculated by FSIS using data from National Centers for Health Statistics (National Center for Health Statistics, *National Vital Statistics Report 48 (11)* (July 24, 2000): 167). NCHS reports the number of years lost before age 75 per 100,000 population under the age of 75. These data were divided by the number of cancer and heart disease deaths for the population under 75 years of age to estimate the average number of life years lost up to age 75. The average number of life years lost were 14.9 for breast cancer, 3.9 for prostate cancer, 9.56 for colorectal cancer, and 10.2 for coronary heart disease. Thus, to calculate a value of life lost to cancer or heart disease, FSIS adjusted the \$5 million estimate downward to reflect the fewer years of life lost to cancer or heart disease, compared to work-related deaths. This calculation is similar to that carried out by Viscusi for estimating the value of statistical lives lost to environmental tobacco smoke (Viscusi, 1995).

FSIS treated the last 36.5 years of life ($L_{36.5}$) as a capital asset with a current value of \$5 million. If the risk market could be characterized as an efficient market, the asset price should be equal to the present value of the service flow the asset produces.

$$L_{36.5} = \$5 \text{ million} = \int_0^{36.5} Re^{-rt} dt$$

R is the (assumed) constant annual value of life and r is the time preference

rate used to discount future benefits. Consider now the case of an individual facing an expected loss of 10.2 years of life from coronary heart disease. From this perspective, the value of the last 10.2 years of life for a victim of coronary heart disease is

$$L_{10.2} = e^{-26.3r} - 1R(1 - e^{-10.2r})$$

The equations for both $L_{36.5}$ and $L_{10.2}$ can be solved for R and equated, yielding

$$L_{10.2} = L_{36.5} e^{-26.3r} (1 - e^{-36.5r})^{-1}$$

The value of cancer avoidance depends on an individual's rate at which future years of life are discounted. At an interest rate of 7 percent, the value is \$636,755. At an interest rate of 3 percent, the value is \$1,056,261.

This estimate is in December, 1990 dollars. Using the CPI-U to update this estimate from 1990 to 2000 dollars (CPI-U = 133.8 in December 1990, and 171.3 average for 2000), the value becomes \$815,218 (7 percent discount rate) and \$1,352,298 (3 percent) in 2000 dollars. Similar calculations were made for deaths associated with the other three diseases considered (which take into account the different number of life years lost for each disease). The results are reported in Tables 13 and 14. To arrive at an estimate of the benefits associated with reductions in mortality due to changes in fat and cholesterol intake, FSIS multiplied the dollar value assigned to each premature death prevented by the number of lives saved due to changes in diet quality. This estimate is reported for each disease as

“Total benefits per year” in Tables 13 and 14. The total for all diseases is \$86.6 million dollars at a 7 percent discount rate and \$145.2 million at 3 percent.

It should be noted that the calculations used to estimate present value explicitly account for the time factor associated with delayed health impacts of dietary change. Decreases in intake of saturated fat, fat, and cholesterol will reduce the incidence of heart disease and cancer, but not immediately—the reductions in illness and death will begin to occur years into the future. However, the formulas used for calculating the present value of the benefits explicitly take this into account, for they reflect the value placed on lost years of life occurring in the future.

TABLE. 13—ESTIMATED LIVES SAVED AND ASSOCIATED ECONOMIC BENEFITS, USING A 7 PERCENT DISCOUNT RATE

	Breast cancer	Prostate cancer	Colorectal cancer	Coronary heart disease	All diseases
Deaths Per Year	41,200	31,900	28,028	228,231	329,359
Lives Saved Due to Dietary Changes from Labeling	6	8	11	87	111
Years of Life Lost Per Premature Death	14.9	3.9	9.6	10.2	N/A
Dollar Value of 1 Life Saved (\$)	1,032,665	384,390	780,670	815,218	N/A
Total Benefits Per Year (\$)	5,906,020	1,513,329	8,273,399	70,936,607	86,629,355
20 Year Present Value (\$)	62,568,456	16,032,277	87,648,507	751,503,430	917,752,620

NOTE: Cancer deaths are for 2000, heart disease deaths are for 1998. Number of lives saved is rounded to the nearest integer. All benefits estimates are in year 2000 dollars.

TABLE. 14—ESTIMATED LIVES SAVED AND ASSOCIATED ECONOMIC BENEFITS, USING A 3 PERCENT DISCOUNT RATE

	Breast cancer	Prostate cancer	Colorectal cancer	Coronary heart disease	All diseases
Deaths Per Year (1998)	41,200	31,900	28,028	228,231	329,359
Lives Saved	6	8	11	87	111
Years of Life Lost Per Death	14.9	3.9	10.6	10.2	N/A
Dollar Value of 1 Life Saved (\$)	1,844,723	570,731	1,395,308	1,352,298	N/A
Total Benefits Per Year (\$)	10,550,343	2,246,945	14,787,213	117,670,918	145,255,419
20 Year Present Value (\$)	156,962,464	33,428,870	219,996,395	1,750,646,120	2,161,033,850

NOTE: Cancer deaths are for 2000, heart disease deaths are for 1998. Number of lives saved is rounded to the nearest integer. All benefits are in year 2000 dollars.

It should be kept in mind that these estimates are based on annual data, and represent only one year's benefits. FSIS assumed that the reduction in mortality would continue each year. Using a twenty-year time horizon, FSIS estimated the present value (discounted at seven percent and three percent) of continuing reduction in premature deaths. This estimate was \$918 million for all diseases at 7 percent, and \$2.161 billion at 3 percent. FSIS requests comment on the benefits analysis above.

Summary of costs and benefits of the proposed nutrition labeling rule. As discussed above, FSIS' preliminary analysis does not allow for a comparison of the net benefits among the regulatory options considered.

For the proposed rule, the present values of benefits estimated in the two scenarios with 7 and 3 percent discount rates, respectively, range from \$918 million to \$2.161 billion. The present value (at a 7 percent discount rate for 20 years) of annualized fixed costs, operating and paperwork burden costs (including paperwork costs for providing nutrition information for the major cuts) for the lower bound estimate amounts to \$659.69 million. In case the higher estimate of fixed costs is used, the fixed, the operating, and the paperwork burden costs amount to \$927.05 million, at a 7 percent discount rate for 20 years.

Percentage labeling. This proposed rule would allow but would not require

a statement of the fat and lean percentage in ground or chopped products. FSIS believes that this nutrition information helps consumers make better food choices and provides incentives to producers to continue producing nutritionally-improved products which contribute substantially to the health benefits associated with nutrition labeling. However, FSIS does not have the data necessary to quantify these benefits. FSIS requests comments concerning the benefits of percentage labeling on ground or chopped products.

Regulatory Flexibility Act (RFA)— Preliminary Analysis

Based on the cost analysis above, FSIS has made an initial determination that this rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C 601). In the cost analysis above, FSIS estimated that the total costs for required nutrition labels on ground or chopped products would be between 1.5 and 2 pennies per pound. Also, as stated above, FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat products should be negligible. FSIS estimates the total one-time costs to all retail establishments combined for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw products will be about \$0.7 million.

The data in Table 1 in the "Baseline" section above suggest that about one-half of the poultry plants were large (28 out of 63) in 1999. The number of "small" and "very small" poultry plants was 23 and 10 respectively. In the absence of the availability of any data on production levels of these plants, FSIS assumes that the very small plants with less than ten employees are likely to produce less than 100,000 pounds per ground poultry product. This assumption is not unrealistic because poultry grinding is a labor-intensive process and less than ten employees are not likely to produce more than 100,000 pounds per ground product because these employees also process other products in these plants. Based on this assumption, 10 very small poultry establishments (or only 15% of all poultry establishments) are likely to be exempt from nutrition labeling requirements for ground or chopped products. However, these establishments would not be exempt if they are owned by a large corporation that owns several plants and employs 500 or more workers among all of its plants or produces more than 100,000 pounds of a particular ground product in total among all of its plants. FSIS did not have data linking these establishments to their corporate ownership.

The EFD indicates that most of the ground meat producing plants are very small. For example, of the 2,426 ground meat establishments, 1470 or 60% are very small. The number of small and large ground meat establishments are 843 and 68, respectively. Therefore, assuming that the very small establishments produce less than 100,000 pounds of a particular ground

meat product, 60% of all these plants would be exempt from nutrition labeling requirements for ground or chopped products. In practice, the number of plants that would be exempt may be smaller than 60 percent because many of these plants may be owned by large, multi-plant corporations. However, FSIS does not have data on corporations that own these individual establishments.

As discussed above, FSIS believes that a significant amount of ground beef is processed at retail. Table 2 in the "Baseline" section above shows the number of retail stores in 1999. Most of these stores grind beef. However, FSIS does not have specific data concerning the levels of ground beef ground at retail or on the size of retail stores that process ground beef. FSIS researched Census data for this information, but specific information related to retail establishments processing ground or chopped product was unavailable. Therefore, FSIS does not currently have all the data necessary for a comprehensive analysis on the effects of this rule on small entities. In addition to the lack of data on retail stores producing ground or chopped product, FSIS does not have data on the specific types and quantities of ground products produced in individual plants to determine the number of single-plant facilities or multi-plant companies or firms that would be exempt from this regulation. Therefore, FSIS is requesting this information and inviting comments concerning potential effects. In particular, FSIS is interested in determining the number and kind of small entities that may incur benefits or costs from implementation of this proposed rule.

FSIS will make available a list of published sources of information so that industry can obtain literature from local libraries. This information will assist in the development of nutrition labels for ground or chopped products. This list of published sources of information should also help minimize the economic effect of this rule on small entities.

FSIS is cognizant of the possibility that while the exempted establishments would not have to incur labeling costs, they might not realize benefits of greater sales of the labeled products, in case they choose not to nutritionally label their products. This is because if demand for the labeled product increases relative to demand for non-labeled products, the exempt establishments would lose their market shares to the nonexempt establishments producing nutritionally labeled products. Therefore, to keep their market shares, these exempt

establishments are likely to voluntarily include nutrition information on the product label. Such a strategy would minimize the adverse impact on these smaller establishments. It would, however, also increase their costs associated with labeling. Economic theory dictates that these establishments would compare the costs of nutrition labels with the benefits of retaining their market shares and would decide to label their products if the benefits of increasing the market shares exceed the label costs.

Nutrition labeling would be required, either on the product label or on point-of-purchase materials, for the major cuts of single-ingredient, raw product. Therefore, if manufacturers do not provide nutrition information on the label, retailers would be required to provide this information at the point-of-purchase or on product labels. However, as noted above, this requirement should not impose major costs or other burdens because many stores are currently providing nutrition information for these products, point-of-purchase materials are available for a nominal fee through FMI's web site (\$12.00 for members, \$24.00 for nonmembers), and FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site.

The economic impact on retail stores is likely to be minimal because recently there has been considerable consolidation of these stores due to mergers and acquisitions resulting in an increased market share of large retailers relative to small ones. For example, recently Royal Ahold, the Dutch Conglomerate, bought out Giant Food. Earlier last year, Ahold also announced the pending purchase of Supermarket General-II Holdings Corporation, parent of the Pathmark chain. Similarly, SUPERVALUE acquired Richfood, Food Lion bought out Hannaford Brothers, and Scarborough, and Albertson's purchased American Stores. (Sean Mehegan, "Consolidation Changes the Face of the North American Supermarket Sector," *Meat & Poultry* (September 1999): 22-25). These mergers and acquisitions are likely to increase market shares of the large retailers at the cost of smaller ones.

Table 2 in the "Baseline" section above shows the number of retail grocery stores in 1999. The economic impact of the first-year costs of compliance on the processors and the retailers is determined by dividing the total first-year costs by the number of processors or retailers. Table 8 revealed the range of first-year costs to processors for labeling ground or chopped products at \$10.3 million to 20.3 million. These

costs include the fixed costs, operating costs, and the paperwork burden costs. Since the number of processors is 2,489 (see Table 1), the impact per processor would range from \$4,138.21 (\$10.3 million/2,489) to \$8,155.89 (\$20.3 million/2,489). Similarly, Table 8 also shows that the first-year costs to retailers for labeling ground or chopped products range from \$ 49.90 million (\$28.8 + \$12.6 million + \$8.5 million) to \$ 64.3 million (\$43.2 million + \$12.6 million + \$8.5 million). In addition, as explained above, the total paperwork burden costs to retailers for providing point-of-purchase materials for the major cuts of single-ingredient, raw products is approximately \$0.7 million. Thus, the total costs to retailers would range from \$50.6 million to \$65 million. Since the number of retail stores (see Table 2) in 1999 was 69,500 (excluding convenience stores that do not normally sell meat products), the impact per retail store would range from \$728.06 (\$50.6 million/69,500) to \$935.25 (\$65 million/69,500). Therefore, the impact of the first-year cost would be greater on the processors relative to retailers.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. However, States and local jurisdictions may 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.

The proposed rule is not intended to have retroactive effect.

If this proposed rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in §§ 306.5 and 381.35 must be exhausted before there is any judicial challenge of the application of the proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under FMIA and PPIA.

Public Notification and Request for Data

FSIS requests information regarding the impact of this proposed rule on minorities, women, and persons with disabilities, including information on the number of minority-owned meat and poultry establishments, the makeup of establishment workforces, and the communities served by official establishments.

Public involvement in all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this proposed rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Paperwork Requirements

Title: Nutrition labeling of ground or chopped meat and poultry products and single-ingredient products.

Type of Collection: New.

Abstract: FSIS has reviewed the paperwork and record keeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, FSIS is requiring several information collection and recordkeeping activities. FSIS is proposing to require nutrition labeling on the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, unless an exemption applies. If the manufacturer provides nutrition information on the label of individual

packages of the major cuts of single-ingredient, raw meat or poultry products, the retailer would not be required to provide the information at the point-of-purchase. However, if the manufacturer does not provide the nutrition information on the label of these products, the retailer would be required to provide the information at their point-of-purchase. In the estimate of burden below, FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw meat and poultry products, because this is an inexpensive means of providing nutrition information for multiple products and because this rule will not require that manufacturers include nutrition labels on the major cuts of single-ingredient, raw meat and poultry products. FSIS is also proposing to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies.

Estimate of burden: FSIS estimates that obtaining point-of-purchase materials and making them available for consumers would take an average of 30 minutes. FSIS believes that the nutrition information on most point-of-purchase materials will be based on the most current representative database values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference. FSIS also believes it is unlikely that there will be any nutrition claims made on the point-of-purchase materials on the basis of the representative data base values. Therefore, these products will not be subject to FSIS compliance review, and there will be no recordkeeping requirements based on this information.

FSIS estimates that developing nutrition labels for ground or chopped products would take an average of 120 minutes. Labels developed at official establishments would be submitted to FSIS. FSIS estimates that each official establishment that produces ground or chopped product would submit three labels to FSIS for approval. FSIS estimates that it would take an average of 15 minutes to prepare and submit the form for prior approval. All ground or chopped product would be subject to FSIS compliance review; therefore, producers of ground or chopped product would be required to maintain records to support the validity of nutrient declarations contained on product labels. FSIS estimates the average time for recordkeeping would be 5 minutes.

Respondents: Meat and poultry establishments and retail stores.

Estimated number of respondents: 71,989.

Estimated number of responses per respondent: 3.

Estimated total annual burden on respondents: 474,549.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th St., Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Lee Puricelli, see address above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. Comments are requested by February 20, 2001. To be most effective, comments should be sent to OMB within 30 days of the publication date.

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List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat Inspection, Nutrition, Reporting and recordkeeping requirements.

9 CFR Part 381

Food labeling, Food packaging, Nutrition, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III, as follows:

PART 317—LABELING, MARKING DEVICES AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C 601-695; 7 CFR 2.18, 2.53.

2. Section 317.300 would be revised to read as follows:

§ 317.300 Nutrition labeling of meat and meat food products.

(a) Unless the product is exempted under § 317.400, nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw products that are not ground or chopped products described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials, except as exempted under § 317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in § 317.301, nutrition labeling must be provided in accordance with the provisions of § 317.309, except as exempted under § 317.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and that are not major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials.

3. A new § 317.301 would be added to read as follows:

§ 317.301 Required nutrition labeling of ground or chopped meat products.

(a) Nutrition labels must be provided for all ground or chopped products (livestock species) and hamburger with or without added seasonings (including, but not limited to, ground beef, ground beef patties, ground sirloin, ground pork, and ground lamb) that are intended for human consumption and offered for sale, in accordance with the provisions of § 317.309, except as exempted under § 317.400.

4. Section 317.309 would be amended as follows:

a. In paragraph (b)(3), the first sentence would be amended by adding “that are not ground or chopped meat products described in § 317.301” after the phrase “single-ingredient, raw products”, and by removing “as set forth in § 317.345(a)(1)”; the second sentence would be revised by adding, “that are not ground or chopped meat products described in § 317.301” after the phrase “single-ingredient, raw products”, and the following new sentence would be added after the first sentence:

* * * * *

(b) * * *

(3) * * * “For single-ingredient, raw products that are not ground or chopped meat products described in § 317.301, if data are based on the product “as consumed,” the data must be presented in accordance with § 317.345(d). * * *

b. Paragraph (b)(10) would be amended by adding the following new sentence at the end of the paragraph:

* * * * *

(b) * * *

(10) * * * The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301, including those that have been previously frozen.

* * * * *

c. Paragraph (b)(11) would be amended by adding the phrase “single-ingredient, raw products that are not ground or chopped meat products described in § 317.301 and” after “exception of”.

d. Paragraph (d)(3)(ii) would be amended by removing the period and adding “or on single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301.” at the end of the paragraph.

e. Paragraph (e)(3) would be amended by adding “, but may be on the basis of

“as consumed” for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301,” after “as packaged”.

f. Paragraph (h)(9) would be amended by removing the phrase “(including ground beef)” products”, by adding, “that are not ground or chopped meat products described in § 317.301” after “products”, by removing the phrase, “its published form, the Agriculture Handbook No. 8 series available from the Government Printing Office”, and by adding, in its place, “its released form, the USDA Nutrient Database for Standard Reference”, and by removing the period and adding the following at the end of the paragraph: “ as provided in § 317.345(e) and (f).”

5. Section 317.343 would be removed.

6. Section 317.344 would be amended by removing the phrases “ground beef regular without added seasonings, ground beef about 17% fat,” and “ground pork.”

7. Section 317.345 would be amended as follows:

a. Paragraph (d) would be amended by removing “should” and adding, in its place, “for products covered in paragraphs (a)(1) and (a)(2) must”.

b. Paragraph (e) would be amended by removing “its published form, the Agriculture Handbook No. 8 series” and by adding, in its place, “its released form, the USDA Nutrient Database for Standard Reference”, and by removing “(including ground beef)”.

c. Paragraph (f) would be amended by adding “provided” after “nutrition information is”.

d. Paragraph (g) would be amended by removing the phrase “(including ground beef)”.

e. The section heading and paragraphs (a) and (c) would be revised to read as follows:

§ 317.345 Nutrition labeling of single-ingredient, raw meat products that are not ground or chopped products described in § 317.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 317.400. If nutrition information is presented on the label, it must be provided in accordance with § 317.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw meat products that are not ground or chopped meat products

described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 317.309.

(3) A retailer may provide nutrition information at the point-of-purchase, by various methods, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 317.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 317.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 317.309(c)(8)) and footnote required by § 317.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 317.309(f).

* * * * *

8. Section 317.362 would be amended by adding a new paragraph (f) to read as follows:

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

* * * * *

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped meat products described in § 317.301 when the product does not meet the criteria for “low fat,” defined in § 317.362(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background as the statement of the lean percentage.

* * * * *

9. Section 317.400 would be amended as follows:

a. Paragraph (a)(1), introductory text, would be amended by removing the comma and adding, at the end of the paragraph, “, except that this exemption does not apply to the major cuts of

single-ingredient, raw products identified in § 317.344.”.

b. Paragraph (a)(1)(ii) would be amended by adding “, including a single retail store,” after the phrase “single-plant facility,” and by adding, “, including a multi-retail store operation,” after “company/firm”.

c. Paragraph (a)(7)(i) would be amended by removing the semi-colon and by adding the following at the end of the paragraph: “, provided, however, that this exemption does not apply to ready-to-eat ground or chopped meat products described in § 317.301 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section;”.

d. Paragraph (a)(7)(ii) would be amended by removing the period and by adding the following at the end of the paragraph: “, provided, however, that this exemption does not apply to multi-ingredient ground or chopped meat products described in § 317.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section.”

e. Paragraph (d)(1) would be amended by removing the period at the end of the first sentence, and by adding the following to the end of the first sentence: “, except that this exemption does not apply to the major cuts of single-ingredient, raw meat products identified in § 317.344.”

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

10. The authority citation for part 381 continues to read as follows:

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

11. Section 381.400 would be revised to read as follows:

§ 381.400 Nutrition labeling of poultry products.

(a) Unless the product is exempted under § 381.500, nutrition labeling must be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw products that are not ground or chopped products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444. Nutrition labeling must be provided for the major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials, except as exempted under

§ 381.500. For all other products that require nutrition labeling, including ground or chopped poultry products described in § 381.401, nutrition labeling must be provided in accordance with the provisions of § 381.409, except as exempted under § 381.500.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and that are not major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials.

* * * * *

12. A new § 381.401 would be added to read as follows:

§ 381.401 Required nutrition labeling of ground or chopped poultry products.

Nutrition labels must be provided for all ground or chopped poultry (kind) with or without added seasonings (including, but not limited to, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of § 381.409, except as exempted under § 381.500.

* * * * *

13. Section 381.409 would be amended as follows:

a. In paragraph (b)(3), the first sentence would be amended by adding “that are not ground or chopped poultry products described in § 381.401” after the phrase “single-ingredient, raw products” and by removing “as set forth in § 381.445(a)(1)”; the second sentence would be amended by adding, “that are not ground or chopped poultry products described in § 381.401,” after the phrase “single-ingredient, raw products”; and the following new sentence would be added after the first sentence:

* * * * *

(b) * * *

(3) * * * For single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401, if data are based on the product “as consumed,” the data must be presented in accordance with § 381.445(d). * * *

b. Paragraph (b)(10) would be amended by adding the following new sentence at the end of the paragraph:

* * * * *

(b) * * *

(10) * * * The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products

that are not ground or chopped poultry products described in § 381.401, including those that have been previously frozen.

* * * * *

c. Paragraph (b)(11) would be amended by adding the phrase “single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401 and” after “exception of”.

d. Paragraph (d)(3)(ii) would be amended by removing the period and adding “or on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401.” at the end of the paragraph.

e. Paragraph (e)(3) would be amended by adding “, but may be on the basis of “as consumed” for single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401,” after “as packaged”.

f. Paragraph (h)(9) would be amended by adding, “that are not ground or chopped poultry products described in § 381.401” after “products”, by removing the phrase, “its published form, the Agriculture Handbook No. 8 series”, and by adding, in its place, “its released form, the USDA Nutrient Database for Standard Reference”, and by removing the period and adding the following at the end of the paragraph: “, as provided in § 381.445(e) and (f).”

14. Section 381.443 would be removed.

15. Section 381.445 would be amended as follows:

a. Paragraph (d) would be amended by removing “should” and adding, in its place, “for products covered in paragraphs (a)(1) and (a)(2) of this section must”.

b. Paragraph (e) would be amended by removing “its published form, the Agriculture Handbook No. 8 series” and by adding, in its place, “its released form, the USDA Nutrient Database for Standard Reference.”

c. Paragraph (f) would be amended by adding “provided” after “nutrition information is”.

d. The section heading and paragraph, (a) and (c) would be revised to read as follows:

§ 381.445 Nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped products described in § 381.401.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 381.500. If

nutrition information is presented on the label, it must be provided in accordance with the provisions of § 381.409. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 381.409.

(3) A retailer may provide nutrition information at the point-of-purchase, by various methods, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 381.409 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 381.409 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 381.409(c)(8)) and footnote required by § 381.409(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 381.409(f).

* * * * *

16. Section 381.462 would be amended by adding a new paragraph (f) to read as follows:

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

* * * * *

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped poultry products described in § 381.401 when the product does not meet the criteria for “low fat,” defined in § 381.462(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background as the statement of the lean percentage.

* * * * *

17. Section 381.500 would be amended as follows:

a. Paragraph (a)(1) would be amended by removing the comma and adding, at the end of the paragraph, “, except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444.

b. Paragraph (a)(1)(ii) would be amended by adding, “, including a single retail store,” after the phrase “single-plant facility,” and by adding “,

including a multi-retail store operation” after “company/firm”.

c. Paragraph (a)(7)(i) would be amended by removing the semi-colon and adding the following at the end of the paragraph: “provided, however, that this exemption does not apply to ready-to-eat ground or chopped poultry products described in § 381.401 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section,” after “establishment”.

d. Paragraph (a)(7)(ii) would be amended by removing the period and adding the following at the end of the paragraph: “provided, however, that this exemption does not apply to multi-ingredient ground or chopped poultry products described in § 381.401 that are processed at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section.” after “establishment”.

e. Paragraph (d)(1) would be amended by removing the period at the end of the sentence, and by adding the following to the end of the sentence: “except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444.”

Done in Washington, DC, on January 8, 2001.

Thomas J. Billy,
Administrator.

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