DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[FDMS Docket No. FSIS–2005–0018]

RIN: 0583–AC60

Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Supplemental Proposed Rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing this supplemental proposed rule that, if finalized, will 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.

DATES: Submit comments on or before February 16, 2010.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the online instructions at that site for submitting comments.
- *Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2–2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5474, Beltsville, MD 20705–5474.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2005–0018. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. All comments submitted in response to this proposal, as well as background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sally Jones, Senior Technical Advisor, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Beltsville, MD 20705; (301) 504–0878.

Section I

SUPPLEMENTARY INFORMATION:

Background

Supplemental Proposed Rule: On January 18, 2001, FSIS published a proposed rule in the **Federal Register** entitled, ''Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products'' (66 FR 4969). Because of the length of time since the publication of the proposed rule, FSIS is providing the public an opportunity to comment on this supplemental proposed rule. FSIS also welcomes comments on relevant issues for which there is new evidence since the proposed rule was issued.

This supplemental proposed rule responds to all comments received on the January 18, 2001 proposed rule and explains how the Agency intends to proceed with a final rule. Although FSIS has come to tentative conclusions regarding the issues raised by the commenters, in this supplemental proposed rule, FSIS is requesting additional comments on policies for which there were significant differences of opinion among commenters.

Specifically, under the ''Provisions of the Supplemental Proposed Rule'' heading below, FSIS is requesting comments on whether nutrition information should be allowed on point-of-purchase materials for ground or chopped products, as an alternative to requiring nutrition information on the product labels. FSIS is also requesting comments on the use of statements of lean percentages on the label or in labeling of ground or chopped products that do not meet the regulatory criteria for ''low fat.'' In addition, under the ''Provisions of the Supplemental Proposed Rule'' heading below, FSIS is requesting comments on whether it should provide an exemption from nutrition labeling requirements for small businesses that include a fat percentage statement and lean percentage statement on the labeling or in labeling of ground or chopped product. FSIS is requesting copies of any studies, surveys, or other data on consumers' perception of and use of point-of-purchase materials versus nutrition labels for ground or chopped product and on consumers' understanding of the nutrient content of ground or chopped products. FSIS is also requesting copies of any studies, surveys, or data on consumers' use and understanding of fat percentage and lean percentage statements on ground or chopped products. FSIS will post on its Web site, with this supplemental proposed rule, all studies and data submitted to the Agency in response to this request. FSIS requests comment on the potential effects of disallowing a statement of lean percentage on ground or chopped products.

FSIS will consider all comments received in response to this supplemental proposed rule. After evaluating the comments, FSIS intends to respond to them, make any appropriate and necessary changes to this rule, and issue the final rule in the **Federal Register**.

The Proposed Rule

Major cuts: FSIS proposed to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 that are not ground or chopped, except for certain exemptions. FSIS proposed that ''ground beef regular without added seasonings,'' ''ground beef about 17% fat,'' and ''ground pork'' would no longer be included in the list of major cuts in § 317.344.

FSIS proposed to make the guidelines in place for the voluntary nutrition labeling program mandatory for the major cuts of single-ingredient, raw products that are not ground or chopped. Thus, for these products, FSIS proposed that nutrition information be provided on the label or at point-of-purchase, unless an exemption would apply. For further explanation of the guidelines for voluntary nutrition labeling, *see* 66 FR 4971, January 18, 2001. For further explanation of the proposal to make these guidelines mandatory for the major cuts of single-ingredient, raw products that are not ground or chopped, *see* 66 FR 4973–4975, January 18, 2001.

In the preamble to the proposed rule, FSIS explained that, in its two most recent surveys of the voluntary nutrition labeling of single-ingredient, raw products, FSIS found that significant participation in the voluntary nutrition labeling program did not exist (66 FR 4972, January 18, 2001). 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 required nutrition labeling provisions for multi-ingredient and heat processed products are referred to as ''the mandatory program.'' The regulations also 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 (§ 317.343 and § 381.443). The term ''companies,'' as used in these regulations, refers to individual stores. FSIS used a representative sample of stores to assess participation (*see* 58 FR 640, January 6, 1993). Based on the survey data from the two most recent surveys, less than 60 percent of stores evaluated were participating in accordance with the guidelines.

In the preamble to the proposed rule, FSIS explained that, because the most recent surveys showed that significant participation in the voluntary nutrition labeling program did not exist, FSIS believed that the proposed rule was necessary. FSIS stated 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 believed that the lack of nutrition information on the labeling of the major cuts was misleading (66 FR 4973–4974, January 18, 2001) because it fails to disclose material facts about the consequences of consumption of these products. Consumers can compare the fat content in major cuts of poultry based on whether the product has skin and based on the levels of attached fat in the product. Similarly, consumers can compare the fat content among major cuts of meat products based on internal marbling and attached fat. However, without nutrition labeling for the major cuts, consumers cannot assess precise levels of fat (*e.g.,* 10 grams vs. 20 grams of fat per serving) and cannot know the levels of specific nutrients, such as saturated fat, in these products. Therefore, without nutrition labeling of these products, consumers cannot make educated choices about consuming the major cuts.

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)). Without nutrition information for the major cuts of single-ingredient, raw products, FSIS tentatively concluded that these products would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA because the label would fail to reveal significant material facts about the consequences of consuming these products(66 FR 4974, January 18, 2001).

As explained in the preamble to the proposed rule, although FSIS believed that nutrition information on the labels of individual packages of single-ingredient, raw products is useful, the Agency proposed that nutrition information for the major cuts could also be provided on point-of-purchase materials, because consumers have reasonable expectations as to the nutrient content of these products. Also, FSIS stated that 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 (66 FR 4974, January 18, 2001).

Ground or Chopped Products: Ground or chopped products that are multi-ingredient or heat processed products are subject to the requirements of the mandatory nutrition labeling program; therefore, these products are already required to bear nutrition labels, unless they qualify for an exemption. FSIS proposed to extend mandatory nutrition labeling requirements to all ground or chopped products, including single-ingredient, raw ground or chopped products, unless an exemption applies. Thus, FSIS proposed to require that nutrition labels be provided for all ground or chopped products (livestock species) and hamburger, with or without added seasonings, unless an exemption applies. Similarly, FSIS proposed to require that nutrition labels be provided for all ground or chopped poultry (kind), with or without added seasonings, unless an exemption applies. Under the proposed rule, products that would be required to bear nutrition labels include single-ingredient, raw hamburger, ground beef, ground beef patties, ground chicken, ground turkey, ground chicken patties, ground pork, and ground lamb.

In the proposed rule, FSIS explained that, 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 that are required to bear nutrition labels (66 FR 4975, January 18, 2001). FSIS noted that other single-ingredient, raw products cannot be formulated in the same manner or to the same degree as ground beef products (66 FR 4976, January 18, 2001).

FSIS noted that it believed that consumers could not 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 (66 FR 4975, January 18, 2001). FSIS also explained that the Agency believed that consumers cannot estimate the level of fat in ground or chopped beef and cannot compare the levels of fat in these products to those in other products (66 FR 4975, January 18, 2001). Similarly, FSIS explained that ground lamb and ground pork may contain varying amounts of fat and varying nutrient content, which consumers cannot visually detect (66 FR 4976, January 18, 2001). Additionally, FSIS noted that producers sometimes use meat from advanced meat recovery (AMR) systems and low temperature rendering in ground or chopped beef or pork products, which can affect their nutrient content (66 FR 4975 and 4976, January 18, 2001). Finally, FSIS noted that, as with the fat on ground meat products, consumers cannot readily detect the fat content of ground poultry products (66 FR 4976, January 18, 2001). For these reasons, FSIS tentatively concluded that ground or chopped meat and poultry products that did not bear nutrition information would be misbranded under section 1(n)(1) of the FMIA and section 4(h)(1) of the PPIA (66 FR 4977, January 18, 2001).

FSIS proposed to require that nutrition information for ground or chopped products appear on the label of these products (unless an exemption applies), as is required for multi-ingredient and heat processed products, rather than on point-of-purchase materials because ground or chopped products are similar to multi-ingredient and heat processed 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 (66 FR 4977, January 18, 2001).

Exemptions: FSIS proposed that certain exemptions from nutrition labeling requirements would apply to the major cuts of single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products. FSIS proposed the following

exemptions from nutrition labeling requirements for ground or chopped products: ground or chopped products that qualify for the small business exemption in §§ 317.400(a)(1) and 381.500(a)(1); ground or chopped products in packages that have a total surface area available to bear labeling of less than 12 square inches, provided that 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; ground or chopped products that are intended for further processing; ground or chopped products that are not for sale to consumers; ground or chopped products that are in small packages that are individually wrapped packages of less than ½ ounce net weight; ground or chopped products that are custom slaughtered or prepared; and ground or chopped products that are intended for export.

FSIS proposed the following exemptions for major cuts of single-ingredient, raw products that are not ground or chopped: major cuts intended for further processing; major cuts not for sale to consumers; major cuts in small packages that are individually wrapped packages of less than ½ ounce net weight; major cuts that are custom slaughtered or prepared; and major cuts that are intended for export.

FSIS proposed to exempt ground or chopped products that qualified for the small business exemption from nutrition labeling requirements for the main reason stated in the January 6, 1993, final rule: because these requirements would create undue economic hardship for small businesses (58 FR 638). FSIS stated in the proposed rule that it did 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 proposed that nutrition information may be provided on labels or, alternatively, at their point-of-purchase. In addition, FSIS explained that it intended to make point-of-purchase materials available over the Internet free of charge. Therefore, the 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 (66 FR 4978, January 18, 2001).

In the preamble to the January 6, 1993, final rule, FSIS explained that it was proposing an exemption from nutrition labeling requirements 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, January 6, 1993). In the January 18, 2001, proposed rule, the Agency proposed these exemptions because the Agency had 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, FSIS proposed that 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 (66 FR 4979, January 18, 2001).

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, January 6, 1993). As explained in the proposed rule, 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 proposed 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 (66 FR 4979, January 18, 2001).

In the preamble to the proposed rule, FSIS explained that restaurant menus that include ground or chopped products generally do not constitute nutrition labeling or fall within the scope of the proposed 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 the proposed regulations. Finally, the preamble explained that, under the proposed rule, 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 not be allowed to 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 (66 FR 4979, January 18, 2001).

In the 1993 final rule on nutrition labeling, FSIS exempted from mandatory nutrition labeling requirements multi-ingredient products processed at retail, and ready-to-eat products packaged or portioned at retail. The reasons that FSIS provided these exemptions in the 1993 final rule were that FSIS believed 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, January 6, 1993).

The proposed rule did not provide an exemption for ready-to-eat ground or chopped products packaged or portioned at retail, or multi-ingredient ground or chopped products that are processed at retail because, as FSIS explained in the 2001 nutrition labeling proposed rule, there may be a significant amount of multi-ingredient ground beef retail processed products or ready-to-eat retail packaged products. Also, FSIS explained that 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*

(*E. coli*) O157:H7 at retail (66 FR 4979, January 18, 2001).

For further explanation of the reasons for the proposed exemptions, *see* 66 FR 4978–4980, January 18, 2001.

Nonmajor Cuts of Single-Ingredient, Raw Meat and Poultry Products That Are Not Ground or Chopped: FSIS did not propose to require nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped. However, FSIS proposed that if nutrition information is provided for these products, it must be provided according to the existing guidelines for the current voluntary nutrition labeling program. Therefore, under the proposed rule, if nutrition information were provided for these products, it would be consistent with the nutrition information required for the major cuts of single-ingredient, raw products. In the preamble to the proposed rule, FSIS explained that the Agency could not determine whether it would be beneficial to require nutrition labeling for nonmajor cuts that are not ground or chopped until it assessed whether adequate nutrition information is being provided for these products (66 FR 4974, January 18, 2001).

Enforcement and Compliance: FSIS conducts sampling and nutrient analysis of products that fall under the mandatory nutrition labeling program. FSIS proposed that the procedures set forth for FSIS product sampling and nutrient analysis in §§ 317.309(h)(1) through (h)(8) and 381.409(h)(1) through (h)(8) would be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. FSIS explained that under the proposal, FSIS would 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 National Nutrient Database for Standard Reference and there are no claims on the labeling. Therefore, FSIS would treat these products as it treats other products required to bear nutrition labels (66 FR 4980, January 18, 2001).

FSIS explained that it would treat ground or chopped products in this way because the fat content of these products can vary significantly. In addition, the preamble to the proposed rule stated that FSIS 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 or chopped product (66 FR 4980, January 18, 2001).

FSIS also proposed that 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's National Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, FSIS would not sample and conduct a nutrient analysis of the products. The preamble explained that, for the major cuts, FSIS personnel can visually identify the particular cut. FSIS further explained that, if the nutrition information for these products is based on USDA's National Nutrient Data Bank or the USDA National 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 the data because they are USDA data. USDA has already evaluated these USDA data and determined that they are valid (66 FR 4980, January 18, 2001).

Permitting Percent Lean Statements on labels or in labeling of ground or chopped products: FSIS also proposed 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,'' provided that a statement of the fat percentage is also displayed on the label or in labeling. FSIS proposed that the required 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. FSIS stated that many consumers have become accustomed to this labeling on ground beef products, and that FSIS believed this labeling provided a quick, simple, and accurate means of comparing all ground or chopped meat and poultry products (66 FR 4981, January 18, 2001).

Provisions of the Supplemental Proposed Rule

Major cuts and nonmajor cuts that are not ground or chopped: Consistent with the proposal, should this rule become final, FSIS will require nutrition information for the major cuts, either on their label or at their point-of-purchase. The provisions of the voluntary nutrition labeling program will be mandatory for the major cuts. As FSIS proposed, ''ground beef regular without added seasonings,'' ''ground beef about 17% fat,'' and ''ground pork'' will no longer be included in the list of major cuts in § 317.344 because FSIS has decided to treat ground meat and poultry products differently than single cuts of meat for the purposes of this regulation. Should this rule become final, ground meat and poultry products will be required to bear nutrition labeling on their packages, unless an exemption applies. Nutrition information at the point-of-purchase for ground or chopped products will not meet the requirements of these regulations.

FSIS believes that without nutrition information, consumers are not able to assess the nutrient content of the major cuts and, thus, cannot make educated decisions about these products based on nutrition information. FSIS has concluded that the lack of nutrition information for the major cuts of single-ingredient, raw products, either on their label or at their point-of-purchase, makes these products misbranded under 21 U.S.C. 601(n)(1) and 453(h)(1). Although FSIS believes that nutrition information on the labels of individual packages of the major cuts of single-ingredient, raw products is useful, this final rule provides that nutrition information for these products may be provided at their point-of-purchase.

In the 1991 proposed rule and the 1993 final rule on nutrition labeling, 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, November 27, 1991; 58 FR 640, January 5, 1993). Therefore, FSIS initiated rulemaking to propose requiring nutrition labeling for the major cuts of single-ingredient, raw products. Through this rulemaking, FSIS has determined that because nutrition information has not been universally available for the major cuts of single-ingredient products, consumers have not been able to assess the nutrient content of these products and, thus, cannot make educated choices about them, and about the significant portion of their diet that these products represent, based on nutrition information. Without nutrition information, the labeling of major cuts of single-ingredient, raw meat and poultry products fails to include material facts about the consequences of consuming these products. FSIS has concluded that the lack of nutrition information for the major cuts of single-ingredient, raw products, either on their label or at their point-of-purchase, makes these products misbranded under 21 U.S.C. 601(n)(1) and 453(h)(1). FSIS has determined that this rule is necessary to ensure that consumers obtain nutrition information concerning

these products. Through the supplemental proposed regulatory impact analysis (PRIA), FSIS has determined that this rule would result in benefits to consumers and net benefits to society.

Consistent with the proposed rule, this supplemental proposed rule will not require nutrition information for nonmajor cuts of single-ingredient, raw meat and poultry products that are not ground or chopped.

FSIS has determined that it is not appropriate or necessary to require nutrition information for nonmajor cuts that are not ground or chopped at this time. They do not contribute in a major way to the diet. Thus, at this time, the consequences of consuming these products cannot be considered to be a material fact. In the future, FSIS will reassess the production and consumption volume of nonmajor cuts that are not ground or chopped and will determine the levels of consumption of these products and whether sufficient nutrition information is being made available about them. After FSIS assesses the volume of these products and assesses the adequacy of nutrition information provided for them, FSIS will determine whether it is necessary to propose nutrition labeling requirements for these products, and whether nutrition labeling requirements for these products would be beneficial.

Should this rule become effective, if establishments or retail facilities voluntarily provide nutrition information for nonmajor cuts of meat and poultry products that are not ground or chopped, they will have to provide it according to the nutrition labeling requirements for the major cuts. Should establishments or retail facilities choose to provide nutrition information for these products, they will have to either provide it at the point-of-purchase, in accordance with § 317.345 or § 381.445, or on their label, in accordance with § 317.309 or § 381.409. Thus, the nutrition labeling provisions for these products will be consistent with those for the voluntary nutrition labeling program.

As proposed, the supplemental proposed rule would allow nutrition information for the major cuts and nonmajor cuts of single-ingredient, raw products that are not ground or chopped to be declared on either an ''as packaged'' basis or an ''as consumed'' basis because most of these products will not need FSIS compliance scrutiny. If FSIS conducts nutrient analysis of products under 317.309(h) or 381.409(h), it does so on the packaged product. If nutrition information for these products is based on USDA's National Nutrient Database for Standard Reference, and there are no claims on the labeling, FSIS will not conduct a nutrient analysis of these raw products and, therefore, will not evaluate ''as packaged'' nutrition labeling information for these products.

Also consistent with the proposed rule, under this supplemental proposed rule, the declaration of the number of servings per container would not need to be included on the nutrition label for the major or nonmajor cuts of single-ingredient, raw products that are not ground or chopped, because these products are typically random weight products. Existing regulations do not require the number of servings on the nutrition label of random weight products (*see* §§ 317.309(b)(10)(iii) and 381.409(b)(10)(iii)).

Ground or Chopped Products: Consistent with the proposed rule, this supplemental proposed rule would extend the mandatory nutrition labeling requirements to all ground or chopped products, including single-ingredient, raw ground or chopped products, unless an exemption applies. Should this rule become effective, FSIS will require that nutrition labels be provided for all ground or chopped products (livestock species) and hamburger, with or without added seasonings, unless an exemption applies. This rule would also require that nutrition labels be provided for all ground or chopped poultry products, with or without added seasonings, unless an exemption applies. After analyzing the comments and for the reasons discussed in the proposed rule and discussed below in the response to comments section, FSIS has concluded that ground or chopped meat and poultry products that do not bear nutrition information on their label are misbranded under 21 U.S.C. 601(n)(1) and 453(h)(1).

FSIS recognizes that single-ingredient, raw ground or chopped products have not been required to bear nutrition labels. In the proposed rule, FSIS explained that, on June 3, 1997, the Center for Science in the Public Interest (CSPI) submitted a petition to the Agency stating that FSIS should require complete ''Nutrition Facts'' on ground beef labels that make nutrient content claims. This petition brought many of the issues concerning the need for nutrition labeling of ground or chopped products to FSIS's attention. Consistent with CSPI's petition, FSIS has determined that nutrition information should be required on packages of all ground or chopped meat and poultry products, unless an exemption applies. (For more information on the petition from CSPI, *see* 66 FR 4975, January 18, 2001).

Most industry commenters did not support requiring on-package nutrition information for ground or chopped products. Some of these commenters supported requiring nutrition labeling for these products at their point-of-purchase. Individuals, consumer organizations, and nutrition organizations supported mandatory nutrition labeling on the packages of ground or chopped products.

FSIS requests comments on how retailers or official establishments would prepare point-of-purchase materials that would address all possible combinations of percent fat and percent lean in ground or chopped products. FSIS also requests comments on how point-of-purchase materials would convey the nutrient values of ground or chopped products that contain AMR product or product from low temperature rendering (*e.g.,* finely textured beef or lean finely textured beef). In addition, FSIS requests comments on how consumers would identify which nutrient values on point-of-purchase materials correspond to specific ground or chopped products available in the store, if a statement of fat percentage or lean percentage is not *required* on the product. Such statements would not be required under this supplemental proposed rule. Finally, FSIS requests surveys, studies, or other data on consumers' perception and use of point-of-purchase materials versus nutrition labels for ground or chopped products and on consumers' understanding of the nutrient content of such products.

Exemptions: This supplemental proposal would provide all the exemptions that it proposed for the major cuts of single-ingredient, raw meat and poultry products and for ground or chopped products for the reasons set forth in the proposal. Consistent with the proposed rule, it does not provide an exemption for ready-to-eat ground or chopped products packaged or portioned at retail or multi-ingredient ground or chopped products that are processed at retail. As FSIS explained in the 2001 nutrition labeling proposed rule, there may be a significant amount of multi-ingredient ground beef retail processed products or ready-to-eat retail packaged products. Also, as was stated in the proposed rule, FSIS no longer believes enforcement of nutrition labeling requirements at retail stores to be impractical because FSIS is already conducting testing for *E. coli* O157:H7 at retail.

In response to comments, the supplemental proposal provides an

exemption from nutrition labeling requirements for products that are ground or chopped at an individual customer's request and that are prepared and served or sold at retail, provided that the labels or labeling of these products bear no nutrition claims or nutrition information.

Enforcement and Compliance: Consistent with the proposed rule and the reasons discussed in it, under this supplemental proposed rule, FSIS would 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 database values contained in USDA's National Nutrient Data Bank or the USDA National Nutrient Database for Standard Reference and there are no claims on the labeling. Also consistent with the proposed rule, for the major cuts that are not ground or chopped, if nutrition labeling of these products is based on USDA's National Nutrient Data Bank or the USDA's National Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, FSIS would not sample and conduct a nutrient analysis of these products.

Permitting Percent Lean Statements on labels or in labeling of ground or chopped products: Consistent with the proposed rule, the supplemental proposed rule would 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,'' as long as a statement of fat percentage is contiguous to, in lettering of the same color, size, and type as, and on the same color background as, the statement of lean percentage. Because the percent fat statement must be contiguous to the percent lean statement and must be in lettering of the same color, size, and type as, and on the same color background as, the lean percentage statement, FSIS believes that the percent lean statements will not mislead consumers.

Under the proposed rule, if small businesses produced ground or chopped product and included a statement of lean percentage and fat percentage on the product's label or in labeling, the business would have been required to include nutrition information on the product label. Based on the National Cattleman's Beef Association (NCBA) National Meat Case Study in 2004, 93 percent of ground beef packages had statements of lean or fat percentages. Sixty-eight percent of packages with such statements had nutrition facts panels and 25 percent did not. Because 25 percent of ground beef packages in the NCBA study had statements of lean or fat percentages but did not have nutrition facts panels, FSIS found it reasonable to conclude that many small businesses may include a statement of the lean percentage on the label of ground products but may not include nutrition facts panels on the product label. On this basis, FSIS concluded that requiring small businesses that use the lean percentage statement on the label of ground products to also include nutrition information on the label of such products may result in significant expenses for small businesses. Therefore, in this supplemental proposed rule, small businesses that use statements of percent fat and percent lean on the label or in labeling of ground products would be exempt from nutrition labeling requirements, provided they include no other nutrition claims or nutrition information on the product labels or labeling.

The majority of industry associations supported the use of a statement of lean percentage on the label or in labeling of ground products that do not meet the regulatory criteria for ''low fat.'' Because of the longstanding use of the statements of percent fat and percent lean on the label or in labeling of ground beef and hamburger products, FSIS has concluded that such statements on the label or in labeling of ground products produced by small businesses will not mislead consumers, even if the small businesses do not include nutrition information on the products' labels.

However, individuals and consumer and nutrition organizations generally did not support the use of statements of lean percentages on the label or in labeling of ground or chopped products that do not meet the regulatory criteria for ''low fat.'' Therefore, FSIS requests comments on whether such statements should be prohibited on the label or in labeling of ground or chopped products that do not meet the regulatory criteria for ''low fat.'' FSIS requests comments on whether lean percentage statements are inherently misleading to consumers on the label or in labeling of ground or chopped product that does not meet the regulatory criteria for ''low fat'' when contiguous to fat percentage statements, as the rule would require. FSIS also requests comments on whether lean percentage statements are redundant on the label or in labeling of such products when contiguous to fat percentage statements. If commenters believe the regulations should prohibit lean percentage statements on the label or in labeling of ground or chopped products that do not meet the ''low fat'' criteria, FSIS requests comments on whether a fat percentage statement on the label or in labeling of such products would be useful. If commenters believe such a statement would be useful, do they believe it should be required on the label or in labeling for these products?

FSIS also requests comments on whether the final rule should allow a lean percentage statement and fat percentage statement on the label or in labeling of ground or chopped products produced by small businesses if such product does not include nutrition information on the product label. If commenters believe that nutrition information should be required on labels of any ground or chopped product for which a lean percentage and fat percentage statement is provided on the label or in labeling, FSIS requests comment on the costs of this requirement for small businesses.

FSIS requests copies of surveys, studies, or other data on consumers' use and understanding of lean percentage and fat percentage statements on ground or chopped products.

Effective Date

Should this rule become final, FSIS intends that the requirements for ground or chopped products would become effective on January 1, 2012. FSIS issued final regulations to establish this date as the uniform compliance date for new food labeling regulations that are issued between January 1, 2009, and December 31, 2010 (73 FR 75564; December 12, 2008). As is discussed in the response to comments below, FSIS issued the uniform compliance regulations to minimize costs associated with on-package labels. Because this supplemental proposed rule would allow for the presentation of nutrition information for the major cuts of single-ingredient, raw meat and poultry products at their point-of-purchase, FSIS intends to make the labeling requirements for the major cuts effective one year from the date of publication of the final rule. FSIS requests comments on these two planned effective dates.

Availability of Nutrition Information

FSIS intends to make available nutrition labeling materials that can be used at the point-of-purchase of the major cuts at the following Internet address: *http://www.fsis.usda.gov.* Also, the Food Marketing Institute (FMI) has made available materials that can be used at the point-of-purchase of the major cuts at the following Internet address: *http://www.fmi.org/consumer/nutrifacts/.*

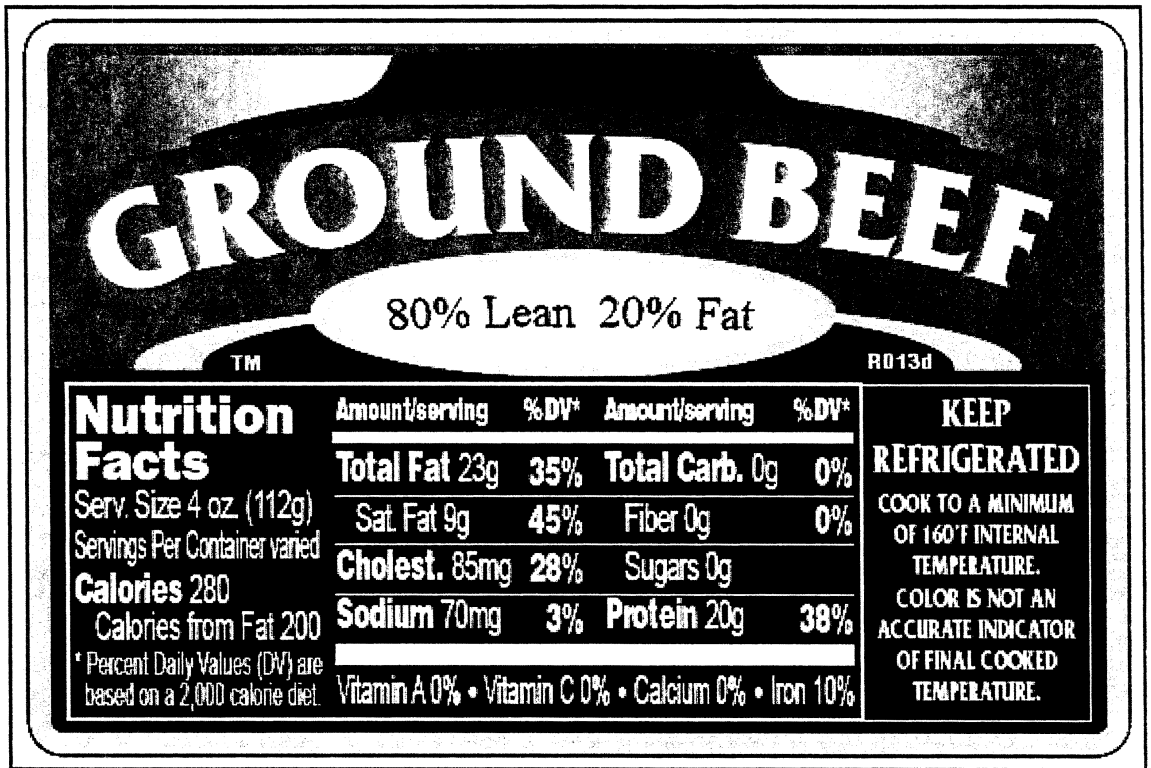
The USDA National Nutrient Database for Standard Reference is developed and maintained by the Agricultural Research Service (ARS) and can be found on the Internet at the following address: *http://www.ars.usda.gov\nutrientdata*. Information is available at this site for ground beef products containing 5%, 10%, 15%, 20%, 25%, and 30% fat. In addition, ARS has included a calculator on the Internet, with the Database. Parties can enter the amount of fat (5% to 30% percent fat) or lean (70% to 95% lean) in a particular raw ground beef product, and the calculator will calculate the nutrient values for the product based on the fat value entered.

The USDA National Nutrient Database for Standard Reference also includes a set of tables with nutrient values for ground pork with fat levels from 4 to 28%, in one percent increments. ARS did not develop a calculator because, at this time, labeling for ground pork at retail does not include statements of percentage fat or percentage lean. The USDA Nutrient Database also includes nutrient values for raw and cooked ground chicken but does not include nutrient values for such product at varying fat levels. Ground chicken is not typically produced over a wide range of fat levels. ARS also has nutrient data for three types of commonly marketed ground turkey products. Nutrient values for these products are not yet in the database. However, ARS expects that the nutrient values for these ground turkey products will be available in the database by August 2010. Most ground poultry products are produced and labeled at Federal establishments rather than at retail.

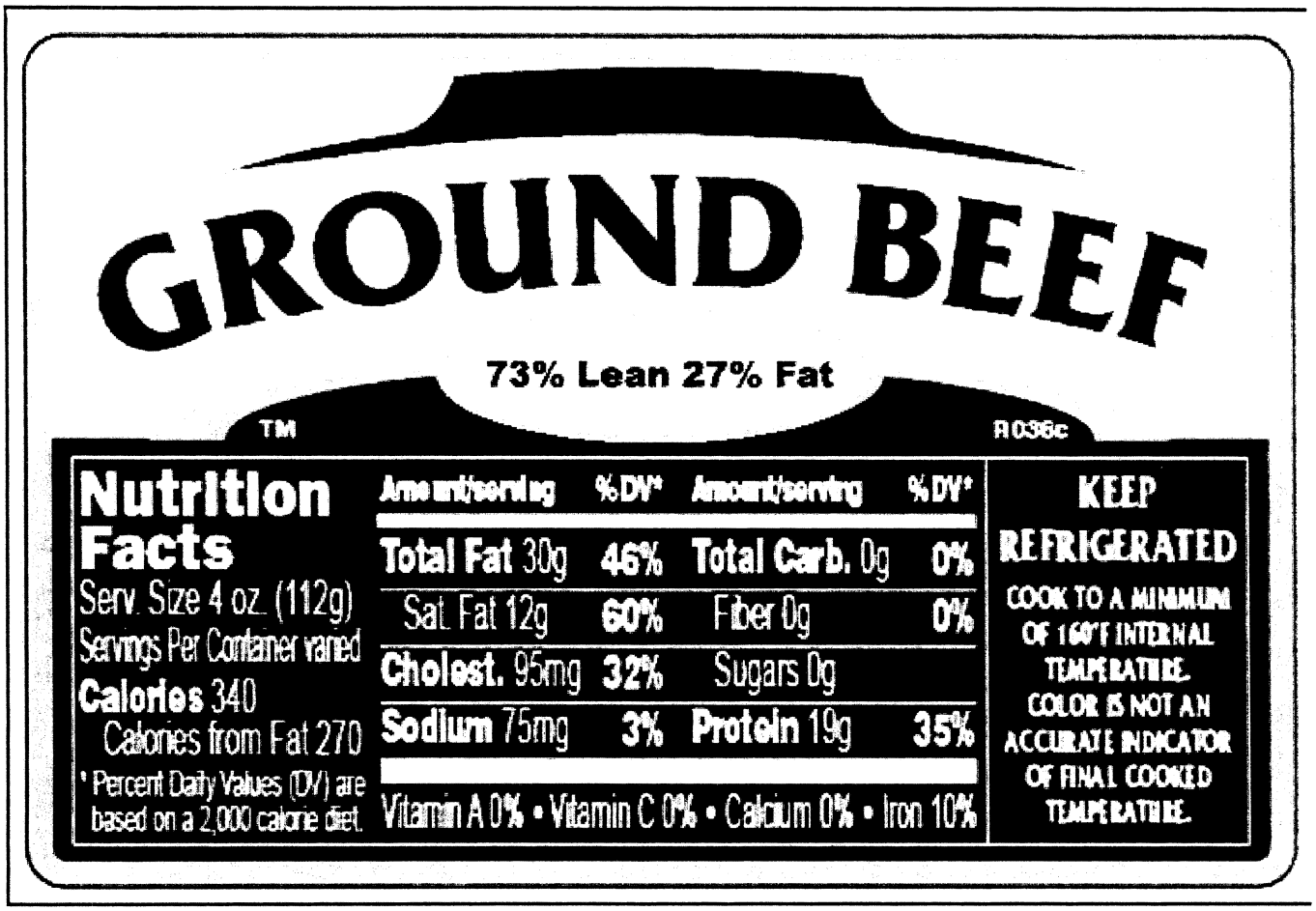
FSIS requests comments on whether provision of nutritional tables will be sufficient for retailers and establishments to provide nutrition labels for ground pork. FSIS also requests comments on whether the available data for ground chicken and ground turkey in the USDA Nutrient Database will be sufficient for retailers and establishments.

Below are examples of nutrition labels for ground or chopped products that would meet the requirements of the supplemental proposed rule. Should this rule become final, FSIS will make additional examples of acceptable nutrition labels for ground or chopped products available on the Agency's Web site.

BILLING CODE 3410–DM–P


GROUND BEEF
80% Lean 20% Fat
TM
R013d
Nutrition Facts
Serv. Size 4 oz. (112g)
Servings Per Container varied
Calories 280
Calories from Fat 200
* Percent Daily Values (DV) are based on a 2,000 calorie diet.
Amount/serving %DV* Amount/serving %DV*
Total Fat 23g 35% Total Carb. 0g 0%
Sat. Fat 9g 45% Fiber 0g 0%
Cholest. 85mg 28% Sugars 0g
Sodium 70mg 3% Protein 20g 38%
Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 10%
KEEP REFRIGERATED
COOK TO A MINIMUM OF 160°F INTERNAL TEMPERATURE.
COLOR IS NOT AN ACCURATE INDICATOR OF FINAL COOKED TEMPERATURE.

100% PURE
Extra Lean Ground Chicken
96% Lean 4% Fat
TM
R006
American Heart Association ®
Meets American Heart Association food criteria for saturated fat and cholesterol for healthy people over age 2.
While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Nutrition Facts
Serv. Size 4 oz. (112g)
Servings Per Container varied
Calories 130
Calories from Fat 25
* Percent Daily Values (DV) are based on a 2,000 calorie diet.
Amount/serving %DV* Amount/serving %DV*
Total Fat 4g 6% Total Carb. 0g 0%
Sat. Fat 1.5g 8% Fiber 0g 0%
Cholest. 65mg 22% Sugars 0g
Sodium 50mg 2% Protein 24g 48%
Vitamin A 0% • Vitamin C 0% • Calcium 2% • Iron 14%
Manufactured By AB, Inc. General Offices Dakota Dunes SD 57049



BILLING CODE 3410–DM–C

Summary of and Response to Comments

FSIS received approximately 5,000 comments on the proposed rule from individuals, consumer advocacy organizations, academia, trade and professional associations, health and nutrition organizations, two county health departments, meat and poultry producers, and food retailers. The majority of the comments (approximately 3,500) were generated from a letter writing campaign initiated by a consumer organization. In addition, there were approximately 450 form letters that expressed consumers' concerns and did not identify an affiliation with any organization, approximately 60 form letters from a consumer co-op organization, and two sets of form letters from relatively small retail chains (approximately 10 letters in each set).

A summary of issues raised by commenters and the Agency responses follows.

Nutrition Labeling for the Major Cuts of Single-Ingredient, Raw Meat and Poultry Products

Comment: The majority of letters from individuals, consumer groups, and health organizations stated that FSIS should require on-package nutrition labeling for all single-ingredient, raw meat and poultry products (major and nonmajor cuts). They stated that point-of-purchase materials fail to convey effectively the nutrition information for specific fresh meat or poultry products because the materials are difficult to find and difficult to read. Some of these commenters also stated that nutrition labels are particularly important for meat and poultry products because they are a major source of fat, saturated fatty acids, and calories.

A health organization stated that because the same cut of meat can be labeled by different names, consumers would be better served by nutrition information on the labels of the products. Several commenters stated that an advantage of including nutrition information on the label is that consumers could review the nutrient content once the product is taken home, and others, besides the primary food purchaser, would have better access to the nutrition information. A nutrition association stated that if FSIS permits point-of-purchase information for fresh meat and poultry packages, the Agency should require on-package messages directing consumers to point-of-purchase labeling at another location in the store.

One consumer association noted that a recent telephone survey showed an overwhelming percentage (78%) of the respondents said that it was ''more useful'' to provide nutrition information about raw meat and poultry products on package labels than on posters or brochures.

Comments from a coalition of health and consumer organizations suggested that the nutrient content for ground products often has less variance than the nutrient content of specific cuts. Thus, the coalition believes that it is more important to provide nutrition information on the labeling of major cuts than on ground products. The coalition also stated that the reasons provided by the Agency for mandating nutrition labeling on the packaging of ground products would be the reasons for mandating nutrition labeling on

packaging of the major cuts of meat or poultry (*see* 66 FR 4977). This coalition also stated that there are more major cuts than there are ground products, and it would be difficult for producers or retailers to develop point-of-purchase materials to address the different formulations and trim levels of the major cuts; and it would be difficult for consumers to locate the appropriate information for a particular cut on the point-of-purchase materials.

One health group stated that although on-package labeling may be a more effective approach for conveying nutrition information than point-of-purchase materials, the organization has historically supported the use of point-of-purchase materials as an acceptable means of nutrition labeling. This commenter also stated that for single-ingredient, raw products, other than ground or chopped products, the use of standardized averages is likely to be the most effective way to provide nutrition information, either on the package or at point-of-purchase. An individual also stated that for many major cuts, having the nutrition label next to the product would be sufficient.

A consumer organization did not believe that consumers have reasonable expectations as to the nutrient content, including the fat, of raw meat and poultry products. The organization referenced a consumer telephone survey in which most respondents were unable to identify which cut of meat had the highest fat content among four choices. One medical organization stated that although it may be true that the nutrient content of the major cuts is relatively uniform, consumers generally have no idea of the nutrient content of these foods.

The majority of industry and industry associations supported the continued use of point-of-purchase nutrition information materials for the major cuts, rather than nutrition labels on the packages of these products. Two of these groups presented results of focus group research demonstrating that consumers currently understand and use point-of-purchase materials in numbers comparable to the number of consumers who read and use the nutrition information on the labeling of products subject to the requirements of the mandatory nutrition labeling program. Additionally, according to the commenters, the focus group research demonstrates that consumers are generally satisfied with the current nutrition information provided for fresh meats.

One industry association stated that the use of individual nutrition labels may result in consumers' viewing a smaller portion of the product and paying a higher amount for the product, because of the cost associated with maintaining a vast number of labels to be placed on the package. Additionally, according to this commenter, if the consumer intends to trim the fat from meat or remove the skin from poultry products, the nutrition information on the label would not adequately represent the product's nutrition information after fat had been trimmed from it or skin from it had been removed.

One industry commenter stated that it is extremely difficult to provide accurate nutrition information for each major muscle cut because nutrient content varies depending on the breed and quality of each animal. Another industry commenter stated that although ''average'' numbers from the USDA database are appropriate for point-of-purchase materials, because of the potential variations in specific individual cuts, trims and grades, the average numbers are not appropriate for on-package labeling, where consumers justifiably expect a label to accurately define the exact nutrient content of what is in that package.

Two industry commenters stated that according to the Agency's own survey, 62.7% of men and 57.9% of women rarely or never use the nutrition information provided on raw meat, poultry or fish (*see* 66 FR 4982, January 18, 2001). They speculated that this low usage may in part be explained by the fact that consumers already have reasonable expectations regarding the nutrient values of these products as a result of industry's voluntary efforts to provide this information. Similarly, one retail association stated that consumers have reasonable expectations as to the nutrient content of major cuts, and that the nutrient content of a given major cut is relatively uniform across the market. An industry commenter stated that, unlike ground meat, consumers can see and remove the fat from whole muscle meat.

Another industry organization stated that single-ingredient, raw meat and poultry products have a unique quality: the structure of the cut, including the amount of fat, is visible both on the exterior and within the muscle cut. As a result, consumers can visibly discern which products are leanest. However, the commenter also believed that consumers would benefit from additional nutrition information because consumers cannot discern the quantitative nutrient content of single-ingredient, meat and poultry products without the nutrition information provided on point-of-purchase materials.

Response: As FSIS proposed, should this rule become final, it will require that nutrition information be provided for the major cuts of single-ingredient, raw meat and poultry products, either on the label or at the point-of-purchase. Although FSIS continues to agree with the commenters who stated that nutrition labels on the major cuts of single-ingredient, raw products are useful, FSIS believes that consumers have reasonable expectations as to the nutrient content of these products and can make comparative judgments about the fat content of the various cuts. While consumers' expectations for these products may not be perfect, they are significantly more aware of the nutritional content of single cuts of meat than the nutritional content of ground meat. Thus, the rule allows an alternative way of providing nutrition information for major cuts of single-ingredient, raw products. As is discussed above, even though FSIS believes that consumers have reasonable expectations concerning the nutrient content of the major cuts, without nutrition information for these products, consumers cannot assess specific nutrient levels in them and cannot make educated choices about consuming them. These educated choices are significant to a consumer's effort to construct a healthy diet.

FSIS does not believe that the telephone survey results used by a consumer organization in support of their belief that most consumers do not have reasonable expectations of the nutrient content of raw meat and poultry demonstrate that consumers do not have reasonable expectations concerning the major cuts. FSIS does not believe it is reasonable to expect consumers in a telephone survey to be able to identify which individual cuts of meat or poultry have the highest fat levels. However, if shown pictures of the various cuts (that are not ground or chopped), FSIS believes that most consumers could identify the cut with the most fat, by its internal marbling and external fat cover. The medical organization commenter that stated that consumers generally have no idea of the nutrient content of the major cuts provided no data to substantiate this statement.

Although individuals, and consumer organization commenters, stated that point-of-purchase materials are difficult to read, they provided no explanation for their assertion that these materials are difficult to read. Their other concern about the difficulty of finding point-of-purchase materials will be taken care of

by this rule. Should it become final, the rule will require that point-of-purchase materials be made available in close proximity to the food (§ 317.345(a)(3) and § 381.445(a)(3)).

Regarding the health organization's comment that the same cut of meat can be labeled by different names, and thus consumers would be better informed by nutrition information on a product's label, FSIS is not aware that consumers are confused about the names of the major cuts of single-ingredient, raw products listed on point-of-purchase materials. FMI was involved in developing these materials, and that organization has the most current names used to designate the major cuts. However, if necessary, retail facilities and establishments can include multiple names for a major cut on point-of-purchase materials. In addition, if FSIS is informed of specific cuts that are identified by different names, FSIS will revise the point-of-purchase materials that it is making available on the Internet.

After the comment period for the proposed rule ended, FSIS received correspondence from industry stating that the list of major cuts in the regulations should be changed to reflect more accurately the most popular cuts in the market. This correspondence recommended removing certain cuts and adding others. Because FSIS did not propose to amend the codified list of major cuts in the regulations and did not provide an opportunity for the public to comment on proposed changes to the list, FSIS is not amending the list of major cuts in the regulations at this time. However, FSIS will review this issue, and if the Agency determines that a change in the list of major cuts is warranted to accurately represent the market, FSIS will pursue future rulemaking.

Regarding the comments that noted that an advantage of including nutrition information on the label is that consumers can review the nutrient content of the product once the product is taken home, and others besides the primary food purchaser would have better access to this information, surveys, including the Diet and Health Knowledge Survey (DHKS), show that a majority of individuals report using labels while buying foods. Although the DHKS shows that adults who are not main household shoppers use labels, the survey shows that the main shoppers use labels at a higher rate than those who are not main household shoppers. Also, FSIS assumes that if individuals in a household have certain nutrition practices and needs, the person who purchases food for the household would take other household members' needs and preferences into account. In addition, FSIS assumes that purchased food would typically be consumed by members of the household and not thrown away.

In response to the comment that the nutrient content of the major cuts may be more variable than that of ground products, FSIS recognizes that there is significant variability in the nutrient content of the major cuts depending on the grade of the product and the levels of exterior fat on the products. However, the point-of-purchase materials that FSIS and FMI have developed to convey nutrition information for the major cuts take into account this variability and reflect average nutrition information for these products. The information on the point-of-purchase materials is meaningful and accurate for the major cuts. Consumers can view the point-of-purchase materials to make educated choices based on nutrition information among the different major cuts. In addition, to further distinguish among different packages of the same major cut, consumers can make comparisons based on levels of visible fat on the product.

This coalition's other concern that it would be difficult for producers or retailers to develop point-of-purchase materials to address the different formulations and trim levels of the major cuts need not be a concern. FSIS and FMI have made available nutrition information that can be displayed at the point-of-purchase of the major cuts of single-ingredient, raw meat and poultry products. These point-of-purchase materials will meet the nutrition labeling requirements of this rule, should it become final. Furthermore, requiring that all major cuts of single-ingredient, raw meat and poultry products bear nutrition labels would be a significant cost to the industry based on FSIS's supplemental proposed cost analysis.

Comment: Two industry commenters stated that it was appropriate for FSIS to provide point-of-purchase materials via the Internet. They believed that this would lessen the burden on retailers unable to develop appropriate customized nutrition information. One of these commenters also stated that the Agency should develop point-of-purchase materials so that the nutrition information supplied would be accurate and consistent.

With regard to the type of point-of-purchase materials used to display nutrition information, several commenters stated that easy to understand charts that convey the information would be more helpful and informative to consumers than a collection of individual labels on display. One industry organization commenter, however, stated that each option of the display of nutrition information on charts or on individual display panels had advantages. This industry organization believed that the presentation of information in charts which have vertical and horizontal columns, that cover multiple products, would allow consumers to make comparisons and would consume less space than individual labels. This organization also stated that charts are readily available to retailers. However, this organization felt that consumers might be more familiar with single nutrition panels than with nutrition charts covering multiple products. Nevertheless, this organization believed that the provision of nutrition panels for every major cut at their point-of-purchase would be costly and would consume a significant amount of space in retail settings. Thus, the organization concluded that retailers should have the freedom to present nutrition information in any way that suits customer needs, so long as it is not misleading. Accordingly, the commenter suggested that USDA conduct research to determine the best method of presenting such information.

Several industry commenters stated that the Agency should describe the information required but should not prescribe a specific format or presentation of the information so that retailers that want to develop customized point-of-purchase materials can develop customized materials. These commenters believed it was important to provide as much flexibility in the development of nutrition materials as possible. One of these commenters also stated that the Agency should only prescribe the specific required presentation of the nutrition information after significant consumer testing.

Response: The Agency will provide nutrition information for the major cuts of single-ingredient, raw products that retailers can use at point-of-purchase at the following Internet address: *http://www.fsis.usda.gov*. Point-of-purchase materials are also available from FMI at the following Internet address: *http://www.fmi.org*. At this time, FSIS intends to provide information on charts with columns that cover multiple products, rather than providing a compilation of individual nutrition facts panels. The Agency does not intend to conduct consumer surveys or additional research to determine whether individual nutrition labels or charts covering multiple products would best address

consumer needs because most comments received on this issue supported the use of charts covering multiple products.

The Agency agrees with commenters that it is important to provide as much flexibility as possible in the presentation of nutrition information on point-of-purchase materials for the major cuts of single-ingredient, raw products. Therefore, should this rule become final, FSIS will allow point-of-purchase nutrition information for the major cuts to be presented through a variety of means, including signs, brochures, notebooks, or leaflets in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. Furthermore, if there is no nutrition claim made on the point-of-purchase materials, they will not be subject to any of the format requirements applicable to on-package nutrition labels. However, if a nutrition claim is made on the point-of-purchase materials, all of the format and content requirements applicable to on-package nutrition labels in §§ 317.309 and 381.409 will apply.

Consistent with existing voluntary and mandatory nutrition labeling program regulations, should this rule become final, the Agency will provide more flexibility for the presentation of nutrition information for the major cuts at the point-of-purchase than for the presentation of nutrition information on labels. FSIS believes this is appropriate and necessary because there is no small business exemption from nutrition labeling requirements for the major cuts. Also, FSIS does not want to impose any burden on retailers that are following the voluntary guidelines for voluntary nutrition labeling.

Comment: One animal protection organization supported allowing nutrition information for the major cuts of single-ingredient, raw products to be provided on an ''as packaged'' basis, as opposed to an ''as consumed'' basis, because there are numerous cooking methods, and the cooking method used could affect the nutrient content of the product. In addition, one industry association supported allowing nutrition information to be provided on an ''as consumed'' basis for the major cuts of single-ingredient, raw products.

Response: As proposed, for the major cuts and nonmajor cuts of single-ingredient, raw products, should this rule become final, it will allow nutrition information on the label or on point-of-purchase materials to be declared on either an ''as packaged'' basis or ''as consumed'' basis because, as noted in the proposed rule, most of the major cuts of single-ingredient, raw meat and poultry products will not need FSIS compliance scrutiny (66 FR 4974, January 18, 2001). If nutrition information for these products is based on USDA's National Nutrient Database for Standard Reference, and there are no claims on the labeling, FSIS will not conduct a nutrient analysis of these raw products and, therefore, will not evaluate ''as packaged'' nutrition labeling information for these products. Consistent with the provisions in the voluntary nutrition labeling program, when nutrition information is presented on an ''as consumed'' basis, retailers or manufacturers will be required to specify a method of cooking that will not add nutrients from other ingredients such as flour, breading, and salt (§§ 317.345(d) and 381.445(d)). FSIS welcomes further comment on this issue.

Comment: An industry association and animal protection organization agreed that it was unrealistic to state the ''servings per container'' on the nutrition labels of the major cuts of single-ingredient, raw products because the majority of these products are random weight items.

Response: FSIS agrees that the number of serving per container is not necessary information on the nutrition labels of the major cuts or nonmajor cuts of single-ingredient, raw products, because these products are typically random weight products. For multi-ingredient and heat-processed products that must bear nutrition labels, the number of servings is not required on random weight products (§§ 317.309(b)(10)(iii) and 381.409(b)(10)(iii)).

Comment: Several industry groups believed that the voluntary nutrition labeling program should remain in place, and that FSIS should not require nutrition labeling of the major cuts of single-ingredient, raw products. One retail association stated that FSIS could improve voluntary compliance with nutrition labeling guidelines without requiring nutrition labeling for the major cuts by making the same free information available that it plans to make available under the new regulations. Similarly, a form letter that multiple retailers submitted stated that FSIS could increase compliance with the voluntary guidelines at less cost to consumers than the regulations would generate by providing free and updated information to retailers. Several individuals stated that the USDA should not establish new labeling requirements for meat products because they believed that current labeling on these products is sufficient.

As noted above, two commenters stated that according to the Agency's own data, 62.7% of men and 57.9% of women rarely or never use nutrition information on raw meat, poultry or fish. Given such low usage, the commenters stated that FSIS should not require nutrition labeling for the major cuts of single-ingredient, raw products but should be more flexible in encouraging greater participation in the voluntary program.

Two industry commenters questioned the accuracy of the USDA surveys that did not find significant participation in the voluntary nutrition labeling program. They stated that the USDA surveys in 1996 and in 1999 checked only for the presence of the ''new'' formatted nutrition information; one of these commenters stated that FSIS did not announce in the **Federal Register** that only ''new'' materials would be considered.

These commenters also noted that FSIS determined whether significant participation in the voluntary nutrition labeling program existed based on the number of stores found to be in compliance. However, these commenters stated that equal consideration should have been given to the volume of product for which nutrition information was provided and the numbers of shoppers given access to the information. These commenters noted that volume-weighted participation would have represented 60 percent participation in the voluntary nutrition labeling program.

One of the commenters that questioned the accuracy of the surveys also stated that the surveys were not conducted every two years; it is not clear that every chain company was included; neither the 1996 nor the 1999 survey reported on nutrition information that was applied in label form directly to the package; and the surveys may have included stores that the organization believes should be exempt from the nutrition labeling guidelines. The other commenter that questioned the accuracy of the surveys stated that, given a variance factor of 4% (a conservative margin of error based on 2,000 stores, according to the survey reports), store participation could have been 70.5% in 1995, 61.5% in 1996, and 58.5% in 1999. In other words, FSIS could have found significant participation existed in two of the surveys.

Response: FSIS continues to believe that nutrition information for the major cuts of single-ingredient, raw products is important and necessary. In addition, FSIS believes that requiring nutrition labeling of the major cuts of single-

ingredient, raw meat and poultry products will result in benefits. FSIS did encourage participation in the voluntary nutrition labeling program through meetings with industry. Further, nutrition labeling materials for the major cuts have been available on FMI's Web site for several years (*http://www.fmi.org*). Despite this and FSIS's encouragement of the use of such materials, the 1999 voluntary nutrition labeling survey found a lower rate of participation than the 1996 survey found. Thus, the fact that nutrition information was available was insufficient to ensure consumers received the necessary nutrition information. By making the guidelines currently in place for the voluntary nutrition labeling program mandatory, FSIS will ensure that consumers are provided with necessary nutrition information concerning the major cuts.

To determine how much of a behavioral response and change in dietary intake might result from providing more nutrition information on meat and poultry products in the proposed rule's benefits analysis, FSIS assumed that when labels and other sources of nutrition information were provided for raw meat and poultry products, the usage rates would rise to match nutrition label usage rates for food products as a whole (66 FR 4990, January 18, 2001). As FSIS noted, although some information was being provided for some single-ingredient, raw meat and poultry products, nutrition information for these products was not required. FSIS noted it could be reasonably assumed that when nutrition information becomes mandatory, more consumers will use the nutrition information for the major cuts of single-ingredient, raw products.

FSIS does not believe that the surveys conducted to determine whether there was significant participation in the voluntary nutrition labeling program were inaccurate because they were not conducted precisely every two years or because of the manner in which FSIS determined whether there was significant participation. FSIS's regulations provide that the Agency would evaluate significant participation every 2 years (§§ 317.343(e) and 381.443(e)). However, the timing of these surveys did not make them invalid. Although FSIS did not conduct the surveys precisely 2 years apart, the Agency conducted the surveys approximately every two years.

Further, the survey conducted in June 1995 included as participants in the voluntary nutrition labeling program those retailers who displayed at point-of-purchase either materials that were developed before or after issuance of the 1993 final rule on nutrition labeling. The older nutrition information materials, which were developed in 1992, 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 the 1995 survey may have actually overestimated participation in the voluntary nutrition labeling program.

Additionally, the 1996 and 1999 surveys correctly only counted a store as providing voluntary nutrition information for meat and poultry products if it displayed point-of-purchase materials that were developed after the final rule was published. FSIS program officials had decided that by 1996 retailers had had enough time to obtain the updated nutrition labeling materials for display in their stores. FSIS did not announce in the **Federal Register** that only ''new'' materials would be considered to meet the voluntary nutrition labeling program guidelines. However, FSIS met with industry organizations and informed them that, in the 1996 survey, the Agency would only consider ''new'' materials to meet the voluntary nutrition labeling program guidelines. It could reasonably be expected that stores that were participating in the program would replace the materials over the course of three years.

Moreover, consistent with its stated intention to sample all chain companies (58 FR 640, January 6, 1993), the contractor that conducted the surveys on behalf of FSIS used various sources to sample all chains, including Retail Diagnostics, Inc.'s listing of supermarkets, Progressive Grocer *Marketing Guidebook,* Progressive Grocer *MarketScope,* Chain Store Guide *Directory of Supermarkets & Convenience Store Chains,* and the latest U.S. Economic Census. Moreover, although the surveys do not report the number of stores found to be providing nutrition information on package labels, the surveys did take this into account. Retailers were considered to be participating in the voluntary program when they provided nutrition information on nutrition labels or on point-of-purchase materials, in accordance with program guidelines, for at least 90 percent of the major cuts sold at the facility.

FSIS correctly did not make a determination of whether there was significant participation in the voluntary nutrition labeling program based on the volume of product for which nutrition information was provided and the number of shoppers given access to the information. FSIS regulations clearly provide that a determination of whether significant participation in the voluntary nutrition labeling program existed was to be based on the percentage of companies evaluated that were participating in accordance with the guidelines. Significant participation would exist if at least 60 percent of all companies that were evaluated were participating in accordance with the guidelines. As is explained above, the term ''companies,'' as used in the regulations, refers to individual stores. The preamble to the 1993 nutrition labeling rule stated, ''FSIS will use a representative sample of stores to obtain the information necessary to assess participation'' (58 FR 640, January 6, 1993). FSIS developed these regulations through notice and comment rulemaking, and FSIS conducted the surveys consistent with the regulations and the 1993 preamble statement. No comments received in response to the November 27, 1991, proposed rule on nutrition labeling stated that significant participation should be based on the volume of product covered and the number of shoppers given access to this information.

In addition, as FSIS explained in the preamble to its final nutrition labeling regulations in 1993, it is important to provide nutrition information to consumers and, to the extent possible, to harmonize with FDA's voluntary program for raw fruit, raw vegetables, and raw fish (58 FR 640, January 6, 1993). Consistent with FSIS's regulations, FDA's regulations provide that substantial compliance exists with the guidelines for the voluntary nutrition labeling for raw fruits, vegetables, and fish when at least 60 percent of all stores that are evaluated are in compliance (21 CFR 101.43(c)).

The 1995 survey found that 66.5% of stores were participating in the voluntary nutrition labeling program; the 1996 survey found that 57.5% of stores were participating; and the 1999 survey found that 54.5% of stores were participating. Based on the regulations, stores were found to be participating in the voluntary nutrition labeling program if they provided nutrition information for 90% of the major cuts in their stores.

FSIS recognizes that, given a variance factor of plus or minus 4%, store participation could have been 70.5% in 1995, 61.5% in 1996, and 58.5% in 1999. However, even assuming a plus 4% margin of error, the 1999 survey showed that significant participation did not exist. Furthermore, given a

variance factor of 4%, store participation also could have been 62.5% in 1995, 53.7% in 1996, and 50.8% in 1999. Significantly, the 1999 participation rate was lower than the 1996 participation rate. As a result, FSIS concluded that it had an obligation under its regulations to institute this rulemaking. The Agency did not survey again after 1999.

Consistent with the regulations, the surveys assessed whether stores provided nutrition information for 90% of major cuts stocked in their stores (§ 317.343(b) and § 381.443.(b)). In addition, the surveys assessed whether stores provided nutrition information for a lower percentage of such products. The 1996 survey found that 59.4% of stores provided nutrition information, according to voluntary guidelines, for 70% to 90% or more of their major cuts. Thus, based on the 1996 survey, even if FSIS includes stores that provided nutrition information according to the voluntary guidelines for only 70% of their major cuts, this percentage of stores is not quite 60% and, thus, still does not meet the ''significant participation'' criteria in the regulations.

In the 1999 survey, 58.3% of stores provided nutrition information, according to the voluntary guidelines, for 50% to 90% or more of their major cuts. Again, this percentage of stores is still not quite 60% and does not meet the ''significant participation'' criteria in the regulations. Based on the 1999 survey, even if FSIS includes stores that provided nutrition information according to the voluntary guidelines for only 50% of their major cuts, FSIS still would not find 60% participation. (*See* Table 7 of the surveys on the FSIS Web site: *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_98-005P.htm).*

Comment: One retail industry association stated that, unamended by a legislative vehicle comparable to the Nutrition Labeling and Education Act, the meat and poultry Acts do not give USDA the statutory authority to mandate nutrition labeling regulations for single-ingredient, raw meat and poultry products.

Response: FSIS believes that without nutrition information, the labeling of major cuts of single-ingredient, raw meat and poultry products fails to include material facts about the consequences of consuming these products. This information is necessary for consumers to have if they are to make educated choices that are necessary in structuring a healthy diet. FSIS has concluded that the lack of this information on the labeling of the major cuts causes the labeling of these products to be misleading. The FMIA and PPIA provide that a product is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 601(n)(1) and 453(h)(1)). Without the nutrition information for the major cuts of single-ingredient, raw products that would be provided if significant participation in the voluntary nutrition labeling program existed, the Agency has concluded that these products would be misbranded under the FMIA and the PPIA (21 U.S.C. 601(n)(1) and 453 (h)(1)).

Mandatory Nutrition Labeling for Ground or Chopped Products

Comment: Many individuals, consumer organizations, and nutrition organizations supported mandatory nutrition labeling on the package for ground or chopped products. Several industry associations also supported these requirements and stated that these requirements were feasible and reasonable. One of these associations also stated that because ground meat products are formulated to have greater consistency and uniformity in their composition than other cuts, retailers can create a standard, on-package label that provides accurate, reliable nutrition information.

Consumer groups noted that several supermarket chains already include full nutrition facts labels on their ground beef products. These commenters believed that required nutrition labels for ground or chopped meat and poultry products would create the most informative and clear information for consumers.

Consumer and industry commenters stated that consumers cannot visually detect the fat content of ground beef products, and without on-package labeling, consumers cannot easily determine what nutrition information provided on point-of-purchase materials would apply to individual packages of ground products. However, one of the industry commenters that supported on-package nutrition labeling had concerns regarding the economic impact of this labeling.

Most industry trade associations and grocer associations did not support on-package nutrition labeling information for ground or chopped products. One industry association stated that the FMIA and PPIA do not support on-pack nutrition labels for ground or chopped products. Another industry association stated that consumer education regarding the nutritional qualities of meat and poultry products, in conjunction with mandatory point-of-purchase labeling, would provide consumers with sufficient information for ground or chopped meat and poultry products. Similarly, a third industry association supported mandatory nutrition labeling for ground or chopped products, provided it could be provided at their point-of-purchase.

Industry commenters stated that there is not room on the label of ground products for a nutrition facts panel. Two commenters stated that nutrition labels for ground or chopped products should be exempt from the current type size requirements or the labels will be too large; alternatively, these commenters suggested that FSIS should allow use of the linear label format.

Two industry commenters stated that results from surveys conducted in March 2001 indicated that the majority of their members routinely test for fat in ground beef. However, they believe that few retailers can determine nutrient or fat content of ground product blended at the store. Similarly, several other industry commenters stated that few retailers have, or could afford, equipment to determine the nutritional content, including fat, for the products they grind. Therefore, according to these commenters, mandating nutrition information on labeling may constrain small operations, limit the variety of ground products, and dissuade the practice of grinding at the request of the customer. An individual also stated that the proposed requirements for ground or chopped products would not be feasible for small grocers.

One retail industry association stated that, although retailers can readily measure the fat content of ground product, establishing the exact nutrient profiles on a daily basis would not be feasible. According to this commenter, if products were analyzed, they would no longer be salable by the time analytical results became available. Another retail industry association stated that some retail stores have access to fat content by using a fat analyzer when doing in-store grinding of meat or poultry products; however, testing for additional nutrient content would require the use of a laboratory and would prove costly. Another industry commenter stated that large, centrally processed ground products can be formulated to precise fat contents, but many ground products produced in retail settings cannot.

Two industry associations supported the required nutrition labels on ground or chopped products that are ''case-ready'' but not for products prepared and packaged at retail. Like other industry commenters summarized above, these commenters stated that retailers do not have the equipment

necessary to determine the finished product's nutrient content.

Two associations stated that most consumers purchase ground products based on percent lean, the cut, or the cost of product, rather than based on the other nutrient content information. Another association stated that according to survey data, 45% of consumers choose ground beef based on price, 23% based on cut, and 9% based on fat content.

Response: Should this rule become final, FSIS will require on-package nutrition information for these products rather than allowing nutrition information to be provided at their point-of-purchase for the reasons stated in the proposed rule. 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 (66 FR 4977, January 18, 2001). If a statement of the fat percentage and lean percentage is not included on a package of ground product, consumers would not know which nutrient data concerning ground product on point-of-purchase materials would apply to that particular ground product. Establishments and retailers are not currently required to provide such a statement and will not be required to provide such a statement when this rule becomes effective.

The FMIA and PPIA do support on-package nutrition labels for ground or chopped products. The FMIA and PPIA provide that a product is misbranded if its labeling is false or misleading in any particular. FSIS has concluded that ground or chopped meat and poultry products that do not bear nutrition information would be misbranded under 21 U.S.C. 601(n)(1) and 453(h)(1). 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 nutritional information is integral to consumer purchase decisions because use of this information may result in the prevention of health problems and the 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 will, therefore, help consumers to construct healthy diets.

Thus, consistent with the recommendations from individuals, consumer organizations, and some industry comments, should it become final, this rule will require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. The rule will also require nutrition labels on packages of single-ingredient, raw ground or chopped products, rather than at their point-of-purchase. These products are similar to multi-ingredient products in the mandatory nutrition labeling program (which requires nutrition information to be on the label of individual packages). Just as producers can control the incoming ingredients and levels of such ingredients in multi-ingredient products, producers can precisely control the fat content of ground or chopped products to obtain the desired product. In addition, just as consumers cannot often see all the ingredients in multi-ingredient products, consumers cannot easily see the fat in ground or chopped 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 fat levels in these products and cannot compare the fat levels in these products to those in other products. Thus, it is difficult for consumers to have a reasonable expectation of the nutritional quality of these products.

Many grocers and manufacturers currently provide nutrition facts panels on ground beef products; therefore, FSIS questions why certain commenters stated that there is not sufficient room on the label of these products for nutrition information. In addition, FSIS continues to believe that, unlike other single-ingredient, raw products, producers are able to formulate precisely the fat content of ground or chopped products. If, as some commenters suggested, grocers cannot determine the fat percentage in ground or chopped beef produced at retail, FSIS questions how they can be certain they produce product that meets the standard of identity for ground or chopped beef, which requires that the product not exceed 30 percent fat (*see* § 319.15).

Information on ground beef products containing 5%, 10%, 15%, 20%, and 25% fat is available through ARS at the following Internet address: *http://www.ars.usda.gov\nutrientdata*. In addition, ARS has included a calculator on the Internet, with the Database, that allows parties to enter the amount of fat (5% to 30% fat) or lean (70% to 95% lean) in a raw ground beef product. The calculator will calculate the nutrient values for the product based on the fat or lean value entered. If retailers are able to determine the fat content, as two industry commenters suggested they could, they can use the ARS nutrient database to obtain the information necessary to help them determine other nutrient values in the product.

Additionally, the nutrition labeling requirements for ground or chopped products should not be particularly difficult for small operations, since ground or chopped product produced by retail establishments and Federal establishments that meet specific small business criteria will be exempt from nutrition labeling requirements (§§ 317.400(a)(1) and 381.500(a)(1)).

Moreover, a new exemption from the nutrition labeling requirements, that is provided in this supplemental proposed rule, should alleviate any concerns that nutrition labeling requirements will discourage retailers from grinding product based on customers' requests. Should it become final, the rule will provide an exemption from nutrition labeling requirements for ground or chopped products that are ground or chopped at an individual customer's request and that are prepared and served or sold at retail, provided that the labels or labeling of these products bear no nutrition claims or nutrition information.

If an individual customer selects an intact product for purchase and requests that the product be ground at the retail facility, FSIS has determined that nutrition information on the package of the ground product would not be necessary. In this instance, the customer has made the decision to purchase the product *before* it was ground. The customer is not selecting the product from among various, formulated, ground or chopped product, and thus the reasons for requiring a nutrition label on such a product would not be applicable here.

Comment: One animal protection organization stated that the nutrition information should be presented on an ''as packaged'' basis for ground or chopped meat and poultry products, and that ''as consumed'' information should be in addition to, not instead of, ''as packaged'' information. No commenters suggested that ''as consumed'' information alone was adequate.

Response: FSIS agrees with the commenter. Should it become final, the rule will require, as proposed, that nutrition information on the labels of

ground or chopped products be presented on an ''as packaged'' or ''raw'' basis. Although not required, a second column can be added to show nutrition information on the product on an ''as consumed'' or ''cooked'' basis. The regulations provide that if a product is commonly combined with other ingredients or cooked before eating, and directions for such combinations or preparations are provided, another column with nutrition information may be used (9 CFR §§ 317.309(b)(15) and (e) and 381.409(b)(15) and (e). Therefore, the nutrition information required on packages of ground or chopped products will be consistent with the information required on multi-ingredient and heat processed products. FSIS requests further comment on this issue.

Comment: FSIS did not receive any comments on how much meat derived from advanced meat/bone separation and recovery (AMR) systems or how much low temperature rendered product is currently being used in ground or chopped products. However, an industry organization stated that the use of product from AMR systems in ground beef products would not cause a dramatic change in the nutrient content of the product such that it would be misleading to consumers. The commenter noted that, based on the data FSIS presented (*see* 66 FR 4976, January 18, 2001), the level of cholesterol in product containing meat from AMR systems is slightly elevated, and the level of iron in the product is above 20 percent of the value of iron product not containing meat from AMR systems. However, according to the commenter, the studies were not performed in a compliance context, and FSIS did not provide information concerning the historical levels of iron or other information that would shed light on whether the difference accords with good manufacturing practices.

Response: FSIS presented information concerning ground beef with AMR product for illustrative purposes only. The data show an increase in the level of calcium over what would occur if good manufacturing practices were used. Similarly, iron levels in ground beef that includes AMR product may be higher than those in ground beef that does not include AMR product.

In meetings with FSIS, representatives of the meat industry have stated that the percentage of ground beef with AMR product and the level of AMR product in ground beef is higher than FSIS previously thought. FSIS continues to believe that one of the reasons nutrition information on the labels of ground or chopped meat products is important is because producers may use product from AMR systems in some of these products, and the use of AMR product can affect the nutrient values of these products. Finally, even though FSIS issued an interim final rule on AMR that provides specific restrictions on the levels of calcium and iron in AMR product (69 FR 1874, January 12, 2004), nutrition labeling of ground products that may contain AMR product is necessary to understand the nutritional profile of the food.

Comment: FSIS received few comments regarding consumer expectations of the fat content of ground products. One industry commenter stated that consumers do not have reasonable expectations of the nutrient content of ground products given the wide variation of fat and lean content.

Response: FSIS agrees that consumers do not have reasonable expectations of the nutrient content of ground or chopped products. Unlike whole muscle product, most consumers cannot visually discern which ground or chopped products have less fat, and which products have more fat, because the fat is ground in with the lean portion. In addition, producers may use meat from AMR systems and low temperature rendering in ground or chopped beef and pork products, which may affect the variability of these products.

No Requirements for Nonmajor Cuts

Comment: Several industry groups supported the proposal *not* to require nutrition labeling on nonmajor cuts that are not ground or chopped (*e.g.,* pork jowls, pigs feet, pork leg, pork shoulder picnic, and beef round rump) and did not believe such labeling was needed in the future. Two industry commenters stated that when grades and trim levels are considered, there are over 3300 cuts of red meat products, and it would be impossible to provide information on this number of products.

One industry group also indicated that the major cuts identified by the nutrition labeling regulations are still relevant today as representing the greatest share of fresh meat consumption, thus suggesting that it is more important that nutrition information be provided for these products than for the nonmajor cuts of single-ingredient, raw products.

As discussed above, the majority of comments from individuals, consumer groups, and health organizations stated that FSIS should require on-package nutrition labeling for all single ingredient, raw meat and poultry products (major and nonmajor cuts). An animal protection organization recommended that FSIS take no more than 24 months to investigate whether required nutrition labeling for single-ingredient, nonmajor cuts that are not ground or chopped is warranted.

Response: At this time, FSIS does not intend to require that nutrition information be provided for nonmajor cuts of single-ingredient, raw products that are not ground or chopped. FSIS has determined that it is not appropriate or necessary to require nutrition information for nonmajor cuts that are not ground or chopped at this time. They do not contribute in a major way to the diet. FSIS stated in the proposed rule that it intended to examine the current state of nutrition labeling for single-ingredient, raw products that are not ground or chopped and that are not major cuts (66 FR 4974, January 18, 2001). FSIS still intends to conduct this assessment but has not yet been able to do so because of competing priorities. Should this rule become effective, FSIS will examine and assess the adequacy of the nutrition information provided for the major cuts and will also determine whether sufficient nutrition information is being made available for the nonmajor cuts.

Permitting Percent Lean Statements on Labels or in Labeling of Ground or Chopped Products

Comment: Individuals and consumer and nutrition organizations generally did not support the use of statements of lean percentages on the label or in labeling of ground or chopped products that do not meet the regulatory criteria for ''low fat.'' A coalition of consumer and health and nutrition organizations stated that permitting such claims on packages of ground meat and poultry is inherently deceptive and will confuse consumers about the healthfulness of fresh ground meat and poultry products compared to other fresh meat, processed meat, and other foods. This coalition and an individual stated that a statement of fat percentage without a statement of lean percentage would be an effective means of allowing consumer comparison of ground products. Similarly, a medical school stated that, instead of a statement of ''lean'' on ground or chopped products, labeling of ground or chopped products should list the actual amount of fat in terms of ''x% fat or less.''

One medical organization suggested that instead of a statement of lean percentage as a quick reference, FSIS should allow a ''percent calories from fat'' statement on labeling of ground or chopped products. According to this commenter, this statement would allow comparisons among ground products and would also allow a comparison of

the amount of fat in the product to the daily amount of fat recommended in USDA dietary guidelines and the daily amount of fat recommended by other health associations.

One animal protection organization suggested that the use of percent lean statements is highly misleading since ''percent lean'' refers to percent by weight not percent of calories.

As a better means to compare ground products than a statement of the percentage fat and percentage lean in the product, one consumer organization noted that many packages of ground meat or poultry would meet the regulatory criteria for ''reduced fat,'' ''light,'' and ''lower fat'' nutrient content claims. This organization stated that such claims are now familiar to consumers, and that the use of such claims would ensure uniformity across product categories and reduce consumer confusion.

In contrast, an industry association did not support ''reduced fat'' labeling on ground products because, according to the commenter, it would penalize retailers who offer only the leanest products and do not offer those with higher fat content. In addition, the commenter believed that ''reduced fat'' labeling would be confusing to consumers who understand and have come to rely on the percentage fat and lean statements that are currently in use.

Two poultry industry associations did not support the provision for statements of lean percentages on ground or chopped products that do not meet the regulatory criteria for ''low fat.'' These associations stated that allowing the use of a statement of lean percentage on ground product that does not meet the regulatory criteria for ''low fat'' would be misleading, and that there is no basis for exempting ground product from the regulatory criteria for ''low fat'' that normally applies to product labeled ''lean'' (*see* §§ 317.362(e)(1) and (2) and 381.462(e)(1) and (2)).

The majority of industry associations supported the use of a statement of lean percentage on the label or in labeling of ground products that do not meet the regulatory criteria for ''low fat.'' They believed that the statement of lean percentage on ground beef products is not misleading and is a useful tool for consumers. Several commenters discussed telephone surveys whose findings indicated that the statement of lean percentage does not mislead consumers. The commenters stated that these surveys indicated that many consumers use the statements of lean and fat percentages as a basis for selecting ground beef products, and that most consumers understand that the statement of fat percentage indicates the percentage of fat in the product, not the grams of fat, percent Daily Value, or percent of calories from fat. Several industry associations stated that the percent lean and percent fat statements, in combination with the nutrition facts panel, will benefit consumers and allow consumers to quickly differentiate among ground products and determine how a serving of ground product fits into their overall diet.

One industry group recommended that FSIS consider allowing retailers to make a statement such as ''not more than 25% fat'' for a 75% lean/25% fat ground beef product, and one industry commenter recommended a tolerance for percentage content statements comparable to the tolerance allowed for nutrient value variations.

Response: The supplemental proposed regulations would 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 regulations would require 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.

Although individuals, consumer commenters and nutrition organizations generally did not support this provision, most industry commenters did. Industry commenters presented information from consumer surveys that showed that consumers understood the meaning of statements of lean and fat percentages on ground beef. Based on the survey information provided, interested consumers use this information as a quick way to compare ground beef products and as a means for ensuring the desired product is purchased. Additionally, based on the survey information discussed in the comments, consumers appear to understand that the percent lean statements simply indicate the percentage of lean versus fat in the products and do not interpret the information as a percent daily value (%DV) or percent of calories from fat in the product.

Producers, according to industry, have been using lean percentage statements on the labeling of ground beef and hamburger products for over 20 years (59 FR 26917, May 24, 1994). Because the percent fat statement must be contiguous to the percent lean statement and must be in lettering of the same color, size, and type as, and on the same color background as, the lean percentage statement, FSIS believes that the percent lean statements will not mislead consumers.

As the coalition and individual commenter suggested, producers may include a percent fat statement on the label or in labeling of ground products without including a percent lean statement, because a percent fat statement is factual information. A percent fat statement on ground or chopped products would be an acceptable alternative to a statement of lean and fat percentage. However, because of the longstanding use of the statements of percent fat and percent lean on the label or in labeling of ground beef and hamburger products, FSIS believes such statements on the label or in labeling of ground products will not mislead consumers.

As the consumer organization noted, ground or chopped products may meet the regulatory criteria for ''reduced fat'' or for ''light.'' The provisions for the statement of percent fat and percent lean in ground or chopped products will not preclude producers from using ''reduced fat,'' ''light,'' and other nutrient content claims.

In response to the suggestion that FSIS allow a ''percent calories from fat,'' FSIS already allows such a statement because it is factual information.

The current regulations do not preclude the use of the phrases ''x% fat or less'' or ''not more than x% fat'' on the labeling of ground or chopped product. The problem with the suggested alternative of listing the actual amount of fat in terms of ''x% fat or less'' or allowing statements such as ''not more than 25% fat,'' is that these statements are implied claims as defined by § 317.369 for red meat and § 381.469 for poultry products. In order to use the implied claim, ground products would need to meet one of the definitions for a nutrient content claim for fat content in § 317.362(b)(2) or (4) or § 381.462(b)(2) or (4). According to these regulations, to use such phrases, the product would have to be ''low fat,'' and most ground beef and hamburger do not qualify as ''low fat.'' Alternatively, the product would have to qualify as having ''reduced fat'' and would need to meet a 25% reduction in fat compared to a similar product.

Finally, in response to the industry suggestion that FSIS provide a tolerance for percentage content statements comparable to the tolerance allowed for nutrient value variations, the same tolerances allowed for nutrient value variations (317.309(h)(5) and (6) and 381.409(h)(5) and (6)) would apply to the statements of the percentages of lean and fat in the product, because these statements are based on information in the nutrition facts panel.

Exemptions for Nutrition Labeling

Comment: Two industry organizations stated that there should be a small business exemption from the nutrition labeling requirements for the major cuts. They argued that the Agency's stated rationale for not providing a small business exemption for these products (*i.e.,* that FSIS intends to make point-of-purchase materials available over the Internet free of charge) shows a lack of understanding of the challenges faced by small businesses and the economic hardships that the regulation imposes. These commenters stated that many small businesses do not have Internet access. Additionally, according to these commenters, small stores may not have space available to post the point-of-purchase materials.

Response: If retailers cannot obtain the point-of-purchase materials over the Internet, should this rule become final, FSIS personnel will have copies of the information to provide to retailers. Furthermore, the regulations will provide flexibility in regard to the manner in which the required presentation and posting of nutrition information for the major cuts must be done, so that all retailers should be able to post the information or have it available to consumers without using much space. For example, posters with nutrition information could be on walls near the products, or brochures or leaflets could be placed in a box near the products.

Comment: One animal protection organization did not support the small business exemption from nutrition labeling requirements for ground or chopped products. This commenter stated that the exemption could create a significant information gap in small towns and rural areas where large chain retail and grocery stores do not have a presence. Similarly, an individual stated that there should be no exemptions from the nutrition labeling requirements.

One industry group stated that ground or chopped products with or without seasonings, processed or packaged at retail must continue to be exempt from nutrition labeling requirements. This commenter stated that the quantity of ground products actually prepared at retail represents a small portion of the average diet.

Two industry commenters stated that FSIS should allow an exemption for ground or chopped products that are custom processed. They stated that when a retailer is only providing a service, not a food product, the retailer should not be expected to bear the cost of providing nutrition information, especially in rural areas where families raise their own animals and have a local meat market or supermarket provide the cutting and grinding service.

Response: FSIS believes that a small business exemption from nutrition labeling requirements is necessary for ground products, with or without seasoning. As explained in the proposed rule, small businesses should be exempt from mandatory nutrition labeling requirements for ground or chopped products 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 (66 FR 4978, January 18, 2001). Therefore, should this rule become final, it will provide a small business exemption for ground or chopped products produced by retail facilities or official establishments that qualify for the exemption.

Should this rule become final, to qualify for the exemption, a retail store will either need to be a single retail store that employs 500 or fewer people or a multi-retail store operation that employs 500 or fewer people and will need to produce no more than 100,000 pounds of each ground product per year. For an official establishment to qualify for the exemption, it will need to be either a single-plant facility that employs 500 or fewer people, or a multi-plant company/firm that employs 500 or fewer people and will need to produce no more than 100,000 pounds per year of each ground product. As explained in the preamble to the proposed rule, ground or chopped products formulated to have different levels of fat would be considered different food products for the purposes of the small business exemption (66 FR 4978, January 18, 2001).

Should this rule become final, ready-to-eat ground or chopped products packaged or portioned at retail stores and similar retail-type establishments, and multi-ingredient ground or chopped products processed at retail stores and similar retail-type establishments, will be required to bear nutrition labels, unless the retail store or similar retail-type establishment qualifies for the small business exemption. 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.

The Economics Research Service determined that ground beef accounted for 42 percent of all beef (boneless, trimmed-weight equivalent) consumed in 1996 (Putnam, Judy and Gerrior, Shirly, ''Americans Consuming More Grains and Vegetables, Less Saturated Fat, *Food Review,* Sept.–Dec., 1997, Vol. 20, Issue 3, pp. 2–12), and, as explained in the preamble to the proposed rule, most ground beef, traditionally, has been ground and packaged at retail (66 FR 4978, January 18, 2001). Therefore, ground beef products actually prepared at retail may represent a significant portion of beef consumed in the average diet.

When butchers custom grind product for customers, this product is considered a custom prepared product, and as such, this product will continue to qualify for an exemption from nutrition labeling requirements, should this rule become final.

Comment: One retail association and one consultant believed that the small business exemption for ground or chopped products should be phased in, in a manner similar to the way the small business exemption was phased in for nutrition labeling requirements in the 1993 FSIS final rule on nutrition labeling.

Response: FSIS disagrees with these commenters. Should this rule become final, the nutrition labeling requirements for ground or chopped meat and poultry products will apply to a much smaller number of products than the number of products subject to the 1993 final regulations on nutrition labeling. At this time, many businesses are familiar with nutrition labeling requirements; that was not the case in 1993. Therefore, as explained in the supplemental PRIA cost analysis, FSIS believes that it will not be costly for companies to add nutrition labels to packages of ground or chopped products.

Furthermore, many of the suppliers of coarse ground products that are then ground and packaged at retail have supplied, or can supply, the nutrition facts panels for the retailers. Most retailers offer a limited selection of ground beef products. Thus, dozens of different nutrition labels for each retailer will not be necessary. In addition, information for ground beef and other products is available through the National Nutrient Database for Standard Reference. In addition, should this rule become effective, the requirements for on-package nutrition labeling for ground or chopped products will not be effective until January 1, 2012.

Comment: Two industry commenters supported the continued exemption for multi-ingredient sausage products produced at retail. They stated that retail constraints in determining nutrient content support the continuation of the exemption. One

commenter asserted that the final regulation should specify that the provisions for ground or chopped products apply to product labeled as ''hamburger, (species or kind) burger or ground or chopped (species or kind)'' in order to differentiate such products from sausage products (ground meat with seasonings). This commenter stated that some parties might believe that the provisions for ground product apply to sausage products manufactured at retail.

Response: Nutrition information for sausage products are not covered by this regulation. Nutrition labeling requirements for these products were previously addressed in the 1993 nutrition labeling rule. Sausage, meat loaf, or beef patty mix are typically multi-ingredient products that are required to bear nutrition labeling, unless they qualify for an exemption, and multi-ingredient sausage products processed at retail will continue to be exempt from nutrition labeling requirements under § 317.400(a)(7)(ii) and § 381.500(b)(7)(ii). Because there is a standard of composition for ground or chopped beef (§ 319.15) and distinct standards of identity for sausage products, industry generally understands which products are referred to and labeled ''ground or chopped products'' and which products are referred to and labeled ''sausage products.''

In the 1993 final rule on nutrition labeling, FSIS exempted from mandatory nutrition labeling requirements multi-ingredient products processed at retail and ready-to-eat products packaged or portioned at retail. Therefore, multi-ingredient sausages processed at retail and ready-to-eat sausages packaged or portioned at retail are exempt from nutrition labeling requirements. The reasons that FSIS provided these exemptions in the 1993 final rule were that FSIS believed 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, January 6, 1993).

Should this rule become final, FSIS will not exempt ready-to-eat ground or chopped products packaged or portioned at retail or multi-ingredient ground or chopped products that are processed at retail because, as FSIS explained in the 2001 nutrition labeling proposed rule, there may be a significant amount of multi-ingredient ground beef retail processed products or ready-to-eat retail packaged products. Also, FSIS 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 (66 FR 4979, January 18, 2001).

Enforcement & Compliance

Comment: One retail association stated that FSIS should include in the regulations provisions comparable to those in the Nutrition and Labeling Education Act (NLEA) such that retailers would not be subject to substantial civil and criminal penalties for violations of the nutrition labeling requirements. This commenter was concerned that, if the USDA requires nutrition labeling for the major cuts, retailers could be penalized for minor violations of these regulations. For example, the commenter suggested that if a poster providing nutrition labeling information falls down, the retailer could suffer substantial penalties.

This commenter also asserted that, with regard to FSIS product sampling and nutrient analysis, FSIS should continue to treat single-ingredient, raw ground products in the same manner it treats other single-ingredient, raw products. Therefore, the commenter stated, FSIS should not sample raw, ground products for which USDA data are used as the basis for the nutrition information on the label. Further, the commenter stated that if FSIS conducts sampling of ground products at retail for nutrient analysis, the ground products should only be analyzed for fat content. According to this commenter, once FSIS verifies the fat content of ground products, products labeled with corresponding USDA data values should not be subject to further compliance and enforcement.

An animal protection organization stated that ground products should be subject to nutrient analysis. This commenter stated that the USDA National Nutrient Database for Standard Reference includes only a limited number of ground products, and there are many others available on the market. According to this commenter, FSIS employees cannot, and should not be expected to, visually assess the product and compare it against its label.

Response: Products under FSIS jurisdiction are not subject to the NLEA. Nonetheless, FSIS does not consider it likely that substantial criminal penalties could be imposed for significant violations of the nutrition labeling requirements. FSIS stated in the preamble to the final January 6, 1993, nutrition labeling rule that it is not the Agency's intent to proceed in a punitive manner when problems surface during compliance monitoring (58 FR 657, January 6, 1993). Should this rule become final, FSIS will likely seek criminal penalties for violations of the nutrition labeling requirements in the same types of circumstances as it would for other labeling violations of the FMIA and PPIA. Consistent with its approach to enforcing existing nutrition labeling requirements, under this rule, if FSIS finds nutrition information on product labels that, based on FSIS or USDA data, is inaccurate, FSIS would contact the company and request that it either correct the information on the label or provide adequate justification to support the information. If the company failed to do so, FSIS would likely issue a letter of warning.

FSIS is authorized to issue letters of warning in lieu of seeking criminal penalties when the Secretary of Agriculture determines the public interest will be adequately served by a letter of warning. If the company continued to use the inaccurate label, FSIS could institute an administrative process to rescind the label approval under 9 CFR § 500.8 and could seize any product in commerce because it is misbranded. However, FSIS considers it highly unlikely that companies will continue to use inaccurate labels after FSIS has contacted them because introducing misbranded product in commerce is a prohibited act under 21 U.S.C. 610 and 458. FSIS is not authorized to impose civil penalties under the FMIA or PPIA.

With regard to FSIS product sampling and nutrient analysis of ground products, as FSIS stated in the preamble to the proposal, 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 AMR systems is used (66 FR 4980, January 18, 2001). Therefore, the procedures set forth for FSIS product sampling and nutrient analysis in §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8) would be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. Should this rule become final, FSIS will not analyze ground or chopped products for fat only, because if the ground product includes AMR product or product from low temperature rendering (*e.g.,* finely textured beef or lean finely textured beef), the use of these materials could affect the nutrient values in the product.

With regard to FSIS product sampling and nutrient analysis, FSIS will not treat single-ingredient, raw ground or chopped products in the same manner that it treats other single-ingredient, raw products primarily because, as explained in the proposed rule, FSIS program employees cannot visually assess whether nutrition information on the label of ground or chopped products accurately reflects the labeled products' content. 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 (66 FR 4980, January 18, 2001). Therefore, should this rule become final, FSIS 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 National Nutrient Database for Standard Reference and there are no claims on the labeling. Therefore, FSIS will treat ground or chopped products as it treats all other products for which the regulations require nutrition information on their package. In the event that FSIS samples and conducts nutrient analysis of ground or chopped beef, if producers know the fat content of their product and have used USDA database values on the nutrition labels, FSIS would find the product's label in compliance with nutrition labeling requirements, provided the product's source materials did not include AMR product or product from low temperature rendering.

Costs and Benefits

Comment: Many commenters stated that the proposed rule would result in increased label costs. For example, one individual stated that it would cost a little more for production but did not think that it would affect the profit of major meat companies. Another individual stated that the rule would increase the final price of the product and require a change in packaging.

A small retailer who carries 26 different packages of ground meat in their stores and packages 6,000 packages per week stated that it would cost the company more than $22,600 a year in added costs due to labor and the additional labels that would be needed. Another small retailer estimated that the cost would approach $10,000 annually for adding a new poster and taking into account the necessary packaging, labor, and machinery modifications for ground or chopped products.

A beef producer believed that FSIS's cost estimates for requiring nutrition labeling for ground or chopped products are too low. This commenter stated that for those producers that must supply their own labels, the cost would be prohibitive. According to this commenter, if retail stores were to provide the information, the costs would be as calculated in the proposed rule. This commenter also believed that FSIS could still achieve its goal of having a large percent of compliance by making information on the label optional for certain groups that would be financially burdened. This commenter noted that FSIS estimated that the average weight of packages of ground or chopped products is 2 pounds and stated that the average weight of a package of pasture fed ground beef is between one and 1.5 pounds.

An animal protection organization contacted a major commercial laboratory that conducts nutrient analysis. This commenter stated that the laboratory charges $130 for a single sample analysis for total fat and saturated fat and $85 for cholesterol. The laboratory gives volume discounts for multiple samples.

According to an industry association commenter, the majority of retailers do not have equipment, such as a Fat-O-Meter or CEM analyzer, to determine the exact nutritional content, including the percentage of fat for their products. It is unlikely, according to this commenter, that retailers will be able to afford this type of equipment because it costs nearly $40,000.

A retail industry organization stated that according to Hobart, the company that manufacturers a large proportion of the scales used by retailers, 50 to 60 percent of supermarkets would need to upgrade their current printers, which represents $45 to $75 million in costs. Also, 40 to 50 percent of supermarkets would be required to replace their entire scale systems at the store level, which Hobart estimates would cost $54 to $90 million. In addition, according to this commenter, substantially more sophisticated and more expensive analytical equipment or laboratory testing will be needed to measure the nutrient profiles in ground products, which are likely to vary significantly in the context of USDA's compliance and enforcement standards.

Another retail industry association stated that a distributing company supplying 200 supermarkets estimated that the labeling requirement for ground or chopped products would affect over 20 million packages annually. Using the FSIS estimate of .005 cents per label, the labels alone would cost $100,000 per year. In addition, this commenter stated that although retail stores may be able to assess fat content by using a fat analyzer when doing in-store grinding, testing for nutrient content would require the use of a laboratory and prove costly. The commenter stated that these costs would cause many retailers that provide on-site custom service to increase prices or sell case-ready meat only, to the detriment of consumer choice.

Two individuals were concerned that the proposed rule would increase the price of meat; one stated that if people wanted nutrition information for meat and poultry products, stores would already provide the information on the packages.

In terms of the overall costs and benefits of compliance, an animal protection organization stated that, if the analyses and costs estimated by FSIS are accurate, it is evident that consumers need more information than they are currently getting. The commenter further stated that the costs to industry are negligible when compared to the benefits to the consumer.

An industry association stated that FSIS will also incur costs. According to this commenter, if the Agency requires on-package labeling for ground product, to verify compliance, it will be diverting a significant portion of its resources to the chemical analysis of numerous ground products produced at retail levels across the United States. The commenter also stated that, while FSIS has increased its level of sampling at the retail level for the purpose of microbiological sampling of *E. coli* O157:H7, it should also be able to collect additional samples for chemical analysis simultaneously. However, the commenter stated that FSIS would also be incurring new costs associated with sending samples to the laboratories as well as the actual cost of the analyses.

Response: FSIS recognized that the proposal, like many regulations promulgated by various government entities, would result in increased costs to various affected parties, so it is not surprising to FSIS that commenters would indicate that they would incur increased compliance costs. The commenter who stated that the rule would cost it $22,464 annually also stated that it produces 6,000 packages of ground beef per week or 312,000 packages per year. This equates to a per label cost of 7.2 cents. Another

commenter who said it would cost them $10,000 annually also said that they sell 100,000 packages annually. This equates to a per label cost of ten cents. Both estimates are significantly higher than any estimate prepared by FSIS. The Agency does not doubt that these retailers may incur higher labeling costs should this rule become final, but FSIS is unsure how their estimates were prepared. For example, FSIS is unsure as to whether these estimates include certain costs that should or should not be attributed to the proposal. At this time, the Agency is not in the position to accept these estimates as being comparable (in methodology or assumptions) to the costs presented by FSIS. As explained in the supplemental PRIA, FSIS estimates that retailers would incur the costs of upgrading store scales and printers to include nutrition information, redesigning larger store labels, providing nutrition analysis for each product, and using larger labels.

The Agency has reviewed the concerns of the beef producer but, with the limited supporting information provided, finds that the commenter's concerns are unconvincing. At no time does the commenter indicate what its costs might be, so it is difficult to determine how burdensome the requirements are for this producer.

The beef producer stated that the average weight of a package of pasture fed ground beef is between one and 1.5 pounds. However, in the supplemental PRIA cost analysis, FSIS estimates that the average weight of a retail package is 2.7 pounds (ranging from 1.7 pounds at the 5th percentile, to 4.35 at the 95th percentile). This estimate is from the National Cattlemen's Beef Association (NCBA), and FSIS believes this estimate better reflects the average weight of a retail package of ground product than the figure the commenter provided for pasture fed ground beef. NCBA's source is the Meat Purchase Diary, which is a survey. Although FSIS believes that NCBA data provide a sound estimate of the average weight of a retail package of ground product, there is some uncertainty in this estimate, because NCBA does not release any detailed data from its survey.

With regard to the comments on the cost of samples and nutrient analysis, the supplemental PRIA cost analysis includes costs of nutrition analysis ranging from $599 to $787 per modified label. These are costs required to create a nutrition facts panel. As explained in the cost analysis below, FSIS does not believe that the cost of a fat analyzer should be attributed to this rule. Stores may receive product for which a fat analysis has been performed and labeled accordingly. Also, as explained above, retailers currently must have a means of knowing that their product meets the standard of identity for ground beef.

With regard to the comment on the costs of upgrading scale printers, FSIS's supplemental PRIA cost analysis estimates the cost of updating scale printers at $2,400 per store or $56.35 million total. FSIS also estimated annual scale maintenance costs at $144 every year after the first year the scale has been purchased. Therefore, the supplemental PRIA analysis is consistent with the comment on updating scale printers.

In response to the comment that costs would cause many retailers that provide on-site custom service to increase prices, products that are ground or chopped at an individual customer's request and that are prepared or sold at retail are exempt from nutrition labeling requirements, provided the labels or labeling of those products bear no nutrition claim or nutrition information.

In response to the comments from individuals concerned that the rule would increase the price of meat, as explained in the supplemental PRIA cost analysis, the cost of this rule is not likely to be excessive relative to the volume of input of ground or chopped meat and poultry products sold at retail. The estimated cost of the rule on a per pound basis is $.0053. This increase in cost should not affect consumer purchases.

In response to the statement that nutrition information would be available if people wanted it, market forces have not been great enough to ensure significant participation in the voluntary nutrition labeling program. This fact could be evidence that consumers are not willing to pay for this information. Nonetheless, as is explained above, FSIS believes that consumers have reasonable expectations concerning the nutrient content of the major cuts of meat and poultry products, but they need precise information about the nutrient content of the major cuts in order to make a fully informed comparative judgment about the various cuts. In addition, the extent that such information conveys a negative credence attribute would limit its availability, if retailers were not required to disclose it. Without nutrition information for the major cuts of single-ingredient products and ground or chopped products, consumers do not have necessary and sufficient information to make informed purchasing decisions.

As far as the overall costs and benefits of compliance, the Agency believes that it has done a reasonable job in estimating the costs and benefits of the proposal.

In terms of cost to FSIS, in the Paperwork Reduction Act analysis, FSIS estimated that the costs of label and records review will total $300,000 annually. Other costs the Agency incurs as a result of this rule will be negligible. The rule will not increase inspection activities substantially. Similarly, it will not increase substantially the laboratory costs associated with FSIS sampling and testing for nutrient analysis. FSIS will conduct inspection and testing activities under this rule concurrent with existing inspection and testing activities.

Comment: A consumer organization asserted that FSIS overestimated the cost of the proposed rule by assuming that 20 percent of establishments would have to install new machinery for stamping, printing, or affixing nutrition labels for ground and chopped meat. The commenter believed that the 20 percent estimate is too high. FSIS's own 1999 survey showed that 97 percent of large chains, 91 percent of large independent retailers, and 84 percent of medium and small independents already complied with the label requirements of the final rule for Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry products. In addition, the commenter noted that small firms are exempt from the proposed rule.

Response: After the proposed rule was published, FSIS contracted with RTI International to assist the Agency in data collection and revising the cost analysis for the supplemental PRIA. Among the several changes based upon RTI's review, FSIS revised the label cost estimates. The supplemental PRIA assumes that retail facilities and official establishments have not yet incurred any costs for nutrition labeling of ground or chopped products or major cuts. However, the supplemental PRIA also estimates the current levels of nutrition labeling and adjusts cost and benefit estimates to reflect current levels of nutrition labeling.

Comment: According to a retail industry association, provisions requiring labels on individual packages of ground meat and poultry products will impose most costs and burdens upon independent retailers that offer custom service rather than pre-packaged case-ready meat. The commenter further alleged that the proposal would disproportionately affect independent operators and their customers, coercing retailers into increasing prices to cover increased costs or eliminating custom service because of the need to provide labeling for nutritional content of products ground in retail stores.

One individual stated that the proposed requirements would adversely affect small businesses. Also, a small producer stated that providing nutrition information on the labels of ground products would be difficult and costly for the small farmer or producer selling beef wholesale to stores.

Response: When Federal Agencies like FSIS issue rules, they are to make sure that the rules are fair to those being regulated. The Regulatory Flexibility Act requires Federal Agencies to consider the affect of regulations on small entities in developing regulations (*see* the Regulatory Flexibility Act Analysis below).

To minimize the burden on small businesses, should it become final, the rule will provide a small business exemption. In addition, the rule will provide an exemption from nutrition labeling requirements for ground or chopped products that are ground or chopped at an individual customer's request and that are prepared and served or sold at retail, provided that the labels or labeling of these products bear no nutrition claims or nutrition information. FSIS also intends to provide nutrition labeling materials for the major cuts of single-ingredient, raw products and for ground or chopped products on a free basis through its Web site. Retailers can display these materials at the point-of-purchase for the major cuts. Also, retailers and official establishments can obtain nutrition information for ground or chopped products at the following Web site: *http://www.ars.usda.gov.*

Comment: A consumer organization argued that FSIS underestimated the benefits of the rule by ignoring both the impact of meat and poultry consumption on non-fatal cases of heart disease and cancer and the impact on obesity and its consequences.

According to the commenter, FSIS limited its estimates of the benefits to the reduction in annual deaths from breast cancer, prostate cancer, colorectal cancer, and coronary heart disease. The commenter stated that this approach ignores the benefits to consumers in reducing the number of non-fatal cases of these four diseases. For example, according to the commenter, when FDA evaluated the benefits of its proposed rule on trans fatty acids in foods, the Agency estimated that only one-third of heart attack cases due to coronary heart disease are fatal. For non-fatal cases, FDA estimated the discounted value of the reduction in functional disability and pain and suffering of the patient and the reduction in medical costs at $282,000 per case (or 33.5 percent of the FDA's estimated value of $840,000 per fatal case). According to the commenter, as there are two non-fatal cases of coronary heart disease for every fatal case, FSIS should increase its benefits from the proposed rule by 67 percent. At a seven percent discount rate, this would increase the benefits over 20 years from a reduction in coronary heart disease from FSIS's current estimate of $752 million to $1.256 billion.

The commenter also stated that similar adjustments could be made to account for the reductions in the non-fatal cases of three types of cancer that FSIS considered. About 42 percent of colorectal cancer cases are fatal, about 16 percent of prostate cancer cases are fatal, and about 21 percent of breast cancer cases are fatal. The commenter believed that one could assume that the ratio of the benefits of reducing these non-fatal cases to the benefits of reducing the fatal ones is the same for these three types of cancer as FDA used for coronary heart disease, *i.e.,* 33.5 percent. Using a seven percent discount rate, the commenter estimated that including the reduction in non-fatal cases would increase the benefits over 20 years from a reduction in these three types of cancer from FSIS's current estimate of $167 million to $316 million.

In sum, including the impact of the proposed rule on non-fatal cases of the four diseases FSIS considered increases the total benefits (using a seven percent discount rate over 20 years) from $918 million to $1.572 billion.

When the commenter looked at the impact of the rule as it related to total fat, saturated fat, and cholesterol, the commenter thought that the proposal might help lead to a reduction in weight, which, in turn, could lead to a reduction in both mortality and morbidity from various diseases. According to the commenter, recent studies placed the cost of obesity in the United States at $39 billion in direct medical costs and $48 billion in indirect loss of output because of both morbidity and mortality. Reducing these $87 billion in annual costs by even 0.15 percent through the provisions of this rule would mean additional annual benefits of $13.05 million, which (at a 7 percent discount rate) means additional benefits over 20 years of about $138 million.

In summary, the benefits of the proposed rule over 20 years (discounted at 7 percent)—taking account of morbidity and obesity—could well be $1.71 billion rather than the $918 million estimated in the proposed rule based on FSIS's examining only mortality.

Conversely, a meat industry organization cautioned FSIS against making the mortality assumptions included in the proposed rule's benefits analysis. This commenter stated that FSIS's assumptions were based on only one part of meat's nutrient content. The commenter stated that, while diets high in saturated fat and cholesterol have been associated with risk of chronic disease, meat has never been shown to cause such diseases.

A farmer/rancher believed that the new nutrition labeling requirements could potentially encourage consumers to eat more meat, which would increase her profits.

Response: In response to the comment concerning non-fatal cases of heart disease and cancer, FSIS has reviewed all of the information provided by this commenter and believes that the information provided on coronary heart disease is potentially useful to the FSIS analysis. The information on the relationship between fatal cases and non-fatal cases of coronary heart disease is reliable in that FDA looked at the relevant literature and medical statistics to determine the annual number of heart attack cases of coronary heart disease that occur and the percent of those (occurring each year) that are fatal. This allows for a total, in a given year, of the number of heart attack cases that are not fatal, based just on new heart attack cases. FSIS agrees that a reduction in non-fatal cases of chronic heart disease would result in a significant benefit to society. The methods for estimating both the number of non-fatal cases avoided annually, and the value of non-fatal cases avoided annually are unsettled and further research is needed to improve the reliability of this information.

The information on colorectal, prostate, and breast cancer is not as reliable as that on non-fatal cases of coronary heart disease. Specifically, the information reported by the American Cancer Society represents the annual number of *new* cases, but the annual number of deaths includes deaths from both old cases and new cases of disease. In other words, the annual number of deaths also represents deaths from cases that were reported as new cases in previous years. Therefore, if FSIS were to adopt the information suggested by this commenter, then the denominator used to calculate the percent of fatal cases to all cases would be too small and the percent of fatal cases would be too high. Consequently, the benefits estimates associated with the reduction of non-fatal cases would be greater than the actual value of benefits. It should be noted however, that to ignore the

benefits associated with the reduction of non-fatal cases is also incorrect because, in fact, some benefits exist even though methods are not available to provide reliable estimates. At this time, it is not possible to provide a quantitative estimate of the benefits associated with reducing the non-fatal cases of colorectal, prostate, breast cancer, and coronary heart diseases.

Although the consumer organization recommended that FSIS revise the benefits estimate to include specific benefits associated with weight loss, FSIS did not account for these benefits in the final analysis. FSIS does not have the data necessary to estimate these benefits, and the commenter did not provide the data.

With regard to the industry comment that cautioned against making the benefits assumptions included in the preliminary benefits analysis, the supplemental PRIA benefits analysis is consistent with the preliminary benefits analysis. Therefore, the supplemental PRIA benefits analysis estimates the value of potential changes from intake of fat, saturated fat, and cholesterol that could occur as consumers respond to newly available nutrition information. The supplemental PRIA analysis uses changes in serum cholesterol to estimate health outcomes, which are reductions in the number of cases and mortality from three cancers and coronary heart disease. FSIS used survey data and a model developed by Zarkin, *et al.* to conduct the benefit analysis. The industry commenter did not provide data that would allow FSIS to conduct an alternative benefit analysis.

With regard to the comment that new nutrition labeling requirements could encourage consumers to eat more meat, FSIS does not have data that indicate that consumers will consume more meat as a consequence of new nutrition labeling requirements. Therefore, the supplemental PRIA benefits analysis does not include increased profits to producers.

Comment: One individual stated that there are benefits to individuals in keeping track of their nutritional intake. This commenter believed that he would find it valuable to know the levels of the different nutrients in meat and poultry products.

Response: FSIS concurs that there are benefits to keeping track of an individual's nutritional intake. The level of benefits associated with nutrition labeling depends on the extent to which consumers change their food consumption in favor of products that are more nutritious. To accomplish this, a consumer needs to keep track of his or her nutritional intake.

Comment: One individual stated that nutrition labeling on raw meat and poultry products could potentially lead to some decreases in the sale of red meat. The commenter also stated that poultry and fish will become more popular. The commenter did not anticipate a big overall change in sales.

An animal protection organization also stated that the net effect of the rule may be a decrease in the overall consumption of meat.

Response: Should this rule become final, the impact of the rule will depend upon the extent to which consumers change their food consumption in favor of products that they believe are more consistent with a healthy diet. Therefore, it is possible, as the commenters stated, that nutrition labeling on raw meat and poultry products could lead to some decreases in the sale or consumption of red meat as well as some increases in the sale of poultry and fish. FSIS has no information that would allow the Agency to measure such impact. Therefore, the supplemental PRIA does not reflect any anticipated changes in the volume of meat and poultry products consumed annually.

Comment: A consumer organization stated that there are significant differences between African Americans and Caucasions in the incidence of the four diseases that the FSIS examined in determining the benefits of the proposed rule. According to this commenter, African Americans are 50 percent more likely than Caucasians to die of heart disease, 43 percent more likely to die of colorectal cancer, 153 percent more likely to die of prostate cancer, and 38 percent more likely to die of breast cancer. African Americans are also 140 percent more likely than Caucasians to die of diabetes, a disease linked to obesity.

Response: The benefits analysis that was prepared for this rulemaking does not estimate benefits attributable to specific groups (*e.g.*, Caucasians or different minority groups). However, the benefits analysis does measure the impact to all affected parties. Therefore, no group of individuals has been excluded. Assuming that the information provided by this commenter is correct, then the rule may have a greater positive impact on minorities than on Caucasians.

Other Comments

Comments: Two industry organizations suggested that other nutrients, *e.g.*, zinc, and B-vitamins, should be required nutrients in nutrition labeling of meat and poultry products. One producer suggested that USDA provide information on omega 3 fatty acids and Conjugated Linoleic Acid (CLA) in the nutrient data base. One commenter suggested the addition of a warning label on meat products stating, ''Meat consumption has been linked in research to a higher risk for heart disease, cancer, hypertension, diabetes, and other serious diseases.''

Response: These comments are beyond the scope of the regulation.

Comment: One industry commenter suggested that what was needed most was more consumer education on understanding and interpreting nutrition facts panels.

Response: FSIS's requirements for nutrition facts panels are consistent with FDA's requirements for nutrition facts panels. FSIS has no information indicating that consumers are confused regarding the information displayed on nutrition facts panels. However, if FSIS receives information indicating that consumers need more education concerning the information on nutrition facts panels, the Agency will consider developing consumer education materials to aid consumers in understanding the nutrition facts panels.

Comment: One commenter suggested that a uniform compliance date should be provided for meat and poultry labeling requirements.

Response: FSIS has published a final rule that establishes January 1, 2012, as the uniform compliance date for new food labeling regulations that are issued between January 1, 2009, and December 31, 2010 (73 FR 75564). FSIS issued these regulations to enhance the industry's ability to make orderly adjustments to new labeling requirements without unduly exposing consumers to outdated labels and to minimize the economic impact of labeling changes. Should this rule become final, the January 1, 2012, effective date will apply to the nutrition labeling requirements for ground or chopped products because nutrition labels will be required on ground or chopped products, unless an exemption applies. Should it become final, this rule will allow nutrition information for the major cuts of single-ingredient, raw meat and poultry products at their point-of-purchase, not on the product. Therefore, FSIS intends to make the labeling requirements for the major cuts effective one year from the date of publication of the final rule.

Comment: One commenter stated that it had heard that the data in the USDA National Nutrient Database for Standard Reference are not current, and that USDA is undertaking nutrient analyses of additional fat/lean combinations (*e.g.,*

93/7; 90/10; 85/15) of ground beef. This commenter recommended that USDA forestall promulgation or implementation of these nutrition labeling regulations until all of the necessary information is available. Should FSIS finalize the rule, the commenter recommended that FSIS adopt an 18-month implementation period for the regulations.

Response: As noted above, the USDA National Nutrient Database for Standard Reference includes nutrient values for ground beef product containing 5%, 10%, 15%, 20%, and 25% fat. In addition, ARS has included a calculator on the Internet that will calculate the nutrient values of a particular ground beef product based on the fat or lean value entered.

Should it become final, the effective date for the nutrition labeling requirements for ground or chopped products will be January 1, 2012. Therefore, the affected industry will likely have more than 18 months prior to FSIS's implementation of the rule for ground or chopped products.

Section II. Executive Order 12866—Supplemental Proposed Rule Regulatory Impact Analysis (PRIA)

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

This supplemental PRIA differs from the PRIA that was published for the proposed rule. The Food Safety and Inspection Service (FSIS), after reviewing public comments, has concluded that further analysis of the costs and benefits of the rule was required. RTI, International performed an in-depth analysis responding to those comments (RTI, International, 2003) that formed the basis for the revisions to the cost analysis. FSIS incorporated the RTI findings with minor changes into this final analysis. FSIS, among other revisions, has also added a discussion comparing the costs of regulatory alternatives, revised the analysis of benefits, and added a new section examining the cost effectiveness of the rule.

This economic analysis uses the most current data available to the Agency. It relies on the U.S. economic census data from 2002, released in a report dated November 2005. Even though the data collection for the ''U.S. Bureau of the Census—2007 Economic Census'' has been completed, because the detailed reporting on the retail firms and establishments that would likely be affected by the final rule is not scheduled to be available to the Agency until about October 2010, FSIS was unable to use that data. Thus, Tables 3, 4, and 5 (below), which rely on the 2002 census data, have the most current information on these retail firms and establishments available. Further, the Agency used data from the FSIS Performance Based Inspection System (PBIS), April 2006, to estimate the number of Federally- and State-inspected meat and poultry slaughter and processing establishments that would likely be affected by the final rule. These are the most representative data available to the Agency on the time period around the 2002 economic census data. In addition, the Agency used 2005 costs because they are the most representative data available to the Agency, for the time period reflected in the 2002 economic census data.

The Agency requested that the Interagency Economic Peer Review Group coordinate a peer review of the final regulatory impact analysis. The peer reviews conducted by two economists from Federal agencies and the FSIS responses to their comments are available in the FSIS docket room and on the FSIS Web page with the supplemental proposed rule.

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. Should this rule become effective, the guidelines for voluntary nutrition labeling will become mandatory for these products.

FSIS is also proposing to amend its regulations to require on-package nutrition labels for ground or chopped meat and poultry products. The Agency has 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, and that these products are similar to products in the current mandatory program that are required to bear nutrition labels. Thus, under this rule, the nutrition labeling requirements for all ground or chopped meat and poultry products will be consistent with the nutrition labeling requirements for multi-ingredient and heat processed products.

The supplementary proposed rule provides for a number of exemptions, including a small business exemption. Should the rule become final, small businesses will be exempt from the requirement for nutrition labeling of single-ingredient, raw ground or chopped products. Small businesses are those with 500 or fewer employees, are owned by companies with 500 or fewer employees, and produce 100,000 pounds or less annually of each ground product affected by the rule.[1]

A. Need for the Rule

FSIS believes that less than the optimal amount of nutrition information is being provided because consumers cannot independently determine the nutritional qualities of the meat and poultry products affected by the rule, thus leading to insufficient incentives for processors and retailers to reveal the nutrient content of these products. To the extent that consumers purchase these products to achieve a nutritional objective, information about the nutritional characteristics of these products has value. Some consumers may purchase or otherwise obtain such information at a cost. However, such information may be costly to obtain for most consumers, and such information may change in value with the development of new products with different nutritional characteristics.

The association between consumption of fat, saturated fat, and cholesterol with three types of cancer and coronary heart disease is discussed in the proposed rule (66 FR 4969, January 18, 2001) and the Supplemental PRIA Benefits Analysis of this section. In 2003, there were about 39,800 deaths in the United States from breast cancer, 29,800 deaths from prostate cancer, and 57,100 deaths from colorectal cancer. There were about 515,200 deaths from coronary heart disease in 2000. Consequently, a decline in the percentage of calories from fat, saturated fat, and cholesterol can lead to a potentially significant number of deaths averted.

A substantial amount of theoretical and applied research has been conducted on the economics of consumer information since first discussed by Stigler, and subsequently by Lancaster and Rosen. Economic theory now treats information on the characteristics of a good along with information on the price of the product as major determinants of consumer choice.

A basis for required labeling exists when the market does not supply enough information to allow consumers to make consumption choices that reflect their individual preferences. Under conditions of asymmetric information, social costs and benefits

[1] It is possible that some very small establishments could potentially be affected by the requirements if they are owned by companies with more than 500 employees and they produce more than 100,000 pounds of any ground product.

may suggest a different labeling outcome than the one resulting from a private firm's labeling decision (Golan, *et al.*). Asymmetric information may particularly be a problem in markets for foods with negative credence attributes [2] as is discussed below regarding products subject to the rule.

In their examination of food consumption patterns before and after the general availability of information about nutritional characteristics, diet-disease connections, and health claims, a number of authors have confirmed the role of nutrition information in enhancing the ability of consumers to make healthier food choices (Kim *et al.,* Neuhouser *et al.,* Tiesl, *et al.* (1997, 2001), Moorman, and Ippolito and Mathios (1990b, 1991, 1995, 1998). The results of these studies are discussed in the Benefits Analysis.

Ground or chopped meat and poultry products are formulated by processors and the nutritional characteristics of these products may vary.[3] In addition, without nutrition information for the major cuts, consumers cannot assess precise levels of fat and cannot know the levels of specific nutrients in these products.[4] Major cuts are generally considered by consumers to be largely undifferentiated products in terms of nutrient content. If one supplier of major cuts provides the nutrient information, and such information is the same regardless of supplier, there is no incentive for other suppliers to incur the cost of providing the information. The extent that such information conveys a negative credence attribute would further limit its availability.

As is explained above, FSIS believes that consumers have reasonable expectations as to the nutrient content of the major cuts. Competitive pressures among processors could over time increase the supply and accuracy of such information (Ippolito and Mathios, 1991). However, the comparison between foods necessary to construct a healthy diet is made difficult if precise information about nutrient content is not provided, significantly different formats are used to provide nutrition information, or the information is difficult to interpret. Thus, the point-of-purchase (POP) nutrition information requirement and enforcement of accuracy will facilitate consumer efforts to construct a healthy diet and facilitate consumer understanding of the information provided.

There is not uniform agreement that nutrition labeling is always an effective policy measure, even if government intervention were warranted on the basis of informational needs and social welfare. Variyam, Blaylock, and Smallwood, 1995 and 1997, found that labels are not an effective means for educating consumers and changing consumption behavior. However, these papers emphasize format and context of the information as important factors affecting the influence of the information on the audience. For example, consumers are more likely to read and understand labels that are clear and concise (Hadden; Magat and Viscusi; Noah). Some of the studies cited above (Tiesl and Levy, 1997, and Ippolito and Mathios, 1995) have found that the effectiveness of nutrition labels are augmented within the context of broader nutrition education programs about diet-health linkages.

Golan, *et al.*, summarize research showing when nutrition labeling is the most appropriate policy tool. Conditions when labeling may be appropriate include:

- Consumer preferences differ. Labeling may be preferable if consumer preferences differ widely with respect to product characteristics, in this case total fat, cholesterol, saturated fat, calcium, and iron for example. As is the case for high sodium foods, consumers show significantly different attitudes to fat content.
- Information is clear and concise. To be effective, the information on the label is clear, concise, and informative. FSIS believes that this criterion will be achieved for both nutrition labels and POP information.

FSIS concludes that these conditions exist for the products subject to the rule or would be accomplished by the rule. FSIS also concludes that nutrition labels and POP information are superior to other tools such as food bans, taxes on fat content, and consumer education programs.

Ippolito and Mathios (1990a) argued that competition among food suppliers and consumer skepticism about suppliers' claims for their foods often leads to well-informed consumers. If, for example, consumers were concerned about dietary intake of sodium, a supplier with a product low in sodium would advertise that attribute. If consumers were also concerned about fat, a supplier with a low-sodium and low-fat product would advertise both attributes. Consumers would know that the low-sodium product that does not make a low-fat claim is likely a higher-fat product. And any product that is silent on both attributes is higher in sodium and fat.

But Ippolito and Mathios also argued there could be conditions under which unfolding of information fails to occur and consumers are not informed about important product attributes. Unfolding might not occur when similar products share a negative attribute, like having a high fat content when consumers are concerned about the fat content of foods. If all competing foods share a high fat content, all suppliers have products embodying a negative attribute, and no supplier would have an incentive to advertise fat content. In that case, mandatory nutrition labels might provide consumers with information they want and did not have.

From a statutory perspective, the lack of nutrition information on the labeling of the major cuts and on ground or chopped products is misleading because material facts or attributes about these products are not disclosed to the public. The FMIA and PPIA provide that product is misbranded if its labeling is false or misleading in any particular way (21 U.S.C. §§ 601(n)(1) and 453(h)(1)). Therefore, without nutrition information for the major cuts and for ground or chopped products, FSIS has concluded that these products would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA (66 FR 4974, January 18, 2001).

FSIS believes that the nutrition labeling requirements, when implemented, will provide consumers with valuable information, leading to improved dietary decisions. By increasing consumer awareness of the levels of total fat, saturated fat, and cholesterol in meat and poultry products affected by the rule, nutrition labeling may serve as a further incentive to food retailers and official establishments to provide products with reduced levels of these nutrients. FSIS has concluded that further action is necessary in order to provide consumers with adequate nutrition information.

[2] Credence attributes are characteristics of the quality of a product that the consumer cannot determine even after consumption (nutritional value, medical expertise). Credence characteristics will always require the consumer to acquire information, such as nutritional information, from the seller or third parties, whose credibility will vary.

[3] Single-ingredient, raw ground or chopped meat and poultry products is one of the two major product categories addressed in the rule. As the definition of this product does not change in the analysis, it will be referred to as ''ground or chopped products''.

[4] Major and nonmajor cuts of single-ingredient, raw meat and poultry products is one of the two major product categories addressed in the rule. The category of products will be referred to as ''major and nonmajor cuts''. In the case where only major cuts of single-ingredient, raw meat and products are considered, they will be referred to as ''major cuts''. Nonmajor cuts of single-ingredient, raw meat and poultry products will be referred to as ''nonmajor cuts''.

B. Baseline

The rule would affect Federal establishments and may affect State establishments [5] that produce ground or chopped meat and poultry products. The rule would also affect retail food establishments such as supermarkets, grocery stores, meat markets, warehouse clubs, and superstores. To be conservative, FSIS has included State establishments in this analysis. The Agency used its Performance Based Inspection System (PBIS) database of April 2006 to determine the number of active Federally-inspected establishments producing ground or chopped products affected by the rule (Table 1).

TABLE 1—SIZE DISTRIBUTION OF FEDERAL ESTABLISHMENTS PRODUCING GROUND OR CHOPPED PRODUCTS

Size	Number
Very Small (9 or fewer employees or less than $2.5 million in sales annually)	1,433
Small (10 to 499 employees)	858
Large (500 or more employees)	109
Total	2,400

Source: FSIS Performance Based Inspection System (PBIS), April 2006.

For purposes of this analysis, very small establishments, defined as those with 9 or fewer employees or less than $2.5 million in annual sales are exempt from the requirement for nutrition labeling of single-ingredient, raw ground or chopped products because they have 500 or fewer employees, are owned by companies with 500 or fewer employees, and FSIS assumes they produce 100,000 pounds or less annually of each ground product.[6] Some small establishments may also be exempt from the regulation for the same reasons that some very small establishments are exempt.[7]

Nutrition labels are designed for company-wide use. FSIS estimated the number of affected companies by dividing the number of small and large Federal establishments in Table 1 by three. Based on research, multi-establishment firms own an average of three establishments (Muth, 2003, RTI, 2003). That is, 858 small establishments + 109 large establishments /3 = 322 small and large firms. Some of these Federal establishments may be independent and may not be part of a multi-establishment firm. Similarly, some very small establishments may be part of a multi-establishment firm. Therefore, this is an area of uncertainty in the analysis. However, FSIS believes its assumptions are reasonable for purposes of estimating costs.

In addition, the Agency used the PBIS to estimate the number of active State establishments producing single-ingredient, raw ground or chopped meat and poultry products that would be affected by the rule (Table 2). The information in PBIS on State establishments may not be complete. Thus, the Agency may be underestimating the number of State establishments, or the total number of these establishments that would be affected by the rule.

TABLE 2—SIZE DISTRIBUTION OF STATE ESTABLISHMENTS PRODUCING GROUND OR CHOPPED PRODUCTS

Size	Number of establishments
Very Small (9 or fewer employees or less than $2.5 million in sales annually)	632
Small (10 to 499 employees)	41
Large (500 or more employees)	0
Total	673

Source: FSIS Performance Based Inspection System (PBIS), April 2006.

Most, if not all, of these State establishments may be independent and may not be part of a multi-establishment firm. Very small State establishments are exempt from the requirement for nutrition labeling of ground or chopped products because they have 500 or fewer employees, and the agency has assumed that they are owned by companies with fewer than 500 employees and produce 100,000 pounds or less annually of each ground product. Some small State establishments may also be exempt from the regulation for the same reasons that some very small Federal establishments are exempt. Nutrition labels are designed for company-wide use. Thus, for purposes of the analysis the number of small State establishments and firms are the same.

The total estimated number of meat and poultry processing firms is 363 firms (322 firms with establishments + 41 firms with State establishments) that would be producing ground or chopped meat and poultry products that would be affected by the rule.

Based on the U.S. Economic Census for 2002, there are 47,688 retail firms and 74,910 retail establishments that would be affected by the POP requirements for the major cuts of meat and poultry (Table 3). Despite FSIS encouragement of retailers' use of (POP) materials for the major cuts, the October 1999 voluntary nutrition labeling survey

[5] Unless stated otherwise, when discussing meat and poultry processing establishments, Federally-inspected establishments will be referred to as ''establishments''. State-inspected establishments will be referred to as ''State inspected establishments''.

[6] It is possible that some very small establishments could potentially be affected by the requirements if they are owned by companies with more than 500 employees and they produce more than 100,000 pounds of any ground product. However, FSIS has concluded that this is a reasonable criterion for defining very small establishments that would be exempt from certain provisions of the rule. FSIS has not received public comment objecting to the use of this criterion and does not believe that establishments would alter their operations to meet this criterion.

[7] The PBIS does not include data on the size of the owning company or on processed food volumes. Therefore, it is not possible to determine whether some of these establishments qualify for the small business exemption.

(USDA, 1999) found a lower rate (54.7 percent of retail stores) of participation than the December 1996 survey (USDA, 1996) found (57.7 percent of retail stores). The effect of existing compliance reduces the cost impacts of the rule are shown in Appendices C and D and are discussed below.[8]

TABLE 3—NUMBER OF RETAIL FIRMS AND ESTABLISHMENTS AFFECTED BY POP NUTRITION INFORMATION REQUIREMENTS FOR MAJOR CUTS OF MEAT AND POULTRY

NAICS code	NAICS description	Firms	Establishments
445110	Supermarket and other grocery (except convenience stores)	42,318	66,150
445210	Meat markets	5,354	5,848
452910	Warehouse clubs and superstores	16	2,912
Total		47,688	74,910

Note: NAICS is North American Industry Classification. A ''firm'' refers to the parent company and an ''establishment'' refers to the retail facility.
Source: U.S. Department of Commerce, U.S. Bureau of the Census—2002 Economic Census, November 2005. ''Establishment and Firm Size: Retail Trade.'' EC02–44SS–SZ. Washington, DC: U.S. Department of Commerce.

Table 4 shows the number of large retail firms and establishments affected by nutrition labeling requirements for ground or chopped products. About 23,479 retail establishments are owned by about 266 companies that have 500 or more employees. Table 5 shows the estimated number of small retail firms and establishments that would be affected by nutrition labeling requirements for ground or chopped products, if there were no waiver related to the use of a ''percentage-lean/percentage-fat'' statement. About 51,431 retail establishments are owned by the 47,422 firms that have less than 500 employees. This policy is discussed below.

TABLE 4—ESTIMATED NUMBER OF LARGE RETAIL FIRMS AND ESTABLISHMENTS AFFECTED BY NUTRITION LABELING REQUIREMENTS FOR GROUND OR CHOPPED MEAT AND POULTRY PRODUCTS

NAICS code	NAICS description	Firms	Establishments
445110	Supermarket and other grocery store (except convenience stores)	253	20,434
445210	Meat markets	2	142
452910	Warehouse clubs and superstores	11	2,903
Total		266	23,479

Note: NAIC is North American Industry Classification. A ''firm'' refers to the parent company and an ''establishment'' refers to the retail facility.
Source: U.S. Department of Commerce, U.S. Bureau of the Census—2002 Economic Census, November 2005. ''Establishment and Firm Size: Retail Trade.'' EC02–44SS–SZ. Washington, DC: U.S. Department of Commerce.

TABLE 5—ESTIMATED NUMBER OF SMALL RETAIL FIRMS AND ESTABLISHMENTS AFFECTED BY NUTRITION LABELING REQUIREMENTS FOR GROUND OR CHOPPED MEAT AND POULTRY PRODUCTS, WHEN THE ''PERCENT-LEAN/PERCENT-FAT'' LABEL IS NO LONGER WAIVED FOR THESE PRODUCTS

NAICS code	NAICS description	Firms	Establishments
445110	Supermarket and other grocery store (except convenience stores)	42,065	45,716
445210	Meat markets	5,352	5,706
452910	Warehouse clubs and superstores	5	9
Total		47,422	51,431

Note: NAIC is North American Industry Classification. A ''firm'' refers to the parent company and an ''establishment'' refers to the retail facility.
Source: U.S. Department of Commerce, U.S. Bureau of the Census—2002 Economic Census, November 2005. ''Establishment and Firm Size: Retail Trade.'' EC02–44SS–SZ. Washington, DC: U.S. Department of Commerce.

Should it become final, the rule would affect an estimated 21.6 billion pounds of meat and poultry products. Of this amount, 16.7 billion pounds are major cuts of single-ingredient, raw products and 4.9 billion pounds are ground or chopped meat and poultry products. The amount of ground or chopped product subject to the provisions by the rule is reduced from an estimated 6.2 billion pounds as a result of exemptions to small businesses. There are approximately 2.9 billion pounds of nonmajor cuts. These products are not affected by the final rule; however they are affected by the requirements of Alternatives 2 and 5 discussed in the following section. The source and derivation of these estimates are provided in Appendix A, Tables 1–4 and discussed in the Cost Effectiveness Analysis.

These estimates, however, do not take into account the level of voluntary compliance with the nutrition labeling requirements for ground or chopped products that currently exists. Consequently, the estimated amounts of ground or chopped products and major cuts that would be impacted by the final rule are overstated. However, in the analysis that follows we take into account the 68 percent compliance rate

[8] The appendices supporting the economic analysis are available from the FSIS docket room and at *http://www.fsis.usda.gov/regulations_&_policies/2009_Proposed_Rules_Index/index.asp*.

(NCBA, 2004) of voluntary nutrition labeling of ground or chopped products and 54.8 percent level of voluntary compliance (USDA, 1999) of stores that provide nutrition labeling for major cuts.

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. USDA conducted three separate one-year surveys for 1994–96 (USDA, 1994–1996). 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 Benefits Analysis (Table 15) where they are used to establish a baseline for intake of fat, saturated fat, and cholesterol. Additional information is then used to estimate the impacts of label usage on dietary intakes of these nutrients, and the resulting human health effects.

C. Regulatory Alternatives

FSIS considered several regulatory alternatives:

- *Alternative 1:* Continuing with the existing voluntary program;
- *Alternative 2:* Making the voluntary program mandatory;
- *Alternative 3 (the supplemental proposed rule):* Requiring nutrition information on labels of all ground or chopped products and making the voluntary program mandatory for the major cuts;
- *Alternative 4:* Requiring nutrition information on labels of the major cuts and on all ground or chopped products; and
- *Alternative 5:* Requiring nutrition information on labels of major and nonmajor cuts and all ground or chopped products.

The provisions for the regulatory alternatives are summarized in the following table.

TABLE 6—NUTRITION LABELING REQUIREMENTS UNDER REGULATORY ALTERNATIVES

	Type of product		
Regulatory alternative	Ground or chopped products	Major cuts of single ingredient, raw products	Nonmajor cuts of single-ingredient, raw products
Alternative 1; (Status quo/current requirements).	On-package nutrition labeling is not required for ground or chopped products that are raw, single-ingredient.	Voluntary program: nutrition information can be on package or at point of purchase.	Voluntary program: nutrition information for these products is not required. However, if nutrition information is voluntarily provided for these products, it must be consistent with the nutrition information required for the major cuts of single-ingredient, raw products.
Alternative 2	Mandatory nutrition labeling requirements. Nutrition information must be provided on package or at the point of purchase. The analysis assumes that a reference manual is provided at the point of purchase which contains the required nutrition information.	Mandatory nutrition labeling requirements. Nutrition information is provided on package or at the point of purchase. The analysis assumes that a reference manual is provided at the point of purchase which contains the required nutrition information.	Mandatory nutrition labeling requirements. Nutrition information is provided on package or at the point of purchase. The analysis assumes that a reference manual is provided at the point of purchase which contains the required nutrition information.
Alternative 3 (Supplemental Proposed Rule provisions).	On-package nutrition labeling is mandatory for all ground or chopped products, including those that are single ingredient, raw products.	Mandatory nutrition labeling requirements. Nutrition information must be provided on package or at the point of purchase. The analysis assumes that placards conveying the required nutrition information will be located at the point of purchase.	Nutrition information for these products is not required. However, if nutrition information is voluntarily provided for these products, it must be consistent with the nutrition information required for the major cuts of single-ingredient, raw products.
Alternative 4	Same as Alternative 3	On-package nutrition labeling is mandatory for these products.	Nutrition information for these products is not required. Nutrition information can be provided on the label or by POP.
Alternative 5	Same as Alternative 3	Same as Alternative 4	On-package nutrition labeling is mandatory for these products.

Uncertainty analyses are conducted to estimate cost distributions for each of the alternatives and the supplemental proposed rule. The stochastic cost model uses @RISK (Version 4.5, Palisades Corp.) to examine the effects of uncertainty. The model, statistical properties, assumptions, documentation, and results are presented in the tables of Appendix B and Appendix D, Tables 2 and 3.[9]

Alternative 1: Continuing With the Voluntary Program

FSIS considered continuing with the existing voluntary program and attempting to increase participation by providing additional assistance to the non-participants. FSIS considered providing nutrition information or POP materials directly to retail stores to encourage their participation in the voluntary nutrition labeling program and providing POP material files on the FSIS Web site that retailers could print and place in their stores.

Under this alternative, 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, 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.

FSIS's efforts to provide nutrition information or POP materials to retail stores to encourage their participation in the voluntary nutrition labeling program and to provide POP material files on the FSIS Web site could lead to additional participation in the voluntary nutrition labeling program. However, FSIS did not choose this alternative because, even though its cost is relatively low, the benefits of the alternative are also relatively low. This option would not ensure that nutrition information is provided for the major cuts of single-ingredient, raw meat and poultry products. In addition, FSIS did not choose this alternative because the Agency has determined that ground or chopped 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. Therefore, POP materials would not be adequate to provide nutrition information for these products.

Alternative 2: Make the Voluntary Program Mandatory

FSIS considered making 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 and the nonmajor cuts of single-ingredient, raw meat and poultry products. Under this alternative, FSIS would assume that most retailers would display POP information for these products rather than nutrition labels, because this is a low-cost means of providing nutrition information for multiple products.

FSIS believes the vehicle chosen by retail establishments for displaying nutrition information at the point of purchase for all major and nonmajor cuts of single-ingredient, raw meat and poultry products would be a reference manual, because placards covering all the major and nonmajor cuts would take up product display space and result in visual clutter. In addition, a manual may be easier for consumers to use than numerous placards covering all major and nonmajor cuts, and all the numerous formulations of ground or chopped meat and poultry products. A manual about the size of the *Uniform Retail Meat and Identity Standards* publication could include nutrition information for all the major and nonmajor cuts, including nutrition information for numerous formulations of ground or chopped products. The *Uniform Retail Meat and Identity Standards* publication is approximately 100 pages, with a page size of 8½x11, in a three-ring binder. The publication provides meat identification standards for all cuts. However, the publication does not provide nutrition information or information on poultry cuts. Such information would have to be assembled from other sources for inclusion in the manual.

This publication, including shipping and handling costs, is available for purchase through the National Cattleman's Beef Association for a minimum cost of $97.50; most-likely cost of $100.00; or a maximum cost of $102.50. In the cost analysis of the alternative chosen, FSIS estimated there are about 74,910 retail establishments (Table 3). FSIS assumed that the manual would be replaced annually. FSIS estimated the labor cost of displaying POP information for the major cuts at $21.11 per hour.[10] The time to obtain and make available POP information for the major cuts per store, an average of 0.5 hour, is the same as that used to estimate the cost of Alternative 3, the supplemental proposed rule. Based on these estimates, the annual costs of this alternative is estimated to be $8,281,675.[11] This estimate is comprised of $790,675 for labor costs (74,910 establishments × $21.11/hour × .5 hours) and $7,491,000 for the cost of the reference manual (74,910 × $100.00/establishment). The average present value of this cost is estimated at $87.74 million[12] when discounted at 7 percent over 20 years.[13]

This alternative would be less expensive than the alternative chosen by the Agency. As explained in the preamble to the proposed rule, FSIS is unable to distinguish between the benefits that would accrue from requiring nutrition labels on products versus nutrition information on POP materials (66 FR 4984–4985, January 18, 2001). Research is not available to differentiate the benefits of nutrition information on labels versus nutrition information on displays. This is a significant area of uncertainty in analyzing benefits of the regulatory alternatives.

The benefits of this alternative may be comparable to the benefits of the alternative chosen if POP nutrition information and on-package labels have roughly the same amount of success[14]

[9] The stochastic model structure or framework, equation specification, statistical properties, assumptions, documentation, and results are presented in the tables of Appendix B and in Appendix D, Tables 2 and 3. In most cases, the minimum (low), maximum (high), and most-likely or mid-points values are to be found in the tables of Appendix B. In general, the values used represent information collected by RTI for the FDA Labeling Model, or other studies such as the NCBA surveys. Other values were assumed to be around a point-value that was collected by RTI, NCBA, or other referenced studies. Assumptions are made and tested for their effect on average cost of the alternatives considered. The results are in tables of Appendix B, and in Appendix D, Table 1 that has the summary of additional costs by alternative. In addition, Appendix D, Tables 2 and 3, have the detailed stochastic model framework of the economic analysis, and results of the preferred Alternative 3.

[10] Department of Labor, 2002. This wage represents an appropriate wage for a combination of managerial and regular staff that would be making available POP materials for major cuts and includes wages of $15.62 and fringe benefits of $5.49 per hour.

[11] This average annual cost has a range of variability of $8.03 million at the 5th percentile and 8.53 at the 95th percentile (*see* Appendix B, Table 10 and Appendix D, Table 1).

[12] This average annual cost has a range of variability of $85.10 million at the 5th percentile and $90.83 million at the 95th percentile (*see* Appendix B, Table 10 and Appendix D, Table 1).

[13] All present value calculations in the analysis of both costs and benefits use a 20-year time horizon.

[14] The term ''success'' or ''successful'' is used to aid the discussion in the cost effectiveness analysis where the effectiveness of the regulatory alternatives is discussed under scenarios where the impact (''success'') of POP nutrition information is varied relative to that of on-package nutrition labels in leading to dietary change. The use of the same term to refer to two different types of comparisons is intended to clarify the discussion.

in leading to dietary change.[15] However, because there are numerous formulations of ground or chopped products, it would be difficult for producers or retailers to develop POP 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 POP materials that include information concerning numerous formulations of these products (66 FR 4977, January 18, 2001). To use POP materials only, without nutrition labels, consumers would have to find the nutrition information for a specific fat and lean formulation among multiple formulations. If a statement of the fat percentage is not included on a package of ground products, consumers would not know which nutrient data concerning ground product on POP materials would apply to that particular ground product. Therefore, because this option may not result in benefits associated with the consumption of ground or chopped products, this option would likely result in lower benefits compared to the option chosen. In addition, FSIS did not choose this alternative because it does not allow for any distinction between major and nonmajor cuts. FSIS has determined that it is not appropriate or necessary to require nutrition information for nonmajor cuts that are not ground or chopped at this time.

Alternative 3 (Supplemental Proposed Rule): Require Nutrition Information on Labels of All Ground or Chopped Products and Make the Voluntary Program Mandatory for the Major Cuts (Other Than Ground Beef, Ground Pork)

Should this rule become final, it will require nutrition information on the labels of all ground or chopped products and requires nutrition information, either on their labels or at their POP, for the major cuts of single-ingredient, raw products, unless such products qualify for an exemption. Under this alternative, retail establishments and processors of meat and poultry products 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 products and other cuts. It also allows for a distinction between major and nonmajor cuts.

Consistent with the regulations, the most recent voluntary nutrition labeling survey (USDA, 1999) only assessed whether retail stores provided nutrition labeling 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.

The derivations of the costs of Alternative 3 are shown in the section, Supplemental PRIA Cost Analysis. The average total present value of the costs of this alternative is $348.06 million, assuming retailers select the lower cost compliance option (Table 14). The average annualized cost associated with this alternative is $32.85 million. As is shown in the section, Supplemental PRIA Benefits Analysis, the present value of the benefits of this alternative is $2.2 billion if POP nutrition information for the major cuts is as successful as on-package labels in leading to dietary changes. The annualized benefit associated with this alternative is $205.5 million. These estimates are not adjusted to account for current compliance, thus over estimate costs and benefits from saved lives.

Alternative 4: Require Nutrition Information on Labels of the Major Cuts and on All Ground or Chopped Products

FSIS considered requiring nutrition information only on labels of the major cuts and on all other ground or chopped products not covered in §§ 317.344 and 381.444.[16] As in Alternative 3, establishments could voluntarily provide nutrition information, either at the POP or on the label, for the nonmajor cuts that are not ground or chopped. This approach allows for a distinction between major cuts and nonmajor cuts that are not ground or chopped.

FSIS estimates that packages of single-ingredient, raw major cuts, including ground beef and ground pork, represent at a minimum 80 percent, most-likely 85 percent, and at a maximum 90 percent of all packages of single-ingredient, raw meat and poultry products sold through retail stores. Therefore, FSIS estimates the minimum, most-likely, and maximum costs of this alternative would be the same as these percentages of the costs of Alternative 5, which requires nutrition information on the package labels of all major and nonmajor cuts sold through retail stores. FSIS has based these percentages on a previous determination by FSIS that the major cuts are representative of the market (56 FR 60307, November 27, 1991) and are the most popular cuts (56 FR 60320). Comments on the 1991 nutrition labeling proposal generally supported the list of major cuts (58 FR 640, January 6, 1993). Similarly, one comment to the January 18, 2001, proposed rule on nutrition labeling stated that the major cuts represent the greatest share of fresh meat consumption. The cost analysis of Alternative 5 follows this discussion.

FSIS estimates the average present value of the costs of this alternative to be $812.99 million ($956.5 million, the average present value cost of Alternative 5, × .85). The average annualized cost associated with this alternative is estimated at $90.28 million.

The benefits of this alternative would be similar to those of the selected alternative if POP nutrition information and on-package labels are equally successful at leading to dietary change. The pounds of product requiring nutrition labeling are the same for both Alternatives 3 and 4. However, this alternative would be significantly more costly than the alternative chosen, because this alternative would require on-package nutrition labels on a large volume of product that are not required to bear labels under Alternative 3.

These estimates are not adjusted to account for current compliance, thus over estimate costs and benefits from saved lives.

Alternative 5: Require Nutrition Labels on All Single-Ingredient, Raw Meat and Poultry Products and on All Ground or Chopped Products

FSIS considered requiring nutrition information on labels of major cuts and nonmajor cuts of single-ingredient, raw meat and poultry products, and on labels of ground or chopped products, unless an exemption applied.

The supplemental PRIA cost analysis for the alternative chosen calculated the costs of requiring nutrition labels on all ground or chopped products. FSIS calculated the costs of requiring labels on all other major and nonmajor cuts of single-ingredient, raw products that are not ground or chopped. The same method for estimating the labeling cost for all ground and chopped products under the alternative chosen was used to estimate the labeling costs for major

[15] As the success of point-of-purchase information declines relative to on-package nutrition labels, there is a proportional decline in dietary changes and consequently a proportional decline in lives saved associated with that measure, given the differences in that amount of product affected.

[16] Ground or chopped products or not covered in §§ 317.344 and 381.444 will be referred to as ''ground or chopped products'' in the remainder of the final regulatory impact analysis.

and nonmajor cuts of single-ingredient, raw products under Alternative 5.

Table 7 shows the number of Federal establishments producing major or nonmajor cuts that are not ground products. Many of these establishments have a mix of operations that fabricate a variety of cuts derived from multiple species in the same establishment. This is especially prevalent in small and very small sized establishments. Thus, the totals of the columns or the rows in this table do not represent the total number of establishments under Federal inspection due to double counting.

TABLE 7—FEDERAL ESTABLISHMENTS THAT FABRICATE MAJOR OR NONMAJOR CUTS THAT ARE NOT-GROUND PRODUCTS

Product	Size			
	Large	Small	Very small	Unknown
Meat:				
Beef	52	886	1303	28
Pork	56	750	1155	23
Lamb	0	319	575	11
Other meat	3	186	338	4
Poultry:				
Chicken	158	611	698	15
Turkey	38	210	264	5
Other poultry	0	0	2	0

Note: Data is from the Performance Based Inspection System (PBIS) April 2006.

Consistent with the supplemental PRIA cost analysis for the selected alternative, FSIS estimates that very small establishments would be exempt from nutrition labeling requirements because they have 500 or fewer employees, are owned by companies with 500 or fewer employees, and FSIS assumes they produce 100,000 pounds or less annually of each product. Also, FSIS assumes that all ''small'' establishments are owned by large, multi-establishment firms and would not qualify for this exemption. Nutrition labels are designed for company-wide use. FSIS estimated the number of affected companies by dividing the number of small and large establishments in the table above by three, the number of establishments owned on average by multi-establishment firms (Muth, 2003; RTI, 2003). FSIS assumed establishments of unknown size are either large or small, to ensure that the Agency did not underestimate the number of affected establishments.

In addition, there are about 41 State establishments that are small that would likely be affected by this rule. Little information is available to the Agency about the number of firms that represent the 41 State establishments. However, it is likely that the 41 State establishments are owned by 41 firms. There are no State establishments that are large. The analysis assumes that State establishments that are small would be affected. Furthermore, the Agency does not have data for these 41 State establishments on the fabrication of major or nonmajor cuts of single-ingredient, raw products. Therefore, the Agency may be underestimating the number of affected firms that own small or large processing establishments that fabricate major and nonmajor cuts.

Thus, the final estimates of the number of affected firms that own small or large processing establishments that fabricate major and nonmajor cuts that are not ground are: 322 beef firms; 276 pork firms; 110 lamb firms; 64 ''other'' meat firms, including goat processors; 261 chicken firms; and 84 turkey firms.[17]

To estimate the average number of cut products fabricated per firm, FSIS estimated that all firms would fabricate all the major cuts (except the ground major cuts, because FSIS has already accounted for those) and an additional 3 nonmajor cuts. FSIS estimated that beef firms would typically fabricate 12 major products; pork firms, 9; lamb firms, 6; chicken firms, 5; and turkey firms, 5 major products. Therefore, the total number of major and nonmajor products fabricated by beef firms is 15 products; pork firms, 12; lamb firms, 9; chicken firms, 8; and turkey firms, 8. FSIS then assumed processors of ''other'' meat products would fabricate 12 products (similar to the number of beef or pork products). In the table above, the PBIS figures for beef processors include veal processors. For purposes of this analysis, FSIS considered the number of major beef cuts rather than veal cuts, because beef is more widely produced and consumed than veal.

FSIS estimated the average, one-time cost to modify on-package labels for prepackaged meat and poultry product by multiplying the average per label modification cost ($2,274 as shown in the Supplemental PRIA Cost Analysis) by the number of affected firms and by the number of products per firm. Based on this formula and the numbers of firms and products shown above, the estimated average label modification costs are: beef and veal firms, $10.85 million ($33,700/firm); pork firms, $7.44 million ($27,000/firm); lamb firms, $2.22 million ($20,000/firm); other meat firms, 1.73 million ($27,000/firm); chicken firms, $4.69 million ($18,000/firm); and turkey firms, $1.51 million ($18,000/firm). The total, one-time average costs of designing labels would be $28.45 million.

In addition to the one-time average costs of designing labels, companies will also incur costs for providing larger labels with nutrition information. To calculate this cost, FSIS estimated that there are 11.25 billion packages (15 billion[18] retail packages of all raw meat and poultry × 75 percent[19] that are single-ingredient, raw packages) of major and nonmajor cuts sold through retail establishments.

Furthermore, in the supplemental PRIA cost analysis for the alternative

[17] The number of firms affected is derived by summing the number of large establishments, small establishments, and establishments of unknown size for each type of species in Table 7 and dividing by 3, the average number of establishments owned by a firm.

[18] The safe handling rule estimated that there were 15 billion retail packages of raw meat and poultry products (58 FR 58925).

[19] Based on information from the July 2004 National Conference on Weights and Measures held in Pittsburgh, PA, FSIS estimates that 25 percent of retail packages of meat and poultry are products with added solutions. Therefore, FSIS estimates that 25 percent of retail packages of fresh meat and poultry products are multi-ingredient products for which nutrition labeling information is already required, unless an exemption applies. Thus, 75 percent (100 percent minus 25 percent) of retail packages of raw meat and poultry products are single-ingredient products for which nutrition labeling information is now required, unless an exemption applies.

chosen, FSIS estimated that there are 2.267 billion packages of ground or chopped products (*see* Appendix B Table 8). Therefore, FSIS estimates that there are 8.983 billion packages (11.25 billion packages of all meat and poultry minus 2.267 billion packages of ground or chopped products) of major and nonmajor cuts that are not ground or chopped sold through retail establishments.

FSIS estimates that 25 percent of 8.893 billion packages of single-ingredient, raw major and nonmajor cuts that are not ground or chopped are packaged by processing establishments, or 2.246 billion packages (8.893 billion packages × 25 percent). Based on information collected by RTI, a blank label is assumed to have a minimum cost of $0.002; most-likely cost of $0.005; and a maximum cost of $0.008. Multiplying 2.246 billion packages by the annual added average cost of $0.005 per label results in an average cost of approximately $11.23 million (2,246 billion packages × $0.005 per label) annually. Total first-year costs (one-time and annual recurring) to processing establishments would be $39.68 million ($28.45 million for one-time cost + $11.23 million annual recurring cost).

Only retail establishments that have 500 or more employees will be affected by nutrition labeling requirements for major and nonmajor cuts because it is not likely that others would produce 100,000 pounds per single-ingredient, raw product. Table 4 shows that 23,479 retail facilities are owned by companies that have 500 or more employees. The stores are owned by 266 firms.

Retail establishments subject to the requirements of the rule could comply by either incorporating nutrition information on the label printed by store scale printer systems (option 1) or by applying an additional preprinted label with nutrition information (option 2).[20] The supplemental PRIA cost analysis for the Alternative chosen shows that option 1 is the less expensive option. Therefore, FSIS assumes stores would choose this option under Alternative 5 as well. FSIS also assumes that, on average, the estimated total cost to upgrade printer scales to provide store-printed labels is $56.35 million (23,479 retail establishments × $2,400 per establishment). The analysis assumes that scales with the added features for making store-printed labels are replaced every five years. The annual maintenance costs for the upgraded scale printer is estimated to be 6 percent of $2,400 or $144 every year after a scale printer has been purchased equal to $3.38 million (23,479 retail establishments × $144 per establishment). FSIS is including these costs here, in addition to the costs for nutrition labeling of ground or chopped products, because FSIS assumes that retail stores would need to have additional scale printers to apply labels to major and nonmajor cuts that are not ground or chopped.

The supplemental PRIA cost analysis shows that for retail stores the average one-time cost estimates for redesigning labels is $0.414 million (Appendix B, Table 3). FSIS is including this cost here and in the ground or chopped products labeling costs to ensure that FSIS does not underestimate the costs of this alternative.

The supplemental PRIA cost analysis estimates that each processor company produces an average of 6.6 unique ground or chopped products (*see* Appendix B, Table 2), that each retail firm and meat market firm offers an average of 4.6 unique ground or chopped products (4.6/6.6 or 69 percent of the number of ground or chopped products produced by processors), and that each warehouse club firm offers an average of 1.33 unique ground or chopped products (1.3/6.6 or 20 percent of the number of ground or chopped products sold by processors, (Appendix B, Table 9).

Excluding ground or chopped products, FSIS estimates that retail and meat market firms package 69 percent of the total number or major and nonmajor cuts produced by establishments. Consequently, these firms would package on average 10.35 beef products, 8.28 pork products, 6.21 lamb products, 5.52 chicken products, 5.52 turkey products; and 8.28 other meat products. Excluding ground or chopped products, FSIS estimates that warehouse club firms package 20 percent of the total number of major and nonmajor cuts by processors. Consequently, these firms would package an average of 3 beef products, 2.4 pork products 1.8 lamb products, 1.6 chicken products, 1.6 turkey products, and 2.4 other meat products. Therefore, FSIS estimates that each retail and meat market firm packages an average of 44.16 unique major and nonmajor cuts. FSIS also estimates that each warehouse club firm packages an average of 12.8 unique major and nonmajor cuts.

Therefore, an average of 11,402 unique major and nonmajor cuts will require nutrition labels applied in retail facilities ((44.16 products × 255 supermarket, grocery store and meat market firms) + (12.8 products × 11 warehouse club and superstore firms)).

Consistent with the cost analysis of the chosen alternative, the average one-time cost to retailers affected by the rule for the nutrition analyses of major and nonmajor cuts[21] is $7.87 million (11,402 unique products × $690 average cost of a nutrition analysis, Appendix B, Table 3).

The use of larger labels is another cost that retail stores may incur. If retail stores package 75 percent of total single-ingredient, major and nonmajor cuts that are not ground or chopped, then an average of 6.737 billion packages (8.983 billion packages × 75 percent) are packaged by retail stores annually. If the added average cost of each label is $0.005 (as assumed in the cost analysis for the alternative chosen), then retailers affected by the rule will incur an added average annual cost of about $33.68 million.

A summary of the frequency of various labeling costs for single-ingredient, raw products for Alternative 5 are shown in Table 8. A summary of the costs for Alternative 5 are shown in Table 9 and in Appendix D.

Alternative 5 is the most expensive alternative that FSIS considered. This alternative would require labels on a larger volume of product than would Alternative 4. As with Alternative 4, this alternative would require labels on a large volume of product not currently required to bear labels.

[20] Options 1 and 2 are described in the Final Rule *Cost Analysis.*

[21] A nutrition analysis is required to create a Nutrition Facts panel. Nutrition information is available from FSIS and other sources for many ground or chopped products, and major and nonmajor cuts of meat and poultry products.

TABLE 8—FREQUENCY OF LABELING COSTS FOR SINGLE-INGREDIENT, RAW MEAT AND POULTRY PRODUCTS, EXCLUDING COST FOR GROUND AND CHOPPED PRODUCTS

Item	Frequency of cost *			
	One-time	Recurring		
	1st year only	Annual	1st year & once/5 years	Other **
	$ Million			
Processing:				
Modify Labels	28.45			
Use larger labels		11.23		
Retail:				
Upgrade printer scales			56.35	
Printer Maintenance				3.38
Redesign larger labels	0.414			
Use larger labels		33.68		
Nutrition analysis	7.87			

* All costs are average costs as derived in Appendix B.
** Costs for printer maintenance occur annually, except for years in which a printer is purchased.

TABLE 9—AVERAGE PRESENT VALUE AND ANNUALIZED COSTS * FOR ALTERNATIVE 5

	Present value 3%	Present value 7%	Annualized 3%	Annualized 7%
	$ Million			
Ground and chopped product:				
Processing	47.70	35.28	3.21	3.33
Retail	381.71	281.70	25.66	26.59
Total ground and chopped	429.41	316.98	28.86	29.92
Raw, single-ingredient cuts:				
Processing	217.33	159.87	14.61	15.09
Retail	652.00	479.62	48.82	45.27
Total raw, single-ingredient cuts	869.33	639.49	58.44	60.36
Total, All Products	1,298.82	956.54	87.20	90.28

* These estimates are not adjusted to account for current compliance, thus over estimate costs.

The benefits of this alternative are comparable to the alternative chosen after taking into account the amount of nonmajor cuts covered by this alternative and on the condition that POP nutrition information is equally as successful as on-package labels in leading to dietary change.

Summary Comparison of Regulatory Alternatives

The Analysis of Alternatives section provides an in-depth comparison of the regulatory alternatives, including a cost-effectiveness analysis. This comparison takes into account the relative success of POP nutrition information compared to on-package nutrition information labels, and the cost of each measure (form in which nutrition information is provided) for the products affected. The discussion of cost-effectiveness centers on Tables 26–29.

D. Costs and Benefit of the Supplemental Proposed Rule

1. Supplemental PRIA Cost Analysis

FSIS analysis of this rule includes many of the same assumptions that were used in the proposed rule. In most cases, FSIS believes that the initial assumptions are still valid. No new data has been presented refining or disputing these original assumptions. However, in other cases FSIS and RTI were able, based upon more current information, to change and improve the original assumptions.

PRIA vs. *supplemental PRIA:* The PRIA 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). In the PRIA, FSIS adjusted the costs of the safe handling rule to reflect the costs related to the volume of ground or chopped products produced. For fixed costs associated with nutrition labeling of ground or chopped products, FSIS assumed 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. Therefore, FSIS estimated the fixed costs for the nutrition labeling of ground or chopped products would total 20 percent of the estimated fixed safe handling labeling costs: $10 million to $20 million for processors and $28.8 million to $43.2 million for retailers (66 FR 4986, January 18, 2001).

The estimates of operating costs to retail establishments in the PRIA are based on the number of packages of ground or chopped products that would be sold through small and large retail stores and the labeling costs per package based on the safe handling labeling costs. FSIS multiplied the estimated

number of ground or chopped products sold through large retail stores by the safe handling label cost for large retail stores to derive an estimate of $6 million in annual operating costs for these stores. Similarly, FSIS multiplied the estimated number of packages of ground or chopped products sold through small retail stores by the safe handling label costs for small retail stores to derive an annual estimate of $4 million in costs for these establishments (66 FR 4988, January 18, 2001). FSIS explained that these operating costs would increase by $2 million to $12 million in current prices. FSIS also estimated the labor costs of small firms applying a separate nutrition label would be $.6 million, based on safe handling label costs (66 FR 4988, January 18, 2001). FSIS assumed processors would incur no additional operating costs associated with nutrition labeling ground or chopped products.

FSIS also estimated one-time paperwork burden costs for nutrition labels on ground or chopped products of $8.8 million. These paperwork burden costs were the estimated costs of label development, recordkeeping, and the costs of submitting label approval applications to FSIS (66 FR 4988, January 18, 2001).

Finally, FSIS estimated that the average time for each retail establishment to obtain POP materials that include nutrition information for the major cuts of single-ingredient, raw meat and poultry products would be 30 minutes. Based on labor costs of $20 per hour, FSIS estimated that total retail costs for obtaining these materials would be $0.7 million. (66 FR 4985–4986, January 18, 2001). The PRIA did not estimate any other costs associated with retailers obtaining or maintaining POP materials.

The revisions in the supplemental PRIA are based on additional information available to FSIS, improved analytical methods, and a more accurate characterization of the impacts of the rule. FSIS revised the supplemental PRIA in response to concerns expressed during the Interagency review of the PRIA about data quality and in response to final guidelines issued by the Office of Management and Budget (OMB, 2002) to Federal Agencies after publication of the proposed rule.

The supplemental PRIA assumes that no establishment or retail facility has incurred any costs associated with the requirements of this regulation prior to its effective date, even though many firms have already been providing the information that is being required.[22] Rather than prorate cost estimates in the safe handling rule based on the volume of ground or chopped products, the supplemental PRIA includes estimates for itemized costs that pertain specifically to nutrition labels. For processing firms, these costs in the supplemental PRIA include administrative costs, graphic design costs, prepress activities costs, plate engraving costs, nutrition analysis costs, and the costs of larger labels.

The supplemental PRIA explains that if retail firms choose to use store scale-printers to print nutrition labels for ground or chopped products, costs to these retailers would include upgrading store scales-printers to include nutrition information, redesigning larger store labels, providing a nutrition analysis for each product, and using larger labels. This method of labeling is referred to as ''Option 1'' in the analysis. If retail firms choose to apply an additional preprinted label with nutrition information to ground or chopped products, the cost to these retail stores would include designing a one-color nutrition label, conducting a nutrition analysis for each product, and purchasing and applying a separate label on packages of ground or chopped product at the retail level. This method of labeling is referred to as ''Option 2'' in the analysis.

The supplemental PRIA assumes that labels will be redesigned for company-wide use. The supplemental PRIA also assumes that small and large plants are owned by large, multi-firm establishments. In addition, the supplemental PRIA assumes that retail stores or chains with fewer than 500 employees produce 100,000 pounds or less annually of each ground or chopped product and are exempt from the nutrition labeling requirements for ground or chopped products. In the supplemental PRIA, the average material and labor cost for POP placards have been revised.

The benefits analysis is revised from the PRIA to reflect a constant value for each premature death prevented by the requirements of the rule to update cost to 2002 dollars. The value of preventing a premature death varied on the basis of age in the benefits analysis of the PRIA. Because of these changes, the benefits in the supplemental PRIA are higher than those of the PRIA.

TABLE 10—AVERAGE COSTS IN THE SUPPLEMENTAL PRIA

Bases of estimates	Total 1st year costs	Present value 7%	Present value 3%
	$ Million		
Retail costs, including POP materials: Option 1	75.58	312.77	424.53
Retail costs, including POP materials: Option 2	50.83	564.36	790.70
Costs to processors only	7.81	35.28	47.70
Total costs (Option 1)	83.38	384.06	472.23

[22] The impacts of a 68 percent compliance rate for nutrition labeling of ground or chopped products (NCBA, 2004) and a 54.8 percent compliance rate for major cuts (USDA, 1999) will be discussed at the conclusion of this section.

TABLE 11—BENEFITS OF THE PRIA AND SUPPLEMENTAL PRIA

Rule status	Annualized benefits		Present value	
	7%	3%	7%	3%
	$ Million			
Supplemental PRIA	205.5	248.3	2,176.7	3,694.4
PRIA	86.6	145.3	917.8	2,161.0

The supplemental proposed rule would require nutrition labels on all ground or chopped products, with or without added seasonings, unless an exemption applies, and would make the voluntary nutrition labeling program mandatory for major cuts, unless an exemption applies.

The cost analysis of the requirements for ground or chopped products is based on the FDA Labeling Cost Model developed by RTI, the Enhanced Facilities Data Base (EFD), Performance Based Inspection System (PBIS), the FSIS Performance Based Inspection System database, AC Nielsen Purchase Data of 2003, and Information Resources Inc. (IRI). The PBIS provides estimates of the number of very small, small, and large processing establishments that grind meat and poultry products. IRI scanner data and AC Nielsen Purchase Data provide estimates of the number of ground or chopped products produced by processing establishments.

Supplemental Proposed Rule Cost Estimates for Major Cuts

For the major cuts, FSIS assumes that retailers will comply by using POP placards. The number of retail establishments affected by the nutrition labeling requirements for the major cuts is based on 2002 data from the Bureau of the Census (Table 3).[23] The Census data are consistent with the establishment numbers used in the analysis of nutrition labeling of ground or chopped products used in the PRIA. The number of retail establishments used in the supplemental PRIA is 74,910 (owned by 47,688 firms) compared to 69,500 (comprised of supermarkets, other stores, and wholesale clubs) used in the PRIA (66 FR 4982, January 18, 2001). The use of the 2002 Bureau of Census data instead of FMI data (from the PRIA) results in a higher estimated cost of the POP requirements in the supplemental proposed rule. The supplemental PRIA's estimate is also higher than the PRIA's estimate because in the PRIA, FSIS assumed retail facilities would incur labor costs only and would not purchase frames and placards.

The cost of three nutrition information placards for displaying POP information for the major cuts is estimated to be $65.17 per store ($28.00 for placards and $37.17 for metal frames), based on information from the Food Marketing Institute (FMI) and *http://www.hubert.com.* Placards will be replaced every two years because of normal wear and tear. The supplemental PRIA estimates that an average of 0.5 hour at labor cost of $21.11 per hour, per store is the amount of time necessary to obtain and make available the POP materials, insert the placards or posters into frames, and post the information in the store. The average labor cost is then $10.16 ($21.11 × 0.5). The total average cost per store is then $75.73.

The average total cost of purchasing and installing posters or placards will be $5.67 million the first year and every other year after that ((74,910 establishments × $21.11 per hour × .5 hours) + (74,910 establishments × $65.17 per establishment)). The present value of this cost is $31.07 million when discounted at 7 percent over 20 years.

Supplemental Proposed Rule Cost Estimates for Ground or Chopped Product

Should this rule become final, both meat and poultry processing firms and retail establishments will incur compliance costs associated with nutrition labeling of ground or chopped products for such items as label redesign, nutrition analysis, larger labels, and upgrading store scale-printers. The following discussion presents the costs associated with nutrition labeling ground or chopped products for meat and poultry processing firms and for retail firms.

Meat and Poultry Processing Firms

The cost of nutrition labeling of ground or chopped products packaged by processing establishments is comprised of costs for redesigning preprinted product labels that will include a nutrition label (one-time cost), for conducting nutrition analysis on products to obtain information for the nutrition label (one-time cost), and for using larger labels that would be needed for the former product labels (recurring cost).

Based on an examination of labels applied to ground or chopped products that are labeled at processing establishments, the most common printing method for these labels is flexography.[24] Nutrition facts are typically printed in one color. The per-label modification estimated midpoint cost, in 2005 dollars, for a one-color change using the flexography printing method is $2,247. The estimated minimum cost is $1,528, and the maximum cost is $3,170. Cost depends upon the complexity of the label design (Table 12). These estimates reflect administrative, graphic design, prepress activities, plate engraving costs, and nutrition analysis. The paperwork costs are included in the administrative costs. FSIS assumes that the paperwork costs are about 14 percent of the midpoint estimate administrative costs. Thus, the midpoint estimate of the paperwork burden costs would be $44.66 ($319 × 14 percent) per label modification. The estimated total per label design modification cost ranges from a low of $929 to a high of $2,383 with a midpoint of $1,557.

[23] November 2005, more of the 2002 Census data was released.

[24] Flexography printing is frequently used for printing on plastic foil, acetate film, and other material used in packaging. Flexography uses flexible printing plates made of rubber or plastic. The inked plates with a slightly raised image are rotated on a cylinder which transfers the image to the substrate. Flexography uses fast-drying inks, is a high-speed print process, can print on many types of absorbent and non-absorbent materials, and can print continuous papers such as gift wrap and wallpaper.

TABLE 12—COSTS PER LABEL MODIFICATION FOR A ONE-COLOR CHANGE USING FLEXOGRAPHY PRINTING METHOD

Type of Cost	Low	Mid-Point	High
	Dollars		
Administrative[1]	137	319	502
Graphic design	342	513	684
Prepress activities	279	401	627
Plate engraving	171	323	570
Total label redesign	929	1,557	2,383
Nutrition analysis[2]	599	690	787
Total	1,528	2,247	3,170

[1] Includes regulatory affair costs that are similar to paperwork burden costs.
[2] RTI assumed that the cost for nutrition analysis would be the cost associated with analysis required to create a Nutrition Facts panel. Source: RTI, 2003, P.7.

Although nutrition information for some ground products will be available from the USDA National Nutrient Database for Standard Reference (USDA, Agricultural Research Service, 2005) or other low-cost sources, in many cases, the regulations would require that companies conduct a separate nutrition analysis for ground or chopped products for which the USDA National Nutrient Database for Standard Reference or other sources have not provided nutrition information. Because of the large variety of ground product formulations, many products will not likely be the same or similar enough to the products for which the USDA National Nutrient Database for Standard Reference or other sources provide nutrition information. Because FSIS could not identify the number of ground or chopped products that would require a separate nutrition analysis versus the number of products for which the USDA National Nutrient Database for Standard Reference or other sources supply complete nutrition information, FSIS estimated a one-time nutrition analysis cost for all ground or chopped products. The per-label cost of this analysis is in the range of $599 and $787, with an average of $690. On average, the Agency assumed that total label design will be $1,557, and a nutrition analysis will be $690.

Nutrition labels are designed for company-wide use. The number of affected companies is estimated by dividing the number of small and large establishments in Table 1 by three, the number of establishments owned on average by multi-establishment firms (Muth, 2003; *See* RTI analysis). Thus, the final estimate of the number of affected firms that own small or large Federal processing establishments that grind meat is 322 ((858 small processing establishments + 109 large processing establishments)/3). For the purposes of this analysis, very small establishments are considered to be exempt from the requirements for nutrition labeling of ground or chopped products because FSIS assumes they have fewer than 500 employees, are owned by companies with fewer than 500 employees, and FSIS assumes they produce 100,000 pounds or less annually of each ground product. The PBIS database does not include data on size of the owning company or processed product volumes. Thus, the total number of establishments affected by the rule for this analysis may be overestimated. In addition, this analysis includes 41 State establishments/firms that are small-sized. These firms were identified in PBIS database as having grinding operations that would produce ground or chopped products.

AC Nielsen Food Purchase data from 2003 and Information Resources Inc. (IRI) were used to identify ground meat and poultry products with or without added seasonings. The purchase data include data for frozen and fresh, ground or chopped products affected by the final nutrition labeling rule. The information shows that an average of 3.3 frozen ground meat or poultry products are produced by companies that grind meat and poultry. The data were then scaled to account for the total number of ground or chopped products by assuming that a typical company produces an equal number of fresh and frozen ground meat or poultry products. Therefore, multiplying 3.3 × 2 results in an average of 6.6 products per firm and 2,396 unique meat and poultry products (6.6 × 363 firms) that are subject to the labeling requirements of the rule.

The one-time, average cost for meat and poultry establishments to modify product labels on prepackaged ground meat and poultry products to include nutrition information at processing establishments is estimated at $5.38 million ($2,247 mid-point per label modification costs × 363 affected companies × 6.6 affected products per company). The average present value of this one time cost discounted over 20 years at 7 percent is $5.03 million.

In addition to the one-time costs of designing labels, companies will also incur costs for providing larger labels. The cost of larger labels was obtained by estimating the volume of ground meat and poultry products packaged by processors and multiplying the results by the incremental cost of larger labels. The cost of applying larger labels is assumed to be the same as the cost of applying smaller labels.

The NCBA's Meat Purchase Diary (RTI, 2003) indicates that an average American household purchases 49.3 pounds of raw ground beef annually from retail stores. Based on 112.0 million households in the United States (U.S. Department of Commerce, 2003), 5.5216 billion pounds (49.3 pounds per household × 112 million households) of ground beef are purchased from retail stores annually. The American Meat Institute estimates that 0.123 pounds of other ground meat and poultry products are consumed for every pound of ground beef. Consequently, an estimated 6.201 billion pounds of ground or chopped meat and poultry (5.5216 billion pounds × 1.123 scale factor) are purchased by consumers annually (66 FR 4987, January 18, 2001).

According to the NCBA, the average weight of a retail package is 2.735 pounds, with a distribution of 1.17 pounds at the 5th percentile and 4.35 pounds at the 95th percentile (McGowan, 2003). Dividing 6.201 billion pounds by 2.735 pounds per package yields an average of 2.267 billion packages of ground or chopped products sold at retail stores annually.

To determine the total number of packages sold at ''exempt''

establishments, the Agency, using U.S. Census 2002 data, FSIS found that 79.3 percent of total dollar sales by supermarkets, meat markets, and warehouse stores were sold by establishments owned by large retail firms and establishments (500 or more employees). These large retail firms and establishments (266) represent 0.006 of the total number of retail firms and establishments (47,688) affected by the rule as shown in Tables 4 and 5 above. Assuming that the percentage of total dollar sales is similar to sales for ground meat and poultry products, about 1.798 billion packages (2.267 billion packages × .793) of ground or chopped products are sold each year by nonexempt processing establishment and retail establishments.

Finally, a study conducted by NCBA, found that less than 25 percent of ground products are packaged by processing establishment (Dopp, 2001). Thus the Agency estimates that at most 566.75 million packages of ground or chopped products are packaged by processing establishments each year (2.267 billion packages × .25).

The Agency assumes that a larger label will cost an additional $0.005 per label, on average. This estimate was based on information from the FDA Labeling Cost Model (Muth, *et al.* 2003), where $0.005 was the difference in cost between the low and high cost estimates for pressure-sensitive labels. This estimate was evaluated by Hobart, a label manufacturer, who believed that it was reasonable (Schuller, 2003). Multiplying 566.75 million packages by the annual added cost of $0.005 per label results in an added cost of approximately $2.83 million, annually. The present value of these annual costs discounted at 7 percent is $30.02 million.

Retail Firms

The cost of nutrition labeling would also affect retail stores. But because of the small business exemption, fewer retail stores are affected by the requirements for ground and chopped products than the 74,910 establishments shown in Table 3. Using U.S. 2002 Census data shown earlier in Table 4, a total of 23,479 stores will be affected. Table 4 shows the number of retail stores that are owned by companies with more than 500 employees. FSIS assumes that stores or chains with 500 or fewer employees produce 100,000 pounds or less annually of each ground or chopped product and are, therefore, exempt from the nutrition labeling requirements for ground or chopped products.

Should the rule become final, retail establishments subject to the requirements of the rule may comply by either incorporating nutrition information on the label printed by store scale printer systems (Option 1) or by applying an additional preprinted label with nutrition information (Option 2). The cost of store-printed labels includes upgrading store scale-printers to include nutrition information, redesigning larger store labels, providing a nutrition analysis for each product, and using larger labels. Based on information from NCBA and FMI (Amstein, 2003) many scale-printers in retail establishments do not have the capability to print nutrition information on store-generated labels without an upgrade of memory capacity and software and either new printers or new printer heads. Based on a pilot study conducted by King Marketing Services, Inc., for the NCBA, the average cost to upgrade a scale-printer system in their study was $1,600 (Amstein, 2003). FSIS assumes that, on average, retail stores have 1.5 scales in their meat departments. Thus the total cost for upgrading printer-scale systems is assumed to be about $2,400 per store ($1,600 per printer × 1.5 printers). The total average cost to upgrade printer scales to provide store-printed labels for ground or chopped products is estimated at $56.35 million (23,749 retail establishments × $2,400 per establishment). The analysis assumes that scales with the added features for making store-printed labels are replaced every five years. The annual maintenance costs for an upgraded scale-printer is estimated to be 6 percent of $2,400 or $144 ($2,400 × .06) every year after a scale-printer has been purchased.[25] [26]

The cost of redesigning larger store logo labels to be used with the scale-printer systems was based upon cost data from the FDA Labeling Cost Model and Census data on the number of large companies that own retail establishments. As for preprinted labels, flexography is the most common printing method for the store logo labels used with scale printer systems. The cost to make a one-color label redesign change depending on the complexity of the label redesign ranges from a minimum of $929, an average of $1,557, and a maximum of $2,383, as shown in Table 12.[27] Because each company will need to redesign only one label, the average cost was multiplied by the 266 firms affected by the rule. The average one-time cost estimates for redesigning labels is $0.414 million ($1,557 per label design × 266 firms). The average one-time cost estimate for the paperwork costs (average regulatory affairs costs of $319 × 14 percent = $44.50) of redesigning labels is $11,837 ($44.50 × 266 firms). As with products packaged by processors, label redesign can not simply be incorporated into the normal label redesign process because it is a fundamental change in the label format. Once the label is redesigned, the costs of subsequent label redesigns will not be affected substantially.

To estimate the cost of conducting nutrition analysis for ground or chopped products packaged by retailers, the number of unique products was estimated. It was assumed that each firm (or parent company) would conduct a nutrition analysis once for each unique product, which might be sold in some or all of their retail facilities. The number of firms shown in Table 4 was multiplied by an average number of store-brand products packaged at each store. To estimate the average number of ground or chopped products packaged at retail, the number of ground or chopped products with store-applied packaging at six different grocery stores and three wholesale clubs was counted.[28] This analysis showed that grocery stores sell an average of 4.57 ground or chopped products and warehouse stores sell an average of 1.33 ground or chopped products packaged at the store. Multiplying 4.57 by the total number of grocery store firms and meat market firms and multiplying 1.33 by the total number of warehouse club firms in Table 4 results in 1,180 ((4.57 products × 255 grocery store and meat market firms) + (1.33 × 11 warehouse club firms))[29] unique products that will

[25] Based upon a communication between Warranty Department, Hobart Corporation, Troy, Ohio, and Gary Becker, USDA, FSIS, September 4, 2003, and a second communication between Sales Department, Hobart Corporation, Beltsville, Maryland, and Gary Becker, USDA, FSIS, September 4, 2003. The suggested retail price for a Quantum scale-printer is between $5,500 and $6,000. A one-year maintenance agreement would cost about $355. Therefore, it has been estimated that operating and maintenance costs would be about six percent of the purchase price annually ($355/$5,750 = 6%).

[26] It is possible that as new scale-printer systems are developed that the cost of including the added feature to new scale-printer systems may be less than $1,600 per scale. But to assume, as RTI reported, that there is no additional cost for these added features in the future results in an underestimate of the compliance costs.

[27] Package redesign varies depending upon what must be changed on the current label. Therefore, three estimates have been provided.

[28] Each store visited by RTI was owned by a different company and included medium and large sized stores. No meat markets were visited because RTI believed that no meat markets owned by companies large enough to be affected by the labeling requirements are located in the Raleigh-Durham area.

[29] Numbers are rounded.

require nutrition labels applied in retail stores. FSIS recognizes that a survey of six grocery stores and three wholesale clubs in one U.S. city is not a nationally representative survey. Because of limited time and Agency resources, information from this survey provided the best available data for FSIS's estimates. Although this is a significant area of uncertainty in the cost analysis, FSIS believes these data allow for reasonable estimates of the costs to retailers.

Using the cost of a nutrition analysis shown in Table 12 above, and the number of unique products that will require nutrition labels applied in retail stores the average cost estimate is $2.65 million ($2,247 × 1,180 unique products).

The use of larger labels is another cost that retail stores may incur should the rule become final. The cost of larger labels is the product of the number of packages of ground or chopped products sold in retail establishments and the cost of using a larger label. Earlier in the analysis, it was estimated that about 25 percent of approximately 2.267 billion packages or about 566.79 million packages of ground or chopped products are packaged by processing establishments each year. If the remaining 75 percent of total package volume of ground or chopped products is packaged at retail stores, then 1.700 billion packages (2.267 billion × .75) are packaged by retail stores annually. If the added average cost of each label is $0.005, then retail stores will incur an added cost of about $8.5 million (1.7 billion packages × $0.005).[30]

FSIS estimates that based on the analysis described above, the resulting average present value of one-time costs of upgrading scale-printer systems, added annual operating and maintenance costs for the scale-printer systems, one-time costs for redesigning larger store labels, one-time costs for conducting nutrition analysis, and present value costs for using a larger label will be about $209.43 million discounted at 7 percent.

The cost of the second method of complying with the labeling requirements for ground or chopped products at retail stores (Option 2) includes designing a one-color nutrition label, conducting a nutrition analysis for each product, and purchasing and applying a separate label on packages of ground or chopped products applied at the retail level. Using the same methodology that was described earlier, it is estimated that 1,180 unique products will be required to have nutrition labels applied in retail stores. Multiplying the number of unique products by the average per-label redesign and nutrition analysis costs (the cost of flexography is $2,470), results in a one-time cost estimate of $2.65 million (1,180 unique products × $2,247 per label design).

To estimate the cost of purchasing and applying labels to packages of ground or chopped products packaged at retail, the per-unit cost estimates from the FDA Labeling Cost Model were multiplied by the volume of packages described earlier.[31] FSIS estimates the annual cost using the average cost of $0.0293 per label applied. The estimated annual cost is $49.77 million ($0.0293 per label and application cost × 1.452 billion retail packages). All of these costs will be incurred by large and small businesses. The present value of these costs is $452.83 million when discounted at 7 percent.

Percentage Lean/Percentage Fat Labeling

In the PRIA, FSIS assumed that the cost per label to provide information regarding percent lean/percent fat would be comparable to those costs for nutrition labeling, $0.0025 to $0.05 per label, if that information was included as part of the price label and $0.01 per label if producers developed separate percent fat/percent lean labels. Based on the National Cattleman's Beef Association National Meat Case Study in 2004, approximately 25 percent of ground beef package labels surveyed had statements of the lean percentage of the packaged products but did not have nutrition facts panels. Therefore, FSIS assumed that many small businesses may currently include a statement of the lean percentage on the label of ground products but may not include nutrition facts panels on the product label. Based on this assumption, FSIS concluded that requiring small businesses that use the lean percentage and fat percentage statement on the label of ground products to also include nutrition information on the label of such products may result in significant expenses for small businesses. An additional 47,422 small businesses with an additional 51,431 retail establishments (stores) (*see* Table 5) may be affected. Based on the FSIS cost model (*see* Appendix B), this may increase the present value (7 percent) of average expenses for small businesses by about $394.16 million or by about $37.21 million when annualized (7 percent). Therefore, in this supplemental proposed rule, small businesses that use statements of percent fat and percent lean on the label or in labeling of ground products will be exempt from nutrition labeling requirements, provided they include no other nutrition claims or nutrition information on the product labels or labeling. FSIS is taking this action, pursuant to 5 U.S.C. 604(a)(5), to minimize the significant impact of the regulation on small and very small establishments and small retailers. By taking this action, many of these small businesses will not be affected by this rule at all.

Summary of Cost Estimates

FSIS estimates that the average present value of the compliance costs associated with the provisions of the supplemental proposed rule for retail and processing establishments is $348.06 million discounted at 7 percent,[32] or $472.23 million discounted at 3 percent[33] (*see* tables 13 and 14). The average annualized costs are $32.85 million and $31.74 million, based on a 7 percent and 3 percent discount rate, respectively. These estimates are based on the assumption that retail stores will choose the less costly of the two options which would be to upgrade their scale-printer systems, redesign larger store labels, conduct a nutrition analysis, and use larger labels. If these retail establishments choose the more costly option, the average present value cost to retail processing establishments could be as high as $599.64 million, discounted at 7 percent and $838.40 million, discounted at 3 percent.

The average present value cost of the supplemental proposed rule for retail establishments under option 1 would be

[30] The Agency assumed an average cost of $0.005 per label for a larger label because it represents the change in cost between low, midpoint, and high cost estimates for pressure-sensitive labels in the FDA Labeling Cost Model (Appendix B). The differences in the low, midpoint, and high cost estimates derive primarily from the differences in the size of labels. Second, a representative from Hobart, which manufactures labels, says that $0.005 was a reasonable estimate for the added cost of a larger label for including nutrition facts.

[31] The Agency estimated the low, mid-point, and high per-unit cost for purchasing and applying one-color pressure-sensitive labels in 2005 dollars to be $0.016, $0.0293, and $0.042, respectively.

[32] The FSIS analysis which takes into account the uncertainty associated with various cost factors shows that the values at the 5th and 95th percentiles for this average present value using a 7 percent discount rate and 20 year time horizon are $282.88 and $474.79 million, respectively. *See* Appendix D, Table 1.

[33] The FSIS analysis which takes into account the uncertainty associated with various cost factors shows that the values at the 5th and 95th percentiles for this average present value using a 3 percent discount rate and 20 year time horizon are $380.76 and $650.23 million, respectively. *See* Appendix D, Table 1.

$312.77 million using a 7 percent discount rate and $424.53 million using a 3 percent rate. However, under Option 2, the average present value cost to retail establishments could be $564.36 million discounted at 7 percent and $790.70 million discounted at 3 percent.

Processing establishments will incur the smallest portion of the cost increases. FSIS expects average present value costs to processing establishments costs to be $35.28 million discounted at 7 percent and $47.70 million discounted at 3 percent.

TABLE 13—COST SUMMARY OF THE SUPPLEMENTAL PROPOSED RULE (NOMINAL)

Measure	Year							
	1	2	3	4	5	6–10	11–20	Total
	$ Million							
Retail: Purchase & Install POP Placards	5.67	0.0	5.67	0.0	5.67	11.35	28.36	56.73
Processing: Modify Labels on Prepackaged Ground or Chopped Products	5.39	0.0	0.0	0.0	0.0	0.0	0.0	5.39
Processing: Larger Labels on Ground or Chopped Products	2.42	2.42	2.42	2.42	2.42	12.10	24.21	48.41
Retail : (Option 1	69.91	12.33	12.33	12.33	12.33	118.01	236.03	473.29
Retail: (Option 2)	45.13	42.51	42.51	42.51	42.51	212.55	425.10	852.86
Total Retail: (Option 1 and POP Placards)	75.58	12.33	18.01	12.33	18.01	129.36	264.39	530.01
Total Retail: (Option 2 and POP Placards)	50.83	42.51	48.18	42.51	48.18	223.90	453.47	909.58
Total All Processing Plants	7.81	2.42	2.42	2.42	2.42	12.10	24.21	53.80
Total Retail: (Option 1 and POP Placards) and Processing	83.39	14.75	20.43	14.75	20.43	141.46	288.60	583.81
Total Retail: (Option 2 and POP Placards) and Processing	58.64	44.93	50.60	44.93	50.60	236.00	477.67	963.38

TABLE 14—COST SUMMARY OF THE SUPPLEMENTAL PROPOSED RULE (DISCOUNTED)

Measure	Year							
	1	2	3	4	5	6–10	11–20	Total
7% Discount Rate	$ Million							
Retail: Purchase & Install POP Placards	5.30	0.0	4.63	0.0	4.04	6.62	10.47	31.07
Processing: Modify Labels on Prepackaged Ground or Chopped Products	5.04	0.0	0.0	0.0	0.0	0.0	0.0	5.04
Processing: Larger Labels on Ground or Chopped Products	2.26	2.11	1.98	1.85	1.73	8.64	7.08	30.24
Retail: (Option 1)	65.37	10.77	10.06	9.41	8.79	73.58	89.91	281.70
Retail: (Option 2)	42.23	37.11	34.69	32.44	30.31	124.36	151.80	533.29
Total Retail: (Option 1 and POP Placards)	70.67	10.77	14.69	9.41	12.84	80.20	100.38	312.77
Total Retail: (Option 2 and POP Placards)	47.53	37.11	39.32	32.44	34.35	130.88	162.28	564.36
Total All Processing Plants	7.71	2.11	1.98	1.85	1.73	7.08	8.64	35.28
Total Retail: (Option 1 and POP Placards) and Processing	79.60	12.88	16.67	11.26	14.56	87.27	109.03	348.06
Total Retail: (Option 2 and POP Placards) and Processing	62.34	39.22	41.29	34.28	36.08	137.95	170.92	599.64
3% Discount Rate	$ Million							
Retail: Purchase & Install POP Placards	5.51	0.0	5.19	0.0	4.90	8.96	18.27	42.82
Processing: Modify Labels on Prepackaged Ground or Chopped Products	5.23	0.0	0.0	0.0	0.0	0.0	0.0	5.23
Processing: Larger Labels on Ground or Chopped Products	2.35	2.28	2.21	2.15	2.09	9.56	13.36	42.46
Retail: (Option 1)	67.88	11.63	11.28	10.95	10.64	95.87	154.06	381.72
Retail: (Option 2)	43.85	40.09	38.90	37.75	36.69	167.87	269.77	747.88
Total Retail: (Option 1 and POP Placards)	73.39	11.63	16.48	10.95	15.54	104.82	172.32	424.53
Total Retail: (Option 2 and POP Placards)	49.36	40.09	44.09	37.75	41.59	176.83	288.04	790.70

TABLE 14—COST SUMMARY OF THE SUPPLEMENTAL PROPOSED RULE (DISCOUNTED)—Continued

Measure	Year							
	1	2	3	4	5	6–10	11–20	Total
Total All Processing Plants	8.00	2.28	2.21	2.15	2.09	9.56	15.36	47.70
Total Retail: (Option 1 and POP Placards) and Processing	82.66	13.91	18.69	13.10	17.63	114.38	187.68	472.23
Total Retail: (Option 2 and POP Placards) and Processing	64.74	42.37	46.30	39.90	43.67	186.39	303.40	838.40

The average cost increases that FSIS has identified are higher than those estimated by RTI in their revised final report to FSIS. RTI had estimated the present value cost to be $159.0 million discounted at 7 percent under Option 1. RTI had also estimated the present value cost to be $396.7 million discounted at 7 percent under Option 2. The FSIS estimates are higher than the RTI estimates because FSIS believes that scale-printers will have to be replaced periodically since they have a limited useful life. This equipment will also have to be maintained on a periodic basis. In addition, the costs are higher because the costs were updated to reflect 2005 costs instead of 2003 costs. Also, the U.S. Census 2002 data was used that indicated that there are more stores selling food products.

Impacts of Exemptions and Existing Compliance on Costs

FSIS did not reduce the compliance costs of the supplemental proposed rule to take into account the level of voluntary compliance with the nutrition labeling requirements for ground or chopped products that currently exists. Consequently, the estimated compliance costs for providing nutrition labeling of ground or chopped products are overstated. However, Appendix C, Tables 1, 2, 3, 4, and 5 show the estimated costs which take into account a 68 percent compliance rate (NCBA, 2004) of voluntary nutrition labeling of ground or chopped products that is currently assumed to exist.

FSIS estimated the costs to all retailers of obtaining and displaying POP information for major cuts. FSIS did not take into account the existing level of compliance with the voluntary guidelines for nutrition labeling of major cuts. Consequently, the estimated compliance costs for providing POP nutrition information are also overstated. The impacts of a 54.8 percent level of voluntary compliance (USDA, 1999) of stores that provide nutrition labeling for major cuts are, however, shown in Appendix C, Tables 1, 2, 3, 4, and 5.

Appendix D, Table 1 provides a summary of the present value costs of the rule after taking into account the levels of voluntary compliance that are currently assumed to exist. The average present value costs of the rule decline to $115.45 million and $156.72 million when using a 7 percent and 3 percent discount rate, respectively.[34]

Impact on Estimated Costs

The estimates of the total undiscounted compliance costs of the final requirements for ground or chopped product and POP requirements for major cuts are $583.81 million under Option 1. The average present value cost is $348.06 million at 7 percent, with all but $31.07 million attributed to the labeling costs for ground or chopped product. The average annualized cost of the supplemental proposed rule for ground or chopped product, using the same 7 percent discount rate, is $32.85 million. This cost is not significant relative to the volume of output of ground or chopped products sold at retail. For example, as noted earlier, the annual volume of these products sold at retail stores is estimated at 6.2 billion pounds. Therefore the annualized cost of the supplemental proposed rule per pound of ground or chopped product is $0.0053 ($32.85 million/6.2 billion pounds). Viewed another way, it was estimated earlier that the average weight of a retail package was 2.735 pounds. Therefore the annualized average cost of the supplemental proposed rule on a per package basis is $0.014 ($0.0053 per pound × 2.735 pounds per package). This increase compares to a price for ground beef that can easily exceed $2.00 per pound or over $5.00 for an average-size package.

Should the rule become final, FSIS believes that the compliance costs of the rule largely will be passed on to consumers in the form of higher product prices because the demand for meat and poultry products is inelastic. Huang (1993) analyzed a group of meats and other animal proteins consisting of products including beef and veal, pork, other meats, chicken, turkey, fresh and frozen fish, canned and cured fish, eggs, and cheese. He concluded that the price elasticity of demand for this group of products was (−0.3611), *i.e.,* a one percent increase in price for one of these products would reduce demand by only 0.3611 percent.

Review of about a dozen recent studies annotated by William Hahn (1996) of the Economic Research Service reveals that estimates of price elasticity of demand for most beef products (ground beef, steak, chuck roast, *etc.*) is less than one. Consequently, consumers are unlikely to reduce their demand for beef, ground meat products, *etc.,* significantly when beef prices increase a few pennies per pound. Some consumers may demand labeled products, even at a higher cost per pound, given the value of the information from a diet/health perspective.

2. Supplemental Proposed Rule Benefit Analysis

Research Findings

FSIS conducted an extensive search of research on the impacts of nutrition labeling and consulted with the Economics Research Service, USDA on the estimation of benefits. FSIS has found that there are a limited number of nationally representative studies on the effect of nutrition label and POP nutrition information use on dietary intakes. In these studies, the authors frequently examine consumer behavior before and after a significant change in the availability of nutrition labeling information (*e.g.,* Nutrition Labeling and Education Act (NLEA) implementation and relaxation on the prohibition of health claims). The general conclusion of the available research is that there is a positive relationship between the availability of nutrition information and improvements in diet quality.

[34] The FSIS analysis which takes into account the uncertainty associated with various cost factors shows that the values at the 5th and 95th percentiles for this average present value using a 7 percent discount rate and 20 year time horizon are $94.72 and $155.97 million, respectively. The values at the 5th and 95th percentiles of the present value cost distribution using a 3 percent discount rate are $127.63 and $213.60 million, respectively. *See* Appendix D, Table 1.

Research by Kim, *et al.* used USDA's Continuing Survey of Food Intake by Individuals, 1994–96 (CSFII) and the associated Diet Health Knowledge Survey (DHKS) to evaluate the impact of nutrition labels required by the NLEA on consumer label use and intake of selected nutrients. They used an econometric model to evaluate the effects of nutrition label usage by comparing the nutrient intake of label users with the expected intake of the label user in the absence of labels. For those who use nutrition facts information, the intake of calories from total fat, saturated fat, cholesterol, and sodium decreases by 6.9 percent, 2.1 percent, 67.6 mg, and 29.58 mg respectively.

However, measuring the effectiveness of nutrition labels on dietary intake is complicated by the relationship between label reading and other factors that also affect diet. For example, consumers with high levels of knowledge and concern about nutrition are likely to eat a healthier diet than consumers who are less concerned about nutrition; they are also more likely to read labels and use labels to guide their diet. A recent study Variyam (2008) uses the same dataset as Kim *et al.* (2000) and finds that the labels increase only fiber and iron intakes of label users compared with label nonusers. The author notes that in comparison, a model that does not account for self-selection implies significant label effects for all but two of the 13 nutrients that are listed on the NFP. Below we provide some information from other studies that show an association between nutrition label and improved diet. However, we note that these studies did not account for the potential self-selection problem and may overstate the effectiveness of nutrition labeling in improving diet. In addition, none of these studies directly assessed the consumer responses to labeling on raw meat products.

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 psychological factors, health behavior and demographic characteristics. They concluded that nutrition label use was significantly associated with lower fat intake and, after controlling for all demographic, psychosocial, and behavioral variables, nutrition label use explained 6 percent of the variance in fat intake, with a probability of 99.9 percent.

Teisl and Levy in 1997 conducted a 3-year study on the direct effects of nutrition shelf label information on consumer purchasing behavior. Shelf labels containing nutrition information were found to have small but significant effects on consumer dietary patterns. The study also found that providing nutrition information may allow consumers to more easily switch consumption away from ''unhealthy'' products in food categories where differences in other quality characteristics, such as taste, are relatively small toward consumption of products in food categories where the difference in taste between the more and less fatty products may be relatively large. The type and format for the nutrition information used in the study, brand specific nutrition information provided on the shelf in conjunction with the products' unit and item price information, may help to explain the results. This research shows that the main effect of the nutrition shelf labeling program occurred relatively quickly. The authors attribute this response, in part, to ancillary activities efforts, such as measures to enhance consumer health education, occurring as part of the initial nutrition labeling program being evaluated.

Related research conducted by Teisl, Bockstael, and Levy in 2001 found that the provision of nutrition information led consumers to change purchase behavior, but may not necessarily lead to their buying more ''healthy'' foods. They conclude that consumer responses to nutrition labeling may take two forms: a ''health'' effect and a ''substitution'' effect. The first arises when consumers reduce net intake of ''unhealthy'' nutrients and increase purchases of ''healthy'' foods. The second effect occurs when consumers increase their level of satisfaction by substitution across food categories using nutrition information to maintain an overall level of health risk while increasing satisfaction from other food attributes, such as flavor. They also note that economic analyses that identify the benefits of health risk reduction as the costs of foregone illness may understate the overall benefits of nutrition labeling. They assert that consumer welfare is improved (and, therefore, there is a willingness to pay for nutrition information) even if health risks are not reduced because consumers make food choices more in line with non-health preferences about food attributes.

Research by Moorman in 1996 examined whether the NLEA increased consumers' understanding of nutrition information at the point of sale, whether understanding of nutrition information has been promoted regardless of individual consumer preferences, and whether understanding of nutrition information at the point of sale has increased for healthful and non-healthful products. Moorman found statistically significant increases in consumers' nutrition information acquisition after the NLEA took effect. Motivated consumers acquired more information after the law went into effect than before and even the less motivated more accurately recalled fat content after the law went into effect. The research also found that consumers retained more information about higher fat products (defined as those having more than 5.5 grams of fat per serving) than they did about lower fat products. The author made the assessment that standardized and adequate nutrition information, as required by the NLEA, raised awareness of the nutritional quality of food products, thereby increasing the focus on higher fat products. Consequently, the NLEA may have spurred product competition, even among high fat products (Aldrich).

Ippolito and Mathios (1995) studied the effect of an FDA relaxation on a prohibition against health claims. Following the decision to allow health claims on labels in 1985, nutrition advertising, a form of nutrition education when such advertising contains factual information, increased significantly. While they found that fat consumption per capita fell prior to the FDA decision to allow health claims on labels, it fell at a faster rate after the prohibition was eased. Their research also found that prior to when health claims were allowed, fat consumption declined among categories of food whose fat or cholesterol content was widely communicated: Meat, eggs, and fats and oils. However, increases in fat content from other foods largely offset these consumption declines. After relaxing the prohibition, people consumed less fat across more categories, with less of an increase in consumption in other categories. The results suggest that more specific information about nutritional content of foods assists consumers in making healthier food choices within food categories.

In related research, 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: The period 1974–1984, when the FDA permitted printing of fiber content on cereal boxes but did not permit printing of any health claims; and the period 1985–1987, 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 dietary 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.

Although the self-selection issue noted above complicates the precise measurement of the incremental impact of labeling, the results of the studies identified above suggest there may be a positive link between nutrition label use and dietary change beyond that resulting from healthier eating habits of those who regularly rely on nutrition labels.

Consumer Response to Nutrition Labeling

FSIS consulted with ERS to develop the empirical analysis of the benefits of nutrition labeling for the proposed rule (Crutchfield, *et al.,* 2001b). The estimated benefits take the form of reductions in the incidence of coronary heart disease and three types of cancer that may accrue as consumers improve their diet quality through increased use of nutrition information generated by the regulation.

As will be shown, survey data on nutrient intake and label use were used to correlate intake of fat, saturated fat, and cholesterol with 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. A model developed by Zarkin *et al.* (1991, 1993) links changes in the serum cholesterol rate to changes in the percentage of total calories from polyunsaturated fat, saturated fat, and dietary cholesterol. 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 economic value to the public health changes were estimated by assuming an implied value of life associated with reductions in premature mortality.

Assumptions were made concerning consumer behavior 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. For example, when nutrition labels and other sources of nutrition information are provided for raw meat and poultry products, FSIS made the assumption that nutrition information usage rates will rise to match nutrition label usage rates for food products as a whole (Table 15).

TABLE 15—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	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. Crutchfield, *et al.,* 2001b.

TABLE 15b—CONSUMER USAGE OF NUTRITION INFORMATION AFTER MANDATORY LABELING FOR RAW MEAT, POULTRY, AND FISH

	Often		Sometimes		Rarely/never		Do not buy	
	Men	Women	Men	Women	Men	Women	Men	Women
Use nutrition facts panel after mandatory labeling	26.1	40.9	25.0	31.9	46.7	25.1	2.2	2.0

Using the proportions of men (2.2 percent) and women (2.0 percent) who report not buying raw meat, poultry or fish, the new assumed label use distribution after mandatory labeling is shown in Table 15b. The percentage of men who would use the label often to buy raw meat, poultry, or fish would be 26.1, which is obtained as 0.267*97.8, where .267 is the proportion of men who use label often in Table 15 and 97.8 is the percentage of men who buy raw meat, poultry, or fish.

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 and ground or chopped products would mean that the nutrition information provided for these products would be comparable to that provided for other food products. The analysis could reasonably assume that nutrition information usage rates for raw meat and poultry products would then become the same as the nutrition 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 15). In this analysis, then, it is assumed that after mandatory nutrition information labeling, 26.7 percent of men would use the nutrition fact panel or POP materials for meat products, which is the nutrition label usage rate for all foods (Row 1 of Table 15). Similarly, the Agency assumed that the percentage of women using nutrition information on meat products ''Sometimes'' would rise from 18 percent to 32.6 percent.

To assess the impacts on diet quality, the Agency assumed in the preliminary regulatory impact analysis that as nutrition information usage rates rise for consumers eating meat and poultry, dietary patterns will change in a manner consistent with current data. However, Crutchfield *et al.* (2001b) note that this is an ''admittedly strong'' assumption. 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, the Agency made the assumption that the provision of additional nutrition information and making that information available to more consumers will lead to behavioral shifts and improved diet quality. Thus, the assumption is made that the effect of providing new nutrition information for meat and poultry products would make some (not all) consumers who currently do not look for nutrition information on

meat and poultry products more aware of the dietary implications of their food choices. As these consumers see the new nutrition labels on packages of meat and poultry products or new POP information, they may begin to use the nutrition label or POP information or to use it more frequently. Some of 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 because they look for such nutrition information as currently is available. 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 nutrition labeling is in place would see a decrease in fat intake from 96 grams to 92.5 grams (Row 1 of Table 16). Women who previously had been using labels ''Sometimes'' who now use them ''Often'' would see a decrease in saturated fat intake from 20.60 grams to 17.39 grams (Row 5 of Table 16). Similar changes in fat and saturated intakes as a percentage of total calories can be assessed from Table 17.

The Crutchfield *et al.* (2001b) study simply assumed consistency of behavior toward label use and changes in diet quality. Whether the assumption leads to overstating or understating health benefits is not known.

Consumers will not use labels to make very significant dietary changes. If diet quality associations found with all other labeled foods do not hold up for nutrition labels on meat, then health benefits in the supplemental PRIA are overestimated. Of course, health benefits are only one way in which benefits might be realized. Consumers might choose to use nutritional information to enhance enjoyment of food, and not to raise their health status. Further, they may be better off than if they had raised their health status, since rational consumers will use information to their best advantage. If we observe rational, well-informed consumers selecting a more enjoyable diet, for these consumers a more enjoyable diet was worth more than better health. Thus, when we restrict benefits estimates to allow only for information to be used to advance health status, we are simultaneously restricting estimated benefits to a lower level of value to consumers. The FSIS analysis imposes that restriction and the resulting benefits estimate must therefore be interpreted as an underestimate of overall benefits.

TABLE 16—DIETARY INTAKE OF FAT, SATURATED FAT, AND CHOLESTEROL 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	21.41	17.27	19.71
Cholesterol	194.32	219.27	216.55	135.89	210.53

Note: Fat intake in grams, cholesterol in milligrams. Crutchfield, *et al.,* 2001b.

TABLE 17—PERCENTAGES OF CALORIES FROM 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	31.67	34.03	33.88	26.69	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 percentages of total calories; cholesterol in milligrams. Crutchfield, *et al.,* 2001b.

Under these assumptions, then, the Economic Research Service of the U.S. Department of Agriculture analyzed how requirements for mandatory nutrition information labeling of raw meat and poultry products could possibly affect diet quality (Crutchfield, *et al.,* 2001b). Table 18 shows the estimated intake of fat, saturated fat, and cholesterol, by gender, after adjusting for the assumed change in patterns of label use. To reach the values shown in Table 18, each cell in Table 16 (the dietary intake of fat, saturated fat, and cholesterol) was multiplied by the associated percentage of label use (nutrition facts panel use) from Table 15. This increased the number of people in the ''often'' and ''sometimes'' cells, and decreased the number of people in the ''rarely/never'' cells, so that the distribution of label usage on meat and poultry products would reflect the distribution of label usage on all products.

TABLE 18—CHANGE IN INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory labeling for meat & poultry	Intake after adjusting for increased label usage	Decreased intake
Men:			
Total fat	92.51	91.31	1.3%
Saturated fat	31.12	30.69	1.37%
Cholesterol	339.1	335.0	4.12
Women:			
Total fat	60.16	58.57	2.65%
Saturated fat	19.71	19.45	1.32%
Cholesterol	210.5	208.2	2.37

Note: Fat intake in grams, cholesterol in milligrams. Fat and saturated fat intake changes are in percentage terms, cholesterol intake changes are absolute changes in milligrams. (Crutchfield, *et al.,* 2001b.)

Applying these new label use percentages of men and women to their intakes in Tables 18 and 19, the new estimated changes in intakes, after accounting for non-buyers, are reported in Tables 18b and 19b.

TABLE 18b—CHANGE IN INTAKE DUE TO INCREASED LABEL USAGE, ASSUMING THAT THE PERCENTAGE OF NON-BUYERS REMAINS UNCHANGED

	Intake prior to mandatory labeling for meat & poultry	Intake after adjusting for increased label usage	Decreased intake
Men:			
Total fat	92.51	90.94	1.7%
Saturated fat	31.12	30.55	1.83%
Cholesterol	339.1	335.0	4.1
Women:			
Total fat	60.16	58.54	2.69%
Saturated fat	19.71	19.40	1.57%
Cholesterol	210.5	210.52	−0.02

Note that the second column in Table 18b is computed as the weighted average of intakes from Table 16, using the percentages in Table 15 as weights. For example, for the total fat intake of men, 81.64 *.261 + 92.49 *.25 + 96.09 *.467 + 74.48 *.022 = 90.94.

Aggregating across categories, a new weighted average intake is obtained, which could be seen after the imposition of mandatory labeling requirements. Table 19 shows the percentage of calories from fat and cholesterol intake that were derived in a similar manner using intakes from Table 17.[35]

TABLE 19—CHANGE IN PERCENTAGE OF CALORIES FROM FAT AND CHOLESTEROL INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory labeling for meat & poultry	Intake after adjusting for increased label usage	Decrease in intake
Men:			
Total fat	33.44	33.33	0.11
Saturated fat	11.19	11.14	0.04
Cholesterol	339.1	335.0	4.12
Women:			
Total fat	32.49	32.37	0.11
Saturated fat	10.64	10.54	0.10
Cholesterol	210.5	208.2	2.37

Note in Table 19 that fat intake is in grams, and cholesterol is in milligrams. Further, fat and saturated fat intake changes are in percentage terms, and cholesterol intake changes are absolute changes in milligrams. (Crutchfield, *et al.,* 2001b).

[35] The calculations in Tables 18 and 19 ignore the fact that 2.2% of men and 2% of women report not buying meat, poultry or fish (Table 15). If these proportions are assumed to remain unchanged after mandatory labeling, then the decrease in intakes estimated in Tables 18 and 19 would be slightly different.

TABLE 19b—CHANGE IN PERCENTAGE OF CALORIES FROM FAT AND CHOLESTEROL INTAKE DUE TO INCREASED LABEL USAGE, ASSUMING THAT THE PERCENTAGE OF NON-BUYERS REMAINS UNCHANGED

	Intake prior to mandatory labeling for meat & poultry	Intake after adjusting for increased label usage	Decrease in intake
Men:			
Total fat	33.44	33.19	0.25
Saturated fat	11.19	11.11	0.08
Cholesterol	339.1	335.0	4.1
Women:			
Total fat	32.49	32.23	0.26
Saturated fat	10.64	10.50	0.14
Cholesterol	210.5	210.52	−0.02

Note: Fat and saturated fat intake changes are in percentage terms, cholesterol intake changes are absolute changes in milligrams.

Applying these new label use percentages of men and women to their intakes in Tables 18 and 19, the new estimated change in intakes, after accounting for non-buyers, are reported in Tables 18b and 19b.

Comparing Table 18b with Table 18 and Table 19b with Table 19, it can be seen that when the proportions of non-buyers are assumed to remain unchanged, the estimated decrease in intakes of fat and saturated fat are higher, decrease in cholesterol is nearly the same for men, whereas for women cholesterol intake increases slightly. This is because the fat and saturated fat intakes of buyers are higher than non-buyers, whereas the cholesterol intakes of women buyers are in general lower than women non-buyers. Based on these magnitudes, if the new numbers are used in the calculations, the benefits of labeling are likely to be even higher.

Evaluation of Health Effects

Based on epidemiological research, the estimated reductions in calories from fat and cholesterol intake (Table 19) were used to estimate the decrease in the incidence of major diseases associated with consumption of fat and cholesterol. The diseases considered in this analysis include three types of cancer 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. Zarkin, *et al.* (1993) developed a model which estimated the relationships between dietary intake of fat and cholesterol to convert fat contents into the change in fat and serum cholesterol:

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

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/1,000 calories.

Mancino and Kuchler (2009) show that the threat of severe adverse health consequences can induce significant improvements in diet quality (improvements from the perspective of the public health community, not from consumers' perspectives). Cigarette smoking and dietary intake of cholesterol, total fat, and saturated fat are lower for those whose physicians told them they have high cholesterol, compared to those with undiagnosed high cholesterol. But, some also choose to compromise diet quality. Mancino and Kuchler found that dietary intake of cholesterol is unaffected by the decision to take cholesterol-lowering medication. However, for those taking cholesterol-lowering medication, diets are higher in total fats and in saturated fats than are diets of those with unmedicated high cholesterol. The waist circumference of those on medication is also larger, although some of the increase may be associated with reduced cigarette consumption. The increased dietary intake of fat and saturated fat, along with increased waist size are telling evidence of offsetting behavior, as medication lowers the health price of unhealthy choices.

Reductions in serum cholesterol are then converted to reduction in risk of coronary heart disease and the three types of cancers. The estimated values of percentage changes in saturated fat and cholesterol intake from the last column of Table 18 were substituted into the model developed by Zarkin, *et al.* Since separate data for polyunsaturated (P) fat were not available, 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 and reductions in mortality are shown in Table 20.

TABLE 20—REDUCTION IN SERUM CHOLESTEROL AND CHANGE IN MORTALITY

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

The calculated values of SC presented above were used 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/1,000 calories was associated with a 1.2-percent increase in the incidence of each of these diseases. This rate was used to convert reductions in total fat, saturated fat, and cholesterol in Table 18 into SC. It is estimated that the

reduction in mortality associated with changing dietary pattern resulting from mandatory nutrition information labeling are 0.024 percent for men, and about 0.014 percent for women. However, Crutchfield *et al.* (2001b) note that: ''the link between fat intake, serum cholesterol, and cancer risk is less clear than for coronary heart disease.''

The PRIA did not estimate changes in total meat or poultry consumption that may result from the rule, because of the assumption that consumers would choose different types of meat and poultry to reduce fat, saturated fat, and cholesterol. For example, consumers may consume more poultry and less red meat, or they may consume more white poultry meat and less dark poultry meat in response to the newly available nutrition information. Also, in response to the nutrition information, consumers may prefer to purchase meat that has been trimmed more closely to remove fat.

The assumption that total consumption of meat or poultry would not change in response to the newly available nutrition information is consistent with the approach taken by other studies that examine consumers' response to health claims. One such study is noted in the PRIA (66 FR 4989, January 18, 2001). There is no research available that establishes a relationship among nutrition labeling information, health effects, and total meat or poultry consumption.

Table 21 presents data on the annual number of deaths 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.

TABLE 21—REDUCTION IN MORTALITY, NUMBER OF DEATHS, AND ESTIMATED LIVES SAVED

	Reduction in mortality (%)		Number of deaths		Number of 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

The fact that FSIS's analysis did not estimate changes in total meat or poultry consumption may be a limitation of the results, but it is not a major concern, because FSIS's analysis assumes that when consumers read the new nutrition information, they will use the information and choose to consume the same mix of products as consumers that are aware of the nutritional quality of meat and poultry. The calculations in the PRIA are based on a distribution of nutrition label usage on meat and poultry that reflects the distribution of nutrition label usage for food products as a whole. FSIS did not receive comments on the fact that the PRIA did not estimate changes in total meat or poultry consumption. The supplemental PRIA incorporates the PRIA's estimates of potential changes from intake of fat, saturated fat, and cholesterol that could occur as consumers respond to the newly available nutrition information. Finally, the Agency attached an economic value to the public health changes by estimating the implied value of life associated with reductions in premature mortality.

Using recent estimates, deaths from breast cancer are estimated at 39,800, prostate cancer at 29,800 and colorectal cancer at 57,100 in 2003. Deaths from coronary heart disease are estimated at 515,204 for 2000. As a result, the estimated lives saved due to dietary changes from nutrition labeling are revised from those shown in Table 21. The revised estimates are as follows: annual deaths from breast cancer are reduced by an estimated 5.5, deaths from prostate cancer by 7.2, deaths from colorectal cancer by 10.8, and deaths from coronary heart disease by 97.8.[36] The total annual lives saved due to dietary changes from nutrition labeling for all diseases is 121.7.

Effect of Nutrition Labeling on Consumer Attitudes About Beef

As reported by the National Cattlemen's Beef Association (2009) the U.S. meat industry trade organizations, namely the National Cattlemen's Beef Association (NCBA), the Food Marketing Institute (FMI) and the National Pork Board (NPB), conducted research to examine the benefits and challenges of implementing on-pack nutrition labeling for meat products. This research included qualitative and quanitative studies (via focus groups) to explore consumer needs, behavior and preference for nutrition labeling on fresh meat products.

Focus Group Key Learnings

Findings from the focus groups indicated that consumers desire more nutrition information, find both on-pack and POP materials useful but prefer on-pack, and still want to see the product they are purchasing. Additional learnings indicate:

—Consumers want to see nutrition information for fresh meat and they want more information on specific nutritional content.

• Information on fat content, calories per serving, cholesterol and proteins are of greatest importance.

• Micronutrients (vitamins and minerals) are also of interest.

—Consumers are generally unaware of the micronutrients found in fresh meat products and they want to see all of the nutrient information a food provides (but aren't interested in what a food doesn't have such as 0 percent for Vitamin C).

—Consumers currently use on-pack labels most often to learn about the nutritional content of meat products because there is higher awareness for labels than for posters or take-home brochures.

Beef Checkoff-Funded Research

Given the beef industry's philosophy that nutrition information should be widely available to help people make informed purchase decisions, yet understanding the challenges many retailers face in providing the information in a simple and easy-to-understand format, NCBA embarked on a number of additional nutrition labeling research projects. The goal of

[36] These estimates are based upon the rates that were calculated for the PRIA.

this subsequent research was to further understand appropriate methods and vehicles for retailers to share the information with consumers.

Effect of Exemptions on Benefits Estimates

Under this rule should it become final, all very small establishments would be exempt from the requirement for nutrition labeling of ground or chopped products because they have 500 or fewer employees, are owned by companies with 500 or fewer employees, and likely produce 100,000 pounds or less annually of each ground product. Finally, retail firms that have 500 or fewer employees would be exempt from nutrition labeling requirements for ground or chopped products, provided they produce 100,000 or less annually of each ground product. This exemption for small businesses will reduce the benefits associated with the rule in proportion to the share of ground or chopped products affected by the rule that are sold at these establishments.

FSIS estimates that the number of packages of ground or chopped product sold or produced through exempt facilities is approximately 469 million packages (2.267 billion packages times 20.7 percent, the estimated share of packages sold at ''exempt'' establishments as shown using U.S. Census 2002 data in the Cost Analysis). At an average of 2.735 pounds per package, the average amount of ground or chopped product sold at these establishments is about 1.283 billion pounds (469 million packages × 2.735 pounds per package). FSIS estimates that of the total of 6.201 billion pounds of ground or chopped meat and poultry products consumed annually, 4.918 billion pounds will be affected by the labeling requirements of the rule.

As discussed above, the rule would provide numerous exemptions from nutrition labeling requirements, in addition to the small business exemptions, for ground or chopped products sold through retail facilities. FSIS reduced costs and benefits to account for the small business exemption regarding the labeling of ground or chopped products. However, FSIS did not reduce the costs or benefits estimates to account for the other exemptions for ground or chopped product because the volume of ground or chopped product that would qualify for these other exemptions is very low.

Should it become final, the supplemental proposed rule would not provide a small business exemption from the nutrition labeling requirements for the major cuts. The rule provides numerous other exemptions from nutrition labeling requirements for the major cuts. However, FSIS did not reduce the costs or benefits estimates to account for the exemptions for major cuts because the volume of major cuts that would qualify for these exemptions is very low.

FSIS estimates that the total amount of major and nonmajor cuts of single-ingredient, raw meat and poultry products is 19.6 billion pounds.[37] Of this amount, FSIS estimates that 16.745 billion pounds, or 85 percent are major cuts, would be subject to the label requirements of the rule as indicated above. The estimate of the total amount of single-ingredient, raw meat and poultry products that are not ground or chopped is based on recent research conducted by the Economic Research Service on beef and pork consumption and on information provided by the National Chicken Council and National Turkey Federation at their Web sites. The derivation of this estimate is shown in Appendix A, Tables 1–4.

Based on these estimates, 16.745 billion pounds of major cuts are affected by the supplemental proposed rule. From above, 4.918 billion pounds of ground or chopped product are affected by the rule, for a total of or 21.663 billion pounds of meat and poultry products. This compares to a total of 63 billion pounds of red meat and poultry products consumed in the United States in 2003.[38] The exemption for small businesses affects 1.283 billion pounds of ground or chopped product, or 5.92 percent of the total amount of meat and poultry products affected by the rule. Consequently, the total annual lives saved due to dietary changes from nutrition labeling for all diseases is reduced accordingly. For example, the maximum number of lives saved annually declines from 121.7 to 114.5 (121.7 × (1.0–0.0592)).

Estimating the Benefits of Preventing Premature Death

The benefits of this supplemental proposed rule would be the lives saved due to the estimated reductions in mortality rates associated with coronary heart disease and selected cancers. The Agency believes that there are potential benefits associated with the reductions in non-fatal cases of coronary heart disease. However, identifying and quantifying the risk reduction of premature death in an economic context is difficult. Similarly, it is also complex applying risk reductions of non-fatal cases of diseases within an economic context.[39] Given questions concerning data quality and unsettled methodological issues in estimating the benefits of a reduction in non-fatal cases of coronary heart disease, FSIS is restricting its analysis of benefits to reductions in premature death.

If food were marketed by risk levels (*e.g.,* probabilities of inducing cancer or heart disease), and consumers treated advertised risk levels as they do other objectively measurable product characteristics (*e.g.,* weight or volume), there would be little difficulty in valuing diet-related food safety risk factors. Product prices could be statistically associated with risk levels, yielding the risk-dollar trade-off consumers make. That is, one could measure, based on consumer purchases, the dollar value consumers attach to particular types of risk reduction. However, there is no ''market'' for reducing diet-related fatal risks and these values can not be measured.

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 informational 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 and reductions in cases of non-fatal diseases.

Ultimately, FSIS wanted to monetize the benefits of diet-related fatal health risk reduction. 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 (Viscusi, 1992).

[37] This amount includes nonmajor cuts of single-ingredient, raw meat and poultry that are not ground or chopped. The data available do not distinguish between major and nonmajor cuts.

[38] *Source:* Per capita consumption estimates are found at U.S. Department of Agriculture, World Agricultural Supply and Demand Estimates and Supporting Materials. Published in Livestock, Dairy, and Poultry Outlook, *http://www.ers.usda.gov/publications/ldp/*. Total consumption is based on a total U.S. population of 288.4 million.

[39] For an in-depth analysis of this issue, *see* Fred Kuchler and Elise Golan, 1999.

FSIS is using a range for the value of life of $5.0 million to $6.5 million with a mean of $5.5 million. The preliminary regulatory impact analysis of the rule used a single value of $5.0 million. The value of a statistical life 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 the gravity of these outcomes.[40]

Viscusi (1992) has summarized the empirical work estimating the value of risk of premature death. Several studies had estimated the risk-dollar trade-off in the labor market by dividing the wage premium for high-risk 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 trade-off 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'' (Ibid., 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. The Economic Research Service, USDA has used a value of $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 spp.,* and *Listeria monocytogenes* (Crutchfield, *et al.,* 2001a). 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 (66 FR 6137, January 19, 2001) and the Consumer Product Safety Commission (Miller, 1997) currently use Viscusi's mid-point value of $5 million for each life saved (Kuchler and Golan, 1999, p.25). Finally, the Food and Drug Administration (68 FR 41434, July 11, 2003, and 69 FR 56824, September 22, 2004) use both $5.0 million and $6.5 million as the value of a statistical life. FSIS believes that the value for a statistical life used in the analysis is consistent with current practices, OMB guidance, and research.

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. To address the uncertainty associated with the reduced incidence of heart disease and cancer, FSIS identified three plausible scenarios that are intended to encompass the actual impact. The scenarios are shown in Table 22. The first scenario assumes that there would not be any reduction in mortality in the first time period covering the first two years after the effective date of the rule. During the second time period covering the third through the seventh years following the effective date, 25 percent of the potential reduction in human health risk is achieved—28.6 lives saved annually as a result of dietary changes. In period 4, covering the last eight years of the period of analysis, the full reduction in human health risk is achieved—114.5 lives saved annually as a result of dietary changes. In scenarios 2 and 3, the benefits of the rule are assumed to occur progressively later in the period of analysis.

TABLE 22—HUMAN HEALTH IMPACT FOR ALTERNATIVE SCENARIOS—ANNUAL PERCENTAGE REDUCTIONS IN MORTALITY AND LIVES SAVED

Percent of Total Reduction	Period 1	Period 2	Period 3	Period 4
	0	25	50	100
Scenario 1				
Years in period following effective date	1–2	3–7	8–12	13–20
Lives saved annually	0	28.6	57.3	114.5
Scenario 2				
Years in period following effective date	1–5	6–10	11–15	16–20
Lives saved annually	0	28.6	57.3	114.5
Scenario 3				
Years in period following effective date	1–8	9–13	14–18	19–20
Lives saved annually	0	28.6	57.3	114.5

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 values assigned to each premature death ($5.0, $5.5, and $6.5 million) prevented by the number of lives saved annually in the three scenarios due to changes in diet quality. The present values of the benefits associated with the reductions in mortality associated with the scenarios identified in Table 22 are shown in Table 23. The net present value of the human health benefits of reduced mortality for all diseases over 20 years is estimated to be a maximum of $5.9 billion under Scenario 1 using a discount rate of 3 percent and $6.5 million for each premature death avoided. The lowest present value of human health benefits occurs under Scenario 3 using a discount rate of 7 percent and $5.0 million for each premature death avoided and is

[40] FSIS revised the method employed in the preliminary regulatory impact analysis of the rule to estimate human health benefits based on guidance to all Federal agencies concerning the estimation of human health benefits. The revised method uses a single value for each premature death prevented, regardless of age. The revised method results in significantly higher human health benefits resulting from the nutrition labeling requirements of the rule.

estimated to be $1.1 billion. These benefits would be distributed among the diseases evaluated in the same share that they represent of total lives saved due to dietary changes from nutrition labeling as shown above.

Based on the information shown in Table 22, FSIS constructed a composite scenario for all diseases by first computing the average number of lives saved annually from the three scenarios. The derivation of lives saved for the composite scenario is shown in Appendix A, Table 5. The annual average for lives saved over the 20 year period under the composite scenario was 50.1. This compares with annual averages of 67.3, 50.1, and 32.9 lives saved under scenarios 1, 2, and 3, respectively (Appendix A, Table 5). To estimate an average human health benefit over the three scenarios, the annual average number of lives saved under the composite scenario is multiplied by each of the three values for a statistical life year. The average is then computed for each year to derive the annual values of lives saved under the composite scenario as is shown in Appendix A, Table 6. Each value was weighted equally. The results of the analysis of the composite scenario show a net present value for lives saved of $3.694 billion using a 3 percent discount rate, and $2.177 billion using a 7 percent discount rate. The corresponding annualized human health benefits from the reduction in all diseases are $248.3 and $205.5 million, respectively. The benefits estimates presented here assume POP nutrition information to be equally successful as nutrition labels in leading to dietary change and consequent reductions in the three cancers studied and coronary heart disease. However, this assumption is not realistic. The analysis of alternatives section below provides a range of benefits estimates using different assumptions about the relative effectiveness of the POP nutrition. These annualized values will be used in the cost-effectiveness analysis.

TABLE 23—PRESENT VALUE OF HUMAN HEALTH IMPACTS FOR ALTERNATIVE SCENARIOS OVER 20 YEARS, 3 PERCENT AND 7 PERCENT DISCOUNT RATES

Scenario/ value of a statistical life	Present value 3%	Present value 7%	Average annual benefit 3%	Average annual benefit 7%
	$ Million			
Scenario 1				
5.0	4,502.4	2,776.4	302.6	260.7
5.5	4,952.7	3,037.5	332.9	286.7
6.5	5,853.2	3,589.8	393.4	338.8
Scenario 2				
5.0	3,223.8	1,865.8	216.7	176.1
5.5	3,546.1	2,052.4	238.4	193.7
6.5	4,190.9	2,425.6	281.7	229.0
Scenario 3				
5.0	2,053.6	1,134.8	138.0	107.1
5.5	2,258.9	1,248.3	151.8	117.8
6.5	2,669.7	1,475.3	179.4	139.3
Composite	3,694.4	2,176.7	248.3	205.5

Effects of Current Compliance Levels

As has been discussed in the Cost Analysis, the level of participation in the voluntary nutrition labeling program is 54.8 percent of stores for major cuts (USDA, 1999). In addition, an estimated 68 percent of ground or chopped products bear nutrition labels (NCBA, 2004). The analysis of benefits presented above assumes no prior compliance. Were these levels of compliance incorporated into the amount of meat and poultry product affected by the supplemental proposed rule, the amount of product affected would decline from 21.6 billion pounds to 9.1 billion pounds[41] (21.6 billion pounds minus 16.7 billion pounds of major cuts × (1.0–0.548) and 4.9 billion pounds ground or chopped product × (1.0–0.68). Since the benefits analysis treats the consumption of types of meat and poultry products the same in terms of their impacts on human health, the benefits would be reduced accordingly. Instead of achieving a maximum number of lives saved of 114.5 annually, which is the starting value for the benefits analysis, the rule would save at most 42.1 lives annually. Under the composite scenario, modified accordingly, the annual number of lives saved would be 18.4. The present values of the benefits are $1.358 and $.800 billion using 3 and 7 percent discount rates, respectively. The corresponding annual benefits are $91.3 million and $75.5 million. The estimated benefits under this scenario can be compared with those in Table 23 above.

[41] The estimates amounts of major cuts and ground or chopped products are shown in Table 24.

3. Minimum Effectiveness of Measures Required by the Supplemental Proposed Rule for Benefits To Exceed Costs

In the cost analysis of the proposed and supplemental proposed rules, FSIS assumes that retailers will display POP nutrition information for the major cuts rather than apply nutrition labels to these products because this is a lower-cost means of providing nutrition information for multiple products. The benefits analysis does not provide separate estimates of the benefits of nutrition labels and POP information as it was not possible to distinguish between the behavioral response and change in dietary intake associated with these two means of conveying nutrition information to the consumer.

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, and that dietary patterns will change in a manner consistent with current data. Labeling, as used in the surveys matching its usage and dietary changes, has generally been interpreted to mean on-package labels rather than POP labeling. Consequently, the discussion of the benefits of the rule has implicitly focused on on-package labels.

In the analysis below, we first estimate the reduction in risk associated with POP nutrition information sufficient to equate its benefits and costs. Then we estimate remaining benefits of the rule that must be attributed to on-package nutrition labels for benefits to exceed costs.

The estimated cost of providing POP nutrition information is $5.67 million starting the year of the effective date and every other year thereafter. The net present values using a discount rate of 3 and 7 percent for the 20-year period of analysis are discounted costs of $42.82 and $31.07 million, respectively. The annualized values for these net present values are $2.88 and $2.93 million, respectively (Table 25). The net present values for the 20-year costs of on-package nutrition labels for ground and chopped products are $429.41 million and $316.99 million, using 3 and 7 percent discount rates, respectively. The annualized cost associated with net present values using 3 and 7 percent discount rates are $28.86 and $29.92 million, respectively.[42] Under the composite scenario discussed in the benefits analysis, there is an average of 50.1 lives saved annually as a result of the nutrition labeling requirements of the rule.

The average reduction in risk for the benefits of POP nutrition information for major cuts of single ingredient, raw products to equal their cost is 0.53 lives saved annually ((2.88+2.93)/2)/5.5) assuming a value of life of $5.5 million (Table 25). The reduction in risk for the benefits of on-package nutrition labels for ground or chopped products to equal their cost is about ten times greater (5.34 lives saved annually).

The estimated total reduction in risk in order for the benefits of these combined measures to exceed costs is 5.87 lives saved annually or about one-ninth (5.87/50.1) of the estimated 50.1 lives saved annually under the composite scenario, using a value of life saved of $5.5 million.

TABLE 25—BREAK-EVEN ANALYSIS OF THE SUPPLEMENTAL PROPOSED RULE MEASURES

Measure	Annualized average costs ($million)		Number of lives saved annually for benefits to equal costs		
	Discount rate		Value of life ($million)		
	3%	7%	5.0	5.5	6.5
POP nutrition information for major cuts of single ingredient, raw products	2.88	2.93	.58	.53	.45
On-package nutrition labels for ground or chopped products [1]	28.86	29.92	5.88	5.34	4.52
Total	31.74	32.85	6.46	5.87	5.97

[1] The costs of on-package labels include all costs that are not directly attributable to providing POP nutrition information as identified in Table 13.

E. Analysis of Alternatives

The previous discussion of regulatory alternatives provided a description of the regulatory alternative considered and information on the likely costs of the alternatives. The analysis that follows provides a quantification of the potential effectiveness of the alternatives as well as a comparison of cost-effectiveness and potential net benefits.

The regulatory alternatives considered by the Agency employ one or both of the following measures: POP nutrition information and on-package nutrition labels. The combination of measures and the products subject to these measures differ among the regulatory alternatives considered. In the supplemental proposed rule (Alternative 3), on-package nutrition labels are required for ground or chopped meat and poultry products (unless an exemption applies), and on-package nutrition labels or POP nutrition information are required for the major cuts of single ingredient, raw meat and poultry products (unless an exemption applies). It is assumed for the purpose of estimating compliance costs that, given the option, retail establishments will provide POP information in the form of placards to convey nutrition information for major cuts of single ingredient, raw meat and poultry products. Alternative 2 stipulates POP nutrition information for ground or chopped product and for major and nonmajor cuts of single ingredient, raw products. It is assumed for purposes of estimating the cost of this alternative that retail establishments will use a reference manual to convey nutrition information for the products covered. Retailers may employ other methods, however. Alternative 4 requires on-package nutrition labels for ground or chopped products and major cuts. Alternative 5 stipulates on-package nutrition labels for ground or chopped product, and both major and nonmajor cuts of single ingredient raw products.

Relative Effectiveness in Providing the Necessary Material Facts

The Agency considered several factors in selecting Alternative 3. The factors reflect the significant differences in the two principal categories of meat and poultry products— ground or chopped products and major and nonmajor cuts, consumer preferences, and the effectiveness with which information about these two categories of products is presented in retail establishments.

Differences in product characteristics, consumer preferences, and demand for nutrition information affect the value of nutrition information for the two general categories of products. The justification for the government action in requiring nutrition information differs for the two categories of products, as has been argued in the need for the rule. Different approaches to labeling may be warranted and what might be an effective approach for

[42] Annualized benefits are defined as the average annual amounts, when discounted, will provide a present value benefits equal to that shown for the selected scenario. It is a means for providing a single annual amount for a scenario showing significant differences on a year-to-year basis.

providing nutrition information for one category may be unsuitable for the other. FSIS finds that this is the case, based on the full range of evidence available.

Ground or chopped product are formulated to achieve a specific fat content and thus are similar to multi-ingredient and heat processed products, which receive on-package nutrition labels. The nutritional characteristics of these products can vary significantly. For example, the percentage of total fat in ground beef may range from 3 to 30 percent. Consequently, consumers have a significant number of choices concerning type of product and nutritional characteristics. Nutrition information enables consumers to match product choices with nutritional preferences.

While the processor formulating the ground or chopped product has knowledge of the nutritional characteristics of each product formulation, such information is not readily available to the consumer. Significant differences in total fat content of ground and chopped products may be difficult for the consumer to distinguish. Consequently, there is little incentive for processors to provide information on ground or chopped products with higher fat content. Yet, consumers' information needs are significant, given the differences in consumer preferences for high fat and low fat products. Under these conditions, readily accessible nutrition information would be highly valued by consumers. FSIS has concluded that clear and concise information should be available to consumers of ground or chopped product in the form of an on-package label. It would be confusing to consumers if nutrition information were provided by POP placards for all potential formulations of these products. Faced with a large array of signage, the potential value of nutrition information could be exceeded by the transactions cost for many consumers seeking such information.

Because there are numerous formulations of ground or chopped product, it would be difficult for producers or retailers to develop POP 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 POP materials that include information concerning numerous formulations of these products (66 FR 4977, January 18, 2001). If a statement of the fat percentage and lean percentage were not included on a package of ground product, consumers would not know which nutrient data concerning ground product on POP materials would apply to that particular ground product. Thus, FSIS on-package nutrition labels would likely enable consumers to make product comparisons far more efficiently because consumers would have more relevant information directly attached to the products to inform their choices.

Major cuts are generally considered by consumers to be largely undifferentiated products in terms of nutrient content (Van Ravenswaay). The nutritional characteristics of one beef chuck blade roast are perceived to be much the same as another. The differences in nutritional characteristics for a particular major cut (*e.g.,* chicken breasts) vary much less than the nutritional characteristics for a type of ground or chopped product (USDA, 2005). This is an important factor to consider as consumer preferences are more likely to differ on the basis of the type of major cut (*e.g.,* chicken breasts versus pork loin chops).

Based on the similarity of nutritional attributes of any specific major cut and the type of information desired by consumers, FSIS has concluded that it would be acceptable for retail establishments to provide nutrition information via POP placards for major cuts. They are an efficient means of providing such information given the relatively small number of products sold at retail establishments, their relatively large share of total meat and poultry consumption, and consumer information needs.

In developing the regulatory alternatives, the Agency concluded that, given the option, retail establishments would most likely not choose to provide nutrition information for nonmajor cuts via POP placards. There are potentially a large number of such products (350 products for meat alone according to the National Live Stock Meat Board). Using POP placards to convey nutritional information on these products could result in excessive signage at retail establishments. Excessive signage would not only be a concern for the retail establishment, but also would not convey information in a manner that would promote its usage by consumers. Retail establishments would be more likely to opt for providing nutrition information for nonmajor cuts in a reference manual. The following table summarizes factors considered by the Agency in its selection of Alternative 3 as the most effective in providing the material information to consumers.

TABLE 24—COMPARISONS OF METHODS FOR CONVEYING NUTRITION INFORMATION AND MEAT AND POULTRY PRODUCT CATEGORIES

Method	Product category	
	Ground or chopped	Single-ingredient, raw
POP Nutrition Information.	• Information asymmetry is greater than the information asymmetry in POP nutrition information for major cuts and nonmajor cuts that are not ground or chopped. • Consumer preferences differ on the basis of fat content. • Nutrition information on formulated products (ground or chopped products) is less accessible on POP materials than it would be on product labels. • Given the number of product formulations, it would be confusing to consumers to use POP nutrition information.	• 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. • Consumer preferences differ on the basis of types of products in the category. Placards. • Efficient means of presenting nutrition information for major cuts—relatively small number of products comprising large share of meat and poultry consumption. • Ineffective means of information delivery for nonmajor cuts that are not ground or chopped: potentially large number of products resulting in excessive signage. • Nonmajor cuts account for small share of consumption. Reference Manual.

TABLE 24—COMPARISONS OF METHODS FOR CONVEYING NUTRITION INFORMATION AND MEAT AND POULTRY PRODUCT CATEGORIES—Continued

Method	Product category	
	Ground or chopped	Single-ingredient, raw
On-Package Labels	• Information asymmetry is greatest for product category. • Consumer preferences differ on the basis of fat content. • Information is clear and concise. • Highly-valued information for consumers because consumer preferences differ most for these types of products on the basis of nutritional content. • Consumer search costs are minimized.	• Reference manual is low-cost means of information delivery. However, high search costs may greatly reduce effectiveness. • Number of nonmajor products is large and amounts comprise about 15% of meat and poultry consumption. • Uniform reference manuals not likely given regional differences in names of similar nonmajor products. • 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. • Consumer preferences differ on the basis of types of products in the category. Major cuts. • Consumers have reasonable expectations as to the nutrient content of these products. Nonmajor cuts. • Consumers have limited access to nutrition information for nonmajor cuts.

A major source of uncertainty in this analysis is the success of POP nutrition information relative to on-package nutrition labels. Research studies on effectiveness of POP information virtually ended with passage of the NLEA. So, most POP research is now quite dated. Thus, the research available does not allow FSIS to make a precise comparison of the relative success of on-package nutrition labels versus POP nutrition information. However, POP nutrition information may be a convenient and effective means for consumers to confirm or gain new information on the nutritional content of the major or nonmajor cuts of single ingredient, raw products. Given these uncertainties, in the analysis that follows, FSIS assumes that POP nutrition information is 50 percent, 10 percent and 5 percent as successful as on-package nutrition labels in causing dietary change to illustrate the impacts of those assumptions on the relative cost-effectiveness as well as net benefits of the alternatives.

Analysis of Cost Effectiveness

A cost-effectiveness analysis (CEA) provides a means to identify alternatives that achieve the most effective use of resources available without requiring the monetization of all benefits or costs by comparing regulatory alternatives with respect to their ability to achieve a specified outcome (*e.g.,* units of human or environmental health). Regulatory alternatives employing the same measures are ordered on the basis of the increased frequency, scope, lethality, or some other criterion. Ideally, a CEA results in comparison of the incremental cost per unit of outcome for each regulatory alternative when the alternatives are ordered on the basis of an increasing level of the specified criterion.

FSIS agrees that cost effectiveness ratios for regulatory options should be calculated incrementally, that is, in terms of the additional cost incurred by the next most stringent option to produce an additional life saved. However, the data available for the analysis and the nature of the regulatory alternatives poses some challenges to conducting a meaningful incremental CEA. First, the regulatory alternatives stipulate the use of one or two measures that may be employed for providing nutrition information for two or three categories of products—ground or chopped product and single-ingredient raw products (major and nonmajor cuts)—of meat and poultry. The two measures are POP nutrition information materials and on-package nutrition labels. Second, the effectiveness of POP nutrition information relative to on-package nutrition labels is uncertain. The greater amount of time required by the consumer to find the relevant nutrition information on POP materials relative to finding such information on the packaging of the products suggests that POP nutrition information may be less successful for some types of products in leading to healthier dietary choices. Given the assumptions we make in order to model the regulatory provisions given the uncertain effectiveness, the result is an incremental cost-effectiveness analysis which shows that multiple alternatives are weakly dominated under all scenarios. Consequently, the analysis that follows provides a comparison of average cost-effectiveness and net-benefits of the regulatory alternatives for each alternative, for different levels of assumed relative effectiveness of POP information.

Average Cost-Effectiveness of Regulatory Alternatives

Cost-effectiveness analysis results based on averages can be misleading in that the regulatory alternative exhibiting the lowest cost-effectiveness ratio may not be the best option. Low ratios are not always an accurate indicator of high net social benefits, the desired economic objective. The following provides information on the average cost effectiveness of the regulatory alternatives and their net benefits.

In order to analyze both the average cost effectiveness of the regulatory alternatives and incremental cost effectiveness of the measures employed by the regulatory alternatives, the share of the reduction in risk associated with the POP nutrition information for ground and chopped products and both major and nonmajor cuts are estimated. Estimates of the number of products subject to on-package nutrition labeling are also provided. The costs corresponding to the risk reduction measures are also estimated. Table 26 provides the information that was used to allocate the annualized costs and reductions in risk.

The reductions in risk associated with the regulatory alternatives reflect the differences in the pounds of product affected. Alternatives 2 and 5 affect ground and chopped products and the

major and nonmajor cuts, a total of 24.5 billion pounds (Table 26). Alternative 3 (the supplemental proposed rule) requires on-package nutrition labels for ground or chopped products and either on-package nutrition labels or POP nutrition information for the major cuts, a total of 21.6 billion pounds. Alternative 4 affects the same amount of product as Alternative 3. The differences in pounds of products affected among the regulatory alternatives are reflected in the annual number of lives saved. The potential number of lives saved annually for Alternatives 2 and 5 are increased proportionately by 13 percent (24.5/21.6 = 1.1343) to reflect the difference in pounds of product affected. Therefore, the maximum number of lives saved annually for Alternatives 3 and 4 is 50.1. The corresponding value for Alternative 2 and 5 is 56.8 lives saved annually (50.1 × 1.1343).

The total cost of Alternative 2, which is exclusively the cost of the POP nutrition information manual, is allocated among ground and chopped product, and major and nonmajor cuts on the basis of the share of products in these categories (CFR §§ 317.344 and 381.444, National Livestock Meat Board, 1995). The costs associated with labeling measures for the product categories (on-package nutrition labels for ground and chopped and major cuts, and on-package labels for these products plus nonmajor cuts for Alternatives 4 and 5, respectively) are allocated on the basis of the relative shares of these products at retail establishments.

TABLE 26—MEAT AND POULTRY PRODUCT INFORMATION

Meat and poultry product volumes affected by regulatory alternatives	Billion pounds	Percent shares for Alternatives 2 & 5	Percent shares for Alternatives 3 & 4
Major and nonmajor cuts	19.6	80.0	77.3
Major cuts	16.7	68.2	77.3
Nonmajor cuts	2.9	11.8	.....
Ground or chopped	4.9	20.0	22.7
All meat and poultry	24.5	100.0	100.0

Products in POP nutrition information manual	Number of products	Percent share for Alternative 2	
Ground or chopped	13	3.0	.....
Major cuts	45	11.0	.....
Nonmajor cuts [1]	350	86.0	.....
Total	403	100.0	.....

Products at retail establishments with on-package nutrition labels	Number of products	Percent share Alternative 5	Percent share	
			Alt. 3	Alt. 4
Ground or chopped	12.50	22.0	100.0	28.3
Major cuts	31.74	56.0	.....	71.7
Nonmajor cuts	12.42	22.0	.....	.....
Total	56.66	100.0	100.0	100.0

[1] A comprehensive listing of nonmajor cuts was provided in the *Uniform Retail Meat Identity Standards* published by the National Livestock and Meat Board. Nonmajor cuts of poultry, of which there are few, are not included. Amenable kinds of poultry are not accounted for. Most ducks, geese, squab are sold as carcasses and there is only a very small market for ostrich cuts/parts; and rhea and emu are used for byproducts mostly.

The present value and corresponding annualized costs for the regulatory alternatives and their measures are shown in Table 27. There are no costs associated with Alternative 1 as it represents the status quo. As is reflected in their costs, the alternatives become increasingly costly due to the increasing share and number of products that receive on-package nutrition labels, which are significantly more costly than POP nutrition information. The present value cost of the alternatives range from a low of $87.74 million for Alternative 2 to $956.48 million for Alternative 5. The present value of the compliance costs of the alternative selected by the Agency is $348.06 million. The table also shows the compliance costs, both present value and annualized, on the basis of the major product categories.

TABLE 27—AVERAGE COSTS OF REGULATORY ALTERNATIVES

Alternative	Present value		Annualized values	
	3%	7%	3%	7%
	$ million			
Alternative 2. POP manuals for all products:				
Total	123.19	87.74	8.28	8.28
Ground & chopped	3.93	2.80	.26	.26
Major cuts	13.59	9.68	.91	.91
Nonmajor cuts	105.68	75.27	7.1	7.1
Alternative 3. On-package labels for ground and chopped, POP placards for major cuts:				

TABLE 27—AVERAGE COSTS OF REGULATORY ALTERNATIVES—Continued

Alternative	Present value		Annualized values	
	3%	7%	3%	7%
	$ million			
Total	472.23	348.06	31.74	32.85
Ground & chopped	429.41	316.98	28.86	29.92
Major cuts	42.82	31.07	2.88	2.93
Alternative 4. On-package labels for ground and chopped products and major cuts:				
Total	1,103.90	812.99	74.20	76.75
Ground & chopped	429.41	316.98	28.86	29.92
Major cuts	674.49	496.00	45.34	46.82
Alternative 5. On-package labels for all products:				
Total	1,298.74	956.54	87.30	90.28
Ground & chopped	429.41	316.99	28.86	29.92
Major cuts	674.49	496.00	45.34	46.82
Nonmajor cuts	194.84	143.49	13.10	13.54

Note: These compliance costs do not take into account the level of voluntary compliance with the labeling required under each alternative. Consequently, the estimated compliance costs are overstated.

The lives saved associated with the nutrition labeling measures for ground or chopped products, and major and nonmajor cuts are based on the amount of product affected by the measures for each of the regulatory alternatives. For example, 16.7 billion pounds of major cuts are affected by POP nutrition information placards under Alternative 3 (Table 26). On-package nutrition labels are required for the 4.9 billion pounds of ground and chopped meat and poultry products affected by Alternative 3. The average annual 30.74 (19.37 + 11.37) lives saved as a result of this alternative, assuming POP nutrition information is 50 percent as successful as on-package nutrition labels in causing dietary change, is obtained as follows. The average annual lives saved as a result POP nutrition information for major cuts is 19.4 lives as shown in Table 28 (16.7/21.6 = 0.77; (0.77 × 50.1) × .5 [43] = 19.4). On-package nutrition labels for ground or chopped products account for the remaining 11.4 lives saved annually (4.9/21.6 = .227; .227 × 50.1 = 11.4).

Table 28 shows the cost-effectiveness of the regulatory alternatives when POP nutrition information is assumed to be half as successful as on-package nutrition labels in bringing about healthier diets and reducing coronary heart disease and cancer. This success rate is considered to be an upper bound. The cost per life saved for Alternative 3 is $1.069 million, when using the composite annual average and annualized costs based on a 7 percent discount rate. The cost per life saved for on-package nutrition labels for ground or chopped products under this alternative is $2.63 million ($29.92 million from Table 27/11.37 lives saved annually, column 1 of Table 28) and $151,000 for POP nutrition information placards under this alternative ($2.93 million from Table 27/19.37 lives saved annually).

As would be expected under this scenario, Alternative 4 and 5 are less cost effective than the supplemental proposed rule measures because they rely entirely on the relatively more costly measures of on-package nutrition labels. Alternative 2 has a lower cost-effectiveness ratio in this scenario because of the assumed high rate of success for POP nutrition information and because it relies entirely on a low-cost POP reference manual.[44] Using an average VSL of $5.5 million, all alternatives show large average annual benefits relative to annual costs with Alternative 5 yielding the highest net benefits.

TABLE 28—AVERAGE COST-EFFECTIVENESS AND NET BENEFITS OF POTENTIAL LIVES SAVED—POP NUTRITION INFORMATION 50 PERCENT AS SUCCESSFUL AS ON-PACKAGE NUTRITION LABEL INFORMATION

Alternatives	Potential lives saved	Cost/life saved 7%	Value of lives saved	Net benefit 7%
		$ million		
Alternative 2. POP manuals for all products:				
Total	28.4	.291	156.3	150.0
Ground/chopped	5.7	.046	31.3	31.0
Major cuts	19.4	.047	106.5	105.6
Nonmajor cuts	3.4	2.112	18.5	11.4
Alternative 3. On-package labels for ground and chopped, POP placards for major cuts:				
Total	30.7	1.069	169.0	136.2
Ground/chopped	11.4	2.633	62.5	32.6
Major cuts	19.4	.151	106.5	103.6

[43] This value reflects the relative success of POP nutrition information relative to on-package labels. This value will change according to the scenario being discussed.

[44] The analysis assumes that the manual containing the nutrition information as specified for Alternative 2 and the POP nutrition information placards specified in Alternative 3 have the same impact on consumer dietary patterns. The use of a nutrition information reference manual is assumed to be the manner by which retail establishments would convey nutrition information under Alternative 2.

TABLE 28—AVERAGE COST-EFFECTIVENESS AND NET BENEFITS OF POTENTIAL LIVES SAVED—POP NUTRITION INFORMATION 50 PERCENT AS SUCCESSFUL AS ON-PACKAGE NUTRITION LABEL INFORMATION—Continued

Alternatives	Potential lives saved	Cost/life saved 7%	Value of lives saved	Net benefit 7%
Alternative 4. On-package labels for ground and chopped products and major cuts:				
Total	50.1	1.532	275.6	198.8
Ground/chopped	11.4	2.633	62.5	32.6
Major cuts	38.7	1.209	213.4	166.2
Alternative 5. On-package labels for all products:				
Total	56.8	1.589	312.6	222.3
Ground/chopped	11.4	2.633	62.5	32.6
Major cuts	27.8	1.628	153.1	106.3
Nonmajor cuts	10.9	1.202	59.9	46.4

Note: These estimates do not take into account the level of voluntary compliance with the labeling required under each alternative. Consequently, the estimated compliance costs as well as potential lives saved are overstated.

Tables 29 and 30 show the impact on the cost effectiveness of Alternatives 2 and 3, and their respective measures, when POP nutrition information is 10 and 5 percent as successful, respectively, as on-package nutrition labels in leading to dietary changes. The cost effectiveness of Alternatives 4 and 5 are not affected as they do not employ POP nutrition information. Consequently, their effectiveness ratios and net benefits are unchanged from Table 28.

The results show that as the success of POP nutrition information declines relative to on-package nutrition labels, the cost-effectiveness measures for Alternative 2 decline more rapidly than those for Alternative 3, given the second alternative's entire reliance on POP nutrition information. When POP nutrition information is 10 percent as successful as on-package nutrition information labels (Table 29), the average cost-effectiveness for Alternatives 2 through 5 are approximately the same (between $1.5 to $2.2 million per life saved). While the average cost-effectiveness ratios of the regulatory alternatives are approximately the same, the annual net benefits of the alternatives differ significantly. This measure ranges from $23 million for Alternative 2 to 10 times that amount for Alternative 5 (Table 26). It should be noted that the cost per life saved associated with POP nutrition information for nonmajor cuts of single ingredient, raw meat and poultry products under Alternative 2 exceeds the value of a life saved and, consequently, the annual benefits associated with the measure are less than the annual costs.

TABLE 29—AVERAGE COST-EFFECTIVENESS AND NET BENEFITS OF POTENTIAL LIVES SAVED —POP NUTRITION INFORMATION 10 PERCENT AS SUCCESSFUL AS ON-PACKAGE NUTRITION LABEL INFORMATION

Alternatives	Potential lives saved	Cost/life saved 7%	Value of lives saved	Net benefit 7%
		$ Million		
Alternative 2. POP manuals for all products:				
Total	5.7	1.457	31.3	23.0
Ground/chopped	1.1	.232	6.3	6.0
Major cuts	3.9	.236	21.3	20.4
Nonmajor cuts	0.7	10.562	3.7	−3.4
Alternative 3. On-package labels for ground and chopped, POP placards for major cuts:				
Total	15.2	2.156	83.8	51.0
Ground/chopped	11.4	2.633	62.5	32.6
Major cuts	3.9	.757	21.3	18.4

Note: These estimates do not take into account the level of voluntary compliance with the labeling required under each alternative. Consequently, the estimated compliance costs as well as potential lives saved are overstated.

When POP nutrition information is 5 percent as successful as on-package nutrition information labels (Table 30), the average cost-effectiveness ratio for Alternative 2 is higher than those for the other alternatives and 15 percent higher than that for Alternative 3. The annual net benefit of POP nutrition information for ground or chopped product under Alternative 2 is declining to marginal levels. The annual net benefit for Alternative 3 is nearly $40.3 million, about 5 times that for Alternative 2.

Due to the differences in search costs for consumers using a POP reference manual versus a POP placard, Alternative 2 is expected to be less successful than Alternative 3 in changing dietary patterns. If POP manuals were 5 percent as successful as on-package labels and placards were 10 percent as effective as on-package labels, a plausible scenario, the cost per life saved for Alternative 3 would be about 75 percent (2.156/2.915) of that for Alternative 2. The number of lives saved annually under Alternative 3 would be about 5 times (15.2/2.8) that found under Alternative 2. The uncertainty associated with the success of a POP reference manual (Alternative 2) is an important factor supporting the effectiveness of Alternative 3 and the Agency's decision to select this alternative relative to Alternative 2.

TABLE 30—AVERAGE COST-EFFECTIVENESS AND NET BENEFITS OF POTENTIAL LIVES SAVED—POP NUTRITION INFORMATION 5 PERCENT AS SUCCESSFUL AS ON-PACKAGE NUTRITION LABEL INFORMATION

Alternatives	Potential lives saved	Cost/life saved	Value of lives saved	Net benefit
		$ million		
Alternative 2. POP manuals for all products:				
Total	2.8	2.915	15.63	7.4
Ground/chopped	0.6	.464	3.13	2.9
Major cuts	1.9	.472	10.70	9.7
Nonmajor cuts	0.3	21.125	1.85	−5.3
Alternative 3. On-package labels for ground and chopped, POP placards for major cuts:				
Total	13.3	2.470	73.16	40.3
Ground/chopped	11.4	2.633	62.51	32.59
Major cuts	1.9	1.514	10.65	7.72

Note: These estimates do not take into account the level of voluntary compliance with the labeling required under each alternative. Consequently, the estimated compliance costs as well as potential lives saved are overstated.

Summary of Analysis of Alternatives

The analysis shows that the POP information does not need to be highly successful for its benefits to exceed its costs, even at low levels of success relative to on-package nutrition labels.

FSIS finds that the measures required in the supplemental proposed rule are generally more effective than the other alternatives when all the qualitative and quantitative evidence is considered. As has been discussed above in this section, FSIS finds that on-package nutrition labels for ground or chopped product are more effective than POP nutrition information in informing consumers about the nutritional characteristics of these products, given the nature of the product, its presentation in the retail environment, and consumer behavior. FSIS also finds that POP nutrition placards are an effective means for informing consumers about the nutritional characteristics of major cuts of single ingredient, raw products for these same reasons.

F. Summary of Costs and Benefits of the Final Nutrition Labeling Rule

FSIS estimates that for the supplemental proposed rule, the discounted average present value of benefits over a 20-year period using a 7 percent discount rate will be $2.2 billion and using a 3 percent discount rate will be $3.7 billion, using a composite of three scenarios for the effectiveness of nutrition labels and three values for reducing a premature death. The corresponding average annual benefits are $205.5 million and $248.3 million (*See* summary Table 30b).

The discounted average present value costs, over a 20-year period, are estimated to be $348.06 million using a 7 percent discount rate and $472.23 million using a 3 percent discount rate. The corresponding annualized average costs are $32.8 and $31.7 million (*See* summary table 30b and Appendix D, Tables 1 and 2).

After taking into account the current assumed levels of compliance with the supplemental proposed rule measures, the average present value costs of the rule decline to $115.45 million and $156.72 million when using a 7 percent and 3 percent discount rate, respectively. The corresponding annualized average costs are $10.9 and $10.5 million. The average present values of the benefits are $0.800 billion and $1.358 billion using 7 and 3 percent discount rates, respectively. The corresponding average annual benefits are $75.5 million and $91.3 million. Table 30c provides a summary of these annualized costs and benefits. These estimates suggest that under plausible assumptions, the impact of this rule in any given year may be less than $100 million. However, given the uncertainties in the analysis, this action is deemed ''economically significant''.

Not included in the quantitative analysis were other likely benefits to providing nutrition labeling: increased profits received by food retailers and manufacturers, and consumers buy products with the attributes they want. FSIS believes that the labeling provisions help consumers make better food choices and provide incentives to producers to continue producing nutritionally-improved products that contribute substantially to the health benefits associated with nutrition labeling. If diet quality associations found with all other labeled foods do not hold up for nutrition labels on meat, then health benefits in the FSIS report are overestimated. Of course, health benefits are only one way in which benefits might be realized. Consumers might choose to use nutritional information to enhance enjoyment of food, and not to raise their health status. Further, they may be better off than if they had raised their health status since rational consumers will use information to their best advantage. If we observe rational, well-informed consumers selecting a more enjoyable diet, for these consumers a more enjoyable diet was worth more than better health. Thus, when we restrict benefits estimates to allow only for information to be used to advance health status, we are simultaneously restricting estimated benefits to a lower level of value to consumers. The FSIS analysis imposes that restriction and the resulting benefits estimate must therefore be interpreted as an underestimate of overall benefits. The estimated costs of the rule's nutrition labeling requirements appear to be justified by the estimated benefits.

TABLE 30b—SUMMARY OF ANNUALIZED AVERAGE NET PRESENT VALUES OF COSTS AND BENEFITS, BEFORE ACCOUNTING FOR LEVELS OF CURRENT COMPLIANCE, *$million/year*

Category	*Primary estimate*	*Low estimate*	*High estimate*	*Units*		
				Year dollars	*Discount (percent)*	*Period covered*
Benefits:						
Annualized	*205.5*	*185.6*	*230.8*	*2002*	*7*	*20 years.*
Monetized $million/year*	*248.3*	*228.4*	*273.6*	*2002*	*3*	*20 years.*
Qualitative:	*Consumers might also choose to use nutritional information to enhance enjoyment of food, and not just to raise their health status.*					
Costs:						
Annualized	*32.8*	*26.7*	*44.8*	*2002*	*7*	*20 years.*
Monetized $million/year*	*31.7*	*25.6*	*43.7*	*2002*	*3*	*20 years.*

Notes: * Monetized benefits of potential lives saved.
Note: These estimates do not take into account the level of voluntary compliance with the nutrition labeling requirements for ground or chopped products that currently exists. Consequently, the estimated amounts of ground or chopped products and major cuts impacted by this supplemental proposed rule are overstated. Consequently, the estimated compliance costs as well as the monetized benefits of potential lives saved are overstated.

TABLE 30c—SUMMARY OF ANNUALIZED AVERAGE NET PRESENT VALUES OF COSTS AND BENEFITS, AFTER ACCOUNTING FOR ASSUMED LEVELS OF CURRENT COMPLIANCE, *$million/year*

Category	*Primary estimate*	*Low estimate*	*High estimate*	*Units*		
				Year dollars	*Discount (percent)*	*Period covered*
Benefits:						
Annualized	*75.5*	*68.1*	*84.8*	*2002*	*7*	*20 years.*
Monetized $million/year*	*91.3*	*83.9*	*100.6*	*2002*	*3*	*20 years.*
Qualitative:	*Consumers might also choose to use nutritional information to enhance enjoyment of food, and not just to raise their health status.*					
Costs:						
Annualized	*10.9*	*8.9*	*14.7*	*2002*	*7*	*20 years.*
Monetized $million/year*	*10.5*	*8.6*	*14.4*	*2002*	*3*	*20 years.*

Notes: * Monetized benefits of potential lives saved.
Note: These estimates take into account the level of voluntary compliance with the nutrition labeling requirements for ground or chopped products that currently exists—the 68 percent compliance rate (NCBA, 2004) of voluntary nutrition labeling of ground or chopped products and 54.8 percent level of voluntary compliance (USDA, 1999) of stores that provide nutrition labeling for major cuts.

Regulatory Flexibility Act (RFA)—Assessment

Based on the cost analysis above, FSIS has made a tentative determination that this rule would not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The supplemental proposed rule would affect meat and poultry processing establishments producing ground or chopped products (Table 1 and 2) and retail firms and establishments (Tables 3 and 4). There are approximately 3,073 potentially affected Federal and State processing establishments and 47,688 potentially affected retail firms with 74,910 retail establishments. A ''firm'' refers to the parent company and an ''establishment'' refers to the retail facility. Processing establishments that grind or chop meat and poultry will be potentially affected. There are 1,433 very small, 858 small, and 109 large Federal establishments that produce ground or chopped products, based on PBIS (April, 2006). The final regulatory analysis assumes that no small processor is independent. That is, all (regardless of their size) are part of a larger organization. Table 13 shows the undiscounted costs of about $53.80 million for all the affected processing establishments.

FSIS does not believe that any very small operations will be affected by the regulation because very small meat and poultry operations employ nine or fewer employees. These establishments would find it difficult to produce over 100,000 pounds per ground product annually because these employees also process other products. Annual revenues associated with 100,000 pounds of annual ground beef total approximately $230,000 for 85 percent lean ground beef, based on a retail value of $2.30 per pound (Agricultural Marketing Service, Market Reports, September 2009). Some small establishments are also likely to be exempt from the regulation because they have 500 or fewer employees, or are owned by companies with 500 or fewer employees, and FSIS assumes they produce less than 100,000 pounds annually of each ground product. FSIS researched this issue to better address the number of establishments that would be affected but does not have better data on corporations that own these individual establishments. However, as discussed earlier in the final regulatory analysis, RTI made the assumption that Federally-inspected processing establishments generally are a part of a larger organization that own, on average, three establishments each. In addition, based on PBIS (April 2006), there are 41 state-inspected processing establishments (Table 2) that are owned by 41 firms. Therefore, there are about 899 (858 + 41) small processing establishments that are affected by the supplemental proposed rule.

As part of the Regulatory Flexibility Assessment, FSIS also examined the impact of the supplemental proposed rule, by altering certain assumptions, to

determine whether the supplemental proposed rule could have a significant impact on a substantial number of small entities. Therefore, even though FSIS believes that small processors would find it difficult to produce over 100,000 pounds per ground product annually because these employees also process other products, FSIS estimated the cost to small grinders if they were not exempt from nutrition labeling requirements. For purposes of this alternative analysis, it is assumed that all 899 small processing firms will be affected by this regulation.[45] Also, based on the analysis for the supplemental proposed rule, there are 6.6 frozen or fresh ground meat or chopped meat and poultry products produced per company. For this alternative analysis, it is assumed that there are 5,933 (899 × 6.6) unique ground or chopped products. FSIS estimates that the one-time average costs of modifying product labels on prepackaged ground or chopped products to include nutrition information at processing establishments will be $13.33 million ($2,247 per label modification costs × 896 affected companies × 6.6 affected products per company) using average cost estimates. The annualized cost over 20 years at 7 percent is $1.26 million. On a per company basis the annualized cost over 20 years is about $1,402 ($1.26 million/896).

In addition to the one-time costs of designing labels, processing establishments will also incur added costs of larger labels. Again, it is assumed that there are 899 small processing establishments that grind or chop meat and poultry, and that all these establishments are small businesses. Based on a study conducted by NCBA, 25 percent of ground or chopped meat and poultry packages are packaged at processing establishments. As explained above, approximately 437.5 million packages of ground and chopped meat and poultry products are packed by processing establishments each year. There are no data available to estimate the number of packages of ground or chopped meat or poultry products packaged by these small establishments, but (for purposes of this analysis) if 25 percent of all of the packages originate at small establishments, then these 899 companies package 109.4 million packages annually (437.5 million × .25). Multiplying 109.4 million packages by 0.5 cents per label (RTI, 2003) results in an annual cost of $547,000 (109.4 million packages × $0.005) or about $509 per company. In total, FSIS estimates that (under the alternative set of assumptions that all small entities will be affected by this supplemental proposed rule and that they package 25 percent of the total) the cost to these 899 small companies (assuming that they package 25 percent of the total) will be about $1,616 ($1,107 + $509) per company on an annualized basis using a 7 percent discount rate.

If, on the other hand, 50 percent of all packages from processing establishments originate at the small establishments, then these 899 companies package about 219 million packages annually. Multiplying 219 million packages by $0.005 per label results in an annual cost of $1,095,000 or $1,218 per company. In total, FSIS estimates that the cost to 899 small companies (under the alternative set of assumptions that all small entities will be affected by this supplemental proposed rule and that they package 50 percent of the total) will be about $2,126 per company ($1,402 + $1,218) on an annualized basis discounted at 7 percent.

Small retail stores will incur the cost of providing POP nutrition information for the major cuts. There are 47,422 small retail firms that own 51,431 small retail stores that would be required to provide POP information for the major cuts of single-ingredient, raw products. FSIS estimates that the cost to a retail store for placards will be $10.56 for labor plus $65.17 for materials or approximately $75.73 per store. The annualized cost, assuming that the placards have to be replaced every two years, is about $41.88 using a 7 percent discount rate. All retail stores, including small and very small businesses will incur these costs. FSIS believes that these costs are not significant—even for very small businesses.

Retail stores will also incur costs related to required nutrition labels for ground or chopped products. For this analysis, it is assumed that they will all comply by following Option 1 (the less costly printing method for labels) because it is the least costly. Based upon the information contained in the regulatory analysis, a total of 74,910 establishments owned by 47,688 firms could potentially be affected. However, 23,479 establishments owned by 266 firms are considered to be large according to the 2002 Economic Census. If they grind or chop over 100,000 pounds of a particular product annually, then as many as 51,431 small establishments owned by 47,422 firms could potentially be affected.[46]

For these establishments, it is assumed that there would be only one scale-printer system instead of the 1.5 scale-printer systems that was assumed in the regulatory analysis. Therefore, the average cost of upgrading scale-printer systems is estimated at $1,600, and this cost would be incurred by these businesses once every five years. FSIS estimates that the annualized cost, since scale-printer systems need to be replaced every 5 years, is about $390 using a 7 percent discount rate. Operating and maintenance costs are estimated at 6 percent (*See* supplemental PRIA for detailed explanation) or $96 annually. Therefore, the sum of the annualized maintenance costs at 7 percent is estimated at $486 annually per establishment ($390 + $96).

The average cost of redesigning larger store labels and conducting nutrition analysis is estimated at $2,247. However, many firms have more than one establishment so the cost per establishment will be much lower. Assuming that each establishment had to redesign its store labels for 4.6 products and conduct nutrition analysis for each unique product, then the added annualized cost over 20 years is estimated at $766 using a 7 percent discount rate.

The use of larger labels is another cost that these retail stores will incur. As explained above, an estimated 1.75 billion packages of ground or chopped meat or poultry products are sold at large retail facilities. Therefore, 460 million packages of ground or chopped products are sold at small retail establishments. Given that 51,431 small retail establishments could be affected, then each small establishment (460 million packages/51,431 establishments) sells 8,039 packages annually. If the added average cost of each label is $0.005, then each retail store will incur an added cost of about $40 annually ($8,039 packages per establishment × .005).

FSIS estimates that using a 7 percent discount rate the sum of the annual/annualized cost to each retail establishment will be $42 for nutrition information placards, $486 for upgrading and maintaining scale-printer systems, $969 for redesigning larger store logo labels, and $40 for using larger labels. The total annual/

[45] Although RTI, in their analysis stated that all of these businesses are large, for this analysis, FSIS is altering the assumption in order to determine the impact (measure the sensitivity) of a set of alternative assumptions.

[46] RTI believes that all of these businesses will be exempt from nutrition labeling requirements. For purposes of conducting a sensitivity analysis, this analysis assumes that they are small for purposes of the Regulatory Flexibility Act and that they will not qualify for the small business exemption.

annualized cost using a 7 percent discount rate will be $1,537. FSIS also estimates that using a 3 percent discount rate the total annual/annualized cost using a 3 percent discount rate will be $1,216. In summary, FSIS concludes from using an alternate set of assumptions, that this supplemental proposed rule would not have a significant impact on a substantial number of small entities.

FSIS is cognizant of the possibility that while exempted establishments would not have to incur labeling costs, they also might not realize the benefits of increased sales of the nutritionally labeled 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 any adverse impact on these smaller establishments. It would, however, also increase their labeling costs. 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 POP materials, for the major cuts. Therefore, if manufacturers do not provide nutrition information on the label, retailers would be required to provide this information at the POP or on product labels. However, as noted above, this requirement should not impose major costs or other burdens. The annual/annualized cost to each retail establishment will be $42 for nutrition information placards.

The economic impact on retail stores is likely to be minimal because recently there has been consolidation of these stores as a consequence of mergers and acquisitions, resulting in an increased market share of large retailers relative to small ones. For example, several years ago Royal Ahold, the Dutch Conglomerate, bought out Giant Food. Also, Ahold 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). More recently, Wal-Mart through its operation Wal-Mart Puerto Rico agreed to acquire Supermercados Amigo, the leading supermarket chain in Puerto Rico. These mergers and acquisitions are likely to increase market shares of the large retailers at the cost of smaller ones.

Based on the 2002 Economic Census of the U.S. Department of Commerce, meat and poultry processing establishments that are small entities had annual revenues from total value of shipments that ranged from $0.454 million to $96.038 million. For each processing (grinding) establishment, average costs as a percent of revenues range from a lower bound of 0.001 percent ($1,402/$96.038 million to an upper bound of 0.3 percent ($1,402/$0.454 million). Further, small entity retail stores (supermarkets and other grocery (except convenience) stores and meat market stores) had annual revenues from sales that ranged from $0.343 million to $8.873 million. Also, the companies or firms of the small retail stores had annual revenues from sales that ranged from $0.343 million to $48.342 million. Costs as a percent of revenues range from the lower bound of 0.02 percent ($1,537/$8.873 million) to the upper bound of 0.4 percent ($1,537/$0.343 million). Many of these retail firms that are small entities own multiple retail stores that are small entity supermarkets and other grocery (except convenience) stores.

The following table shows the upfront, first year costs for all businesses affected by the rule, compared to the first year, upfront costs for small businesses. The table also shows the percent of total first year costs of the rule that will be incurred by small businesses. Based on the cost estimates for the rule, assuming retailers choose Option 1 for labeling ground or chopped products, small businesses will incur 10.1 percent of total estimated first year costs.

TABLE 32—DISTRIBUTION OF FIRST YEAR COSTS—3 PERCENT DISCOUNT RATE

	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant
	$ Million					$ Million—Present value				
All entities	61.88	39.88	6.00	67.88	45.88	60.09	38.72	5.83	65.91	44.55
Only small entities	2.84	2.84	3.98	6.82	6.82	2.76	2.76	3.86	6.62	6.62
	Percent									
Small entitles share of total costs	4.59	7.12	66.33	10.05	14.86	4.59	7.12	66.33	10.05	14.86

TABLE 33—DISTRIBUTION OF FIRST YEAR COSTS—7 PERCENT DISCOUNT RATE

	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant
	$ Million					$ Million—Present value				
All Entities	61.88	39.88	6.00	67.88	45.88	57.86	37.29	5.61	63.47	42.90

TABLE 33—DISTRIBUTION OF FIRST YEAR COSTS—7 PERCENT DISCOUNT RATE—Continued

	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant	Option 1 retail	Option 2 retail	Processing plant	Option 1 retail + processing plant	Option 2 retail + processing plant
Only small entities ...	2.84	2.84	3.98	6.82	6.82	2.66	2.66	3.72	6.38	6.38
	Percent									
Small entitles share of total costs	4.59	7.12	66.33	10.05	14.86	4.59	7.12	66.33	10.05	14.86

Executive Order 12988

This supplemental 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 supplemental proposed rule would not be intended to have retroactive effect.

Administrative proceedings would 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 rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under FMIA and PPIA.

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 supplemental proposed rule in accordance with the Paperwork Reduction Act. Should this rule become final, FSIS will require several information collection and recordkeeping activities. FSIS will requiring nutrition labeling on the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their POP, 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 POP. 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 POP. In the estimate of burden below, FSIS is calculating that all retailers would display POP information for the major cuts of single-ingredient, raw meat and poultry products, because this is a low-cost 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 requiring 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 POP materials and making them available for consumers would take an average of 30 minutes. FSIS believes that the nutrition information on most POP materials will be based on the most current representative database values contained in USDA's National Nutrient Data Bank or the USDA National Nutrient Database for Standard Reference. FSIS also believes it is unlikely that there will be any nutrition claims made on the POP 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 6 hours. Labels developed at official establishments would be submitted to FSIS. FSIS estimates that each official establishment that produces ground or chopped product would submit 6.6 labels to FSIS for approval. FSIS estimates that it would take an average of 1.5 hours 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 30 minutes.

Respondents: Meat and poultry establishments and retail stores.

Estimated number of respondents: 75,539.

Estimated number of responses per respondent: 18.04.

Estimated total annual burden on respondents: 66,062 hours

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, 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 FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS'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 both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs,

Office of Management and Budget, Washington, DC 20253.

To be most effective, comments should be sent to OMB within 60 days of the publication date of this supplemental proposed rule.

E-Government Act Compliance

FSIS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this supplemental proposed rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2009_Proposed_Rules_Index/index.asp*. FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Section III

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 stated 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 continues to read as follows:

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

2. Section 317.300 is 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 POP 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 is 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.(b). [Reserved]

4. Section 317.309 is amended as follows:

a. In paragraph (b)(3), the first sentence is 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 is amended 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 is added after the first sentence: ''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) is amended by adding the following new sentence at the end of the paragraph: ''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) is 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) is 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) is 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) is amended by removing the phrase ''(including ground beef)'', 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 National 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).''

§ 317.343 [Amended]

5. Section 317.343 is removed.

6. Section 317.344 is amended by removing the phrases ''ground beef regular without added seasonings, ground beef about 17% fat,'' and ''ground pork.''

7. Section 317.345 is amended as follows:

a. The section heading and paragraphs (a) and (c) are revised.

b. Paragraph (d) is amended by removing ''should'' and adding, in its place, ''for products covered in paragraphs (a)(1) and (a)(2) must''.

c. Paragraph (e) is amended by removing ''its published form, the Agriculture Handbook No. 8 series'' and by adding, in its place, ''its released form, the USDA National Nutrient Database for Standard Reference'', and by removing ''(including ground beef)''.

d. Paragraph (f) is amended by adding ''provided'' after ''nutrition information is''.

e. Paragraph (g) is amended by removing the phrase ''(including ground beef)''.

The revisions 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 is 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 is amended by:

a. Revise paragraph (a)(1) introductory text.

b. Paragraph (a)(1)(ii) is 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) is amended by removing the semi-colon and ''and'' 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 (a)(1);''.

d. Paragraph (a)(7)(ii) is 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 (a)(1); and''

e. Add a new paragraph (a)(7)(iii).

f. Paragraph (d)(1) is 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.''

The revision and addition read as follows:

§ 317.400 Exemption from nutrition labeling.

(a) * * *

(1) Food products produced by small businesses, other than the major cuts of single-ingredient, raw meat products identified in § 317.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 317.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 317.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

* * * * *

(7) * * *

(iii) Products that are ground or chopped at an individual customer's request.

* * * * *

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 is 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 is 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 is amended as follows:

a. Revise paragraph (b)(3).

b. Paragraph (b)(10) is amended by adding the following new sentence at the end of the paragraph: ''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) is 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) is 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) is 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) is 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 National 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).''

The revision reads as follows:

§ 381.409 Nutrition label content.

* * * * *

(b) * * *

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products that are not ground or chopped poultry products as described in § 381.401 may be declared on the basis of the product ''as consumed.'' 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). In addition to the required declaration on the basis of ''as packaged'' for products other than single ingredient, raw products that are not ground or chopped poultry products as described in § 381.401, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

* * * * *

§ 381.443 [Removed]

14. Section 381.443 is removed.

15. Section 381.445 is amended as follows:

a. The section heading and paragraph (a) and (c) are revised.

b. Paragraph (d) is amended by removing ''should'' and adding, in its place, ''for products covered in paragraphs (a)(1) and (a)(2) must''.

c. Paragraph (e) is amended by removing ''its published form, the Agriculture Handbook No. 8 series'' and by adding, in its place, ''its released form, the USDA National Nutrient Database for Standard Reference.''

d. Paragraph (f) is amended by adding ''provided'' after ''nutrition information is''.

The revisions 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 is 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 is amended by:

a. Revising paragraph (a)(1) introductory text.

b. Paragraph (a)(1)(ii) is 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) is amended by removing the semi-colon and ''and'' 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 (a)(1);''.

d. Paragraph (a)(7)(ii) is 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 (a)(1); and''

e. Add a new paragraph (a)(7)(iii).

f. Paragraph (d)(1) is 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.''

The revision and addition reads as follows:

§ 381.500 Exemption from nutrition labeling.

(a) * * *

(1) Food products produced by small businesses other than the major cuts of single-ingredient, raw poultry products identified in § 381.444 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 381.401 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 381.462(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

* * * * *

(7) * * *

(iii) Products that are ground or chopped at an individual customer's request.

* * * * *

Done in Washington, DC, on December 3, 2009.

Alfred V. Almanza,

Administrator.

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