

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

[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:** Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products on labels or at point-of-purchase, unless an exemption applies. FSIS is also amending its regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. In addition, the rule provides that, when a ground or chopped product does not meet the regulatory criteria to be labeled "low fat," a lean percentage statement may be included on the label or in labeling as long as a statement of the fat percentage that meets the specified criteria also is displayed on the label or in labeling.

DATES: Effective Date: This final rule is effective on January 1, 2012.

FOR FURTHER INFORMATION CONTACT:

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Section I.**SUPPLEMENTARY INFORMATION:****Background**

The Nutrition Labeling and Education Act (NLEA) of 1990 required nutrition labeling of most foods regulated by the Food and Drug Administration (FDA). Because FSIS is committed to providing consumers with the most informative labeling system possible, FSIS published regulations establishing comparable nutrition labeling requirements for meat and poultry products. FSIS published an advance notice of proposed rulemaking on nutrition labeling of meat and poultry products on April 2, 1991 (56 FR 13564), a proposed rule on November

27, 1991 (56 FR 60302), a final rule on January 6, 1993 (58 FR 632), and subsequently other amendments to the rule.

The Agency's regulations currently require nutrition labels on the packages of all multi-ingredient and heat processed meat and poultry products, unless an exemption applied. The required nutrition labeling provisions are referred to as "the mandatory nutrition labeling program." The Agency's 1993 regulations also established guidelines for voluntary nutrition labeling of single-ingredient, raw meat and poultry products, including single-ingredient, raw ground or chopped products.

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 published a supplemental proposed rule on December 18, 2009, to provide the public an additional opportunity to comment (74 FR 67736). This final rule is consistent with the provisions in the supplemental proposed rule.

Nutrition labeling continues to be an integral part of USDA's efforts to educate consumers concerning nutrition and diets. Since 1980 USDA and the Department of Health and Human Services (HHS) have jointly published the Dietary Guidelines for Americans every five years. The Dietary Guidelines provide advice concerning food choices that promote health and prevent disease. The Dietary Guidelines for Americans, 2005, advises consumers to aim for a total fat intake between 20 to 35 percent of calories (page viii). In addition, the Dietary Guidelines for Americans, 2005, includes a chart showing the recommended upper limits for grams of saturated fat per day for a range of total calories per day (page 31). The nutrition information that FSIS is requiring in this final rule on the labels of ground or chopped products and on either labels or point-of-purchase materials for the major cuts of single-ingredient, raw meat and poultry products would include the number of calories and the grams of total fat and saturated fat the product contains. The information FSIS is requiring would, therefore, assist consumers in following the advice in the Dietary Guidelines for Americans, 2005.

Major cuts: This final rule requires 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. For these products, the final rule requires that nutrition information be provided on the label or at point-of-purchase, unless an exemption applies.

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). Under 9 CFR 317.343 and 9 CFR 381.443, if FSIS finds that there is not significant participation by retail stores in the voluntary nutrition labeling program to provide nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products, FSIS is obligated to institute rulemaking to require that such labeling be provided. FSIS regulations provide that a food retailer participates 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. Significant participation by food retailers exists if at least 60 percent of all companies that were evaluated were participating in accordance with the guidelines. Based on the survey data from the two most recent surveys from 1996 and 1999, less than 60 percent of stores evaluated were participating in accordance with the guidelines. Therefore, significant participation in the voluntary nutrition labeling program did not exist, and FSIS proceeded with rulemaking.

Under § 317.4, FSIS's Labeling and Program Delivery Division (LPDD) reviews labels on meat and poultry products that have been submitted for approval. Based on its label review, FSIS has not seen an increase in nutrition labeling of the major cuts of single-ingredient raw, meat and poultry products since the surveys were conducted. Compliance investigators in FSIS's Office of Program Evaluation, Enforcement & Review (OPEER) also have not seen an increase in the number of packages of the major cuts of single-ingredient, raw meat and poultry products that have nutrition facts panels on their labels at retail or an increase in the availability of point-of-purchase materials that provide nutrition information for such products at retail since the last compliance surveys were conducted. For these reasons and because no other evidence has been submitted to FSIS that significant participation in the voluntary program

now exists, FSIS has concluded that this final rule is necessary.

FSIS has determined that major cuts of single-ingredient raw, meat and poultry products that do not bear nutrition information on their labels or on point-of-purchase materials will be misbranded, under section 1(n) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(n)(1)) and section 4(h)(1) of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(h)(1)). Without nutrition information on their labeling, FSIS has concluded that the labeling of these products will be false or misleading because it will not provide consumers with sufficient information to assess the nutrient content of the major cuts and will not enable consumers to select major cuts that fit into a healthy diet that meets their individual needs.

Consumers are given a rough indication of the fat content of major cuts of poultry based on whether the product has skin and based on the levels of attached fat in the product. Similarly, consumers are given a rough indication of the fat content of 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.

To provide flexibility, the rule allows nutrition information to be provided on the labels of individual packages of the major cuts of single-ingredient, raw products and, to be provided on point-of-purchase materials. Further, FSIS has determined that point-of-purchase labeling is appropriate because consumers can generally estimate the fat content in these products, and because the nutrient content of any given major cut is relatively uniform across the market.

Ground or Chopped Products: This final rule requires 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, this final rule requires that nutrition labels be provided for all ground or chopped poultry (kind), with or without added seasonings, unless an exemption applies. Under this final 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.

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. Other single-ingredient, raw products cannot be formulated in the same manner or to the same degree as ground products.

In ground or chopped products, the fat is uniformly distributed throughout the product and is not clearly distinguishable on the surface of the product. The Agency has concluded that consumers cannot estimate the level of fat in these products and cannot compare the levels of fat in these products to those in other products. Additionally, producers sometimes use meat from advanced meat recovery (AMR) systems and low temperature rendering (LTR) in ground or chopped beef or pork products, which can affect their nutrient content. For these reasons, FSIS has concluded that ground or chopped meat and poultry products that do not bear nutrition information will be misbranded under section 1(n)(1) of the FMIA and section 4(h)(1) of the PPIA.

FSIS is requiring 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 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.

Non-major Cuts of Single-Ingredient, Raw Meat and Poultry Products that are not Ground or Chopped: FSIS is not requiring nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped. But, if nutrition information is provided for these products, it must be provided in accordance with the nutrition labeling requirements for the major cuts. Therefore, under the final rule, if establishments or retail facilities choose to provide nutrition information for these products, they will either provide

it at 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.

Permitting Percent Lean Statements on labels or in labeling of ground or chopped products: The final rule permits 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. The required statement of fat percentage must 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. Many consumers have become accustomed to this labeling on ground beef products, and FSIS has concluded that this labeling provides a quick, simple, and accurate means of comparing ground or chopped meat and poultry products.

Exemptions: Under this final rule, the following exemptions from nutrition labeling requirements will apply to the major cuts of single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products:

- Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,
- Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,
- Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,
- Products that are custom slaughtered or prepared, and
- Products intended for export.

This final rule also provides the following additional exemptions 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),
- Products that are ground or chopped at an individual customer's request and that are prepared and served at retail, provided that the labels or labeling of these products bears no nutrition claims or nutrition information,
- Ground or chopped products in packages that have a total surface area for 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, and

- Ground products produced by small businesses that use statements of percent fat and percent lean on the label or in labeling of ground products, provided they include no other nutrition claims or nutrition information on the product labels or labeling.

FSIS believes an exemption for ground or chopped products produced by small businesses is necessary because the burden of mandatory nutrition labeling may force some small firms to stop producing the product because of the cost of nutrition labeling and eventually force some small firms out of business. FSIS believes it would not be feasible for some small businesses to incur the additional costs of nutrition labeling because of their low volume of sales or low volume of ground product. FSIS believes it is feasible for larger businesses to incur the additional costs of nutrition labeling because of their higher volume of sales or larger levels of production of ground product. This final rule, with an exemption for ground or chopped products that qualify for the small business exemption in §§ 317.400(a)(1) and 381.500(a)(1), provides nutrition labeling on the maximum volume of ground or chopped product while assuring that small businesses producing low volumes of product are not at risk of going out of business or materially reducing the variety of products they deliver to their customers. Further, FSIS believes that the relatively small additional benefits of requiring small businesses to put nutrition labels on all ground or chopped products are outweighed by the larger additional costs. FSIS estimates that without the exemption there would be a \$3 million reduction in annual average net benefit. Without the exemption, the projected compliance average total cost increase annually of \$54 million would not be the only type of cost that would be incurred. FSIS believes that without the exemption many small businesses would have to close or substantially reduce the variety of products they now offer. Reductions in purchase options would be a cost to consumers that could not be quantified for FSIS's analysis.

Under this final rule, there is not a small business exemption for the major cuts of single-ingredient, raw meat and poultry products because nutrition information for these products may be provided on labels or, alternatively, at their point-of-purchase. Additionally,

FSIS will 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.

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, the small business would have been required to include nutrition information on the product label. These small businesses would not have qualified for the small business exemption because the labels for these products included nutrition claims. Based on the National Cattlemen's Beef Association (NCBA) National Meat Case Study in 2004, 93 percent of ground beef packages had statements of lean or fat percentages (74 FR 67741). Sixty-eight percent of packages with such statements had nutrition facts panels and 25 percent did not (74 FR 67741). Because about 95 percent of grinders are small businesses, FSIS concluded that many of the 25 percent of packages that included lean or fat percentage statements without nutrition facts panels were produced by small businesses. Therefore, FSIS believes many small businesses include statements of lean or fat percentage on the label of their ground products but not the nutrition facts panel. Also, 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 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 (74 FR 67741). Many consumers have become accustomed to this labeling on ground beef products, and FSIS believes that this labeling provides a quick, simple, and accurate means of comparing ground or chopped meat and poultry products. Therefore under the final rule, small businesses that use statements of percent fat and percent lean on the label of ground products, provided they include no other nutrition claims or nutrition information on the product labels or labeling, are exempted from the nutrition labeling requirements.

Additionally, under this final 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 will 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.

Finally, this final rule makes clear that the current regulatory exemptions for ready-to-eat (RTE) product packaged or portioned at retail and multi-ingredient product processed at retail do not apply to RTE ground or chopped products packaged or portioned at retail or multi-ingredient ground or chopped products that are processed at retail because there may be a significant amount of multi-ingredient ground beef retail processed products or RTE retail packaged products (66 FR 4979, January 18, 2001). For further explanation of the reasons for the foregoing exemptions, see 58 FR 638–639; 66 FR 4978–4979; and 75 FR 67740–67741.

Enforcement and Compliance: After the final rule is implemented, FSIS will collect samples of ground product at retail for nutrient analysis. In addition, FSIS will assess whether nutrition information is available for the major cuts, either on package labels or at the point-of-purchase.

Under this final rule, the procedures set forth for FSIS product sampling and nutrient analysis in §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8) will be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. 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 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. Therefore, FSIS will treat these products as it treats other products required to bear nutrition labels.

FSIS will treat ground or chopped products in this way because the fat content of these products can vary significantly. 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.

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 will not sample and

conduct a nutrient analysis of the products because FSIS personnel can visually identify the particular cut. If the nutrition information for these products is based on USDA's National Nutrient Data Bank or the USDA 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 data and determined that they are valid (66 FR 4980, January 18, 2001).

Outreach: FSIS personnel will conduct meetings and Webinars on the final rule and will provide additional information and guidance as needed. If retailers cannot obtain point-of-purchase materials over the Internet, FSIS personnel will have copies of the information to provide to retailers.

Six months prior to the effective date, 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 at the following Internet address: <http://www.fmi.org/consumer/nutrifacts/>.

In addition, 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](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. 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. ARS also has published nutrient values for ground turkey with fat levels of 0%, 7%, and 15%. In the supplemental proposed rule, FSIS provided examples of nutrition labels for ground or chopped products that would meet the requirements of the final rule (74 FR 67742). Six months prior to the effective

date, FSIS will make additional examples of acceptable labels for such products available on the Agency's Web site.

Effective Dates: The requirements for ground or chopped products will become effective on January 1, 2012. FSIS issued a final rule 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). FSIS established the uniform compliance date to minimize costs associated with on-package labels. Because this final rule allows for the presentation of nutrition information for the major cuts of single-ingredient, raw meat and poultry products at their point-of-purchase, no change in on-package labels will be necessary to effect this aspect of this final rule. Thus, in the supplemental proposed rule, FSIS proposed that the labeling requirements for the major cuts would be effective one year from the date of publication of the final rule. Because one year from the date of publication will only be a few days before the effective date for ground and chopped products, January 1, 2012, FSIS is also establishing January 1, 2012 as the effective date for the labeling requirements for the major cuts.

Summary of and Response to Comments

FSIS received 33 comments on the supplemental proposed rule from individuals, a consumer organization, members of the regulated industry, trade and professional associations, and a city health department.

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: Many individuals, several trade associations, a city health department, a perishable items tracking company, and an industry commenter all generally supported required nutrition information for the major cuts, either on their label or at their point-of-purchase. Several individuals and the city health department stated that providing this nutrition information will help consumers make healthier, informed food choices and will allow them to monitor the amount of fat, cholesterol, and sodium that they consume. According to the city health department, cardiovascular disease, diabetes, and cancer are the leading causes of death, disability, and compromised quality of life in the

United States. This commenter also argued that these illnesses are connected with nutrition, and improved access to nutrition information through nutrition labeling can help people reduce their risk of developing these illnesses. A trade association stated that nutrition labeling allows consumers to quickly differentiate between meat products and identify leaner choices. One individual stated that many people need to check the specific nutritional content of foods for medical reasons.

One individual stated that most retailers do not participate in the voluntary nutrition labeling program at a significant level because the program is voluntary.

A consumer organization, a city health department, and an individual supported the proposed rule but argued that the final rule should mandate that nutrition information for major cuts of meat be provided through on-package labels rather than point-of-purchase materials. These commenters stated that on-package labeling helps people make more informed decisions. The consumer organization noted that a recent telephone survey showed an overwhelming percentage (86%) of the respondents preferred nutrition facts labels on meat packages rather than nutrition information on wall posters or signs. The city health department and the consumer organization argued that point-of-purchase materials are not an effective means of communication because their success depends on external factors, such as the retailer's placement of the point-of-purchase materials and layout limitations in small stores. The consumer organization and one individual stated that some of the disadvantages to using point-of-purchase materials are that they are hard to find, inconvenient to use, and difficult to read and comprehend. One individual also believed it was time-consuming and embarrassing for shoppers to read posters regarding nutrition information. Another individual stated that on-package labeling allows consumers to quickly compare products and provides the nutrition information to other consumers at home.

The consumer organization stated that point-of-purchase materials are not subject to any formal requirements under the supplemental rule. The consumer organization stated that FSIS should specify format and placement requirements for point-of-purchase materials. This organization stated that the USDA should work with the FDA to update format and readability requirements for posters. This organization believed that posters are

likely to omit many cuts or give them a different name than what appears on the package. The organization also stated that USDA should conduct a survey to determine whether consumers are better served by on-package nutrition labels than point-of-purchase materials. According to this consumer organization, many companies and grocery chains already use on-package nutrition labeling. Additionally, the consumer organization stated that if similar nutrition labels and labeling equipment are required for ground products, then retailers would not incur substantial additional costs by adding nutrition labels to major cuts.

The consumer organization disagreed with FSIS's position that consumers can visually determine the difference in fat content between various cuts. This organization noted that a recent telephone survey showed an overwhelming percentage (80%) of respondents could not determine which cuts of meat had the least amount of fat. The consumer organization suggested that the USDA does not have any data to support its assumption that consumers can visually determine the difference in fat content between various cuts.

Several trade associations, an industry commenter, and the food marketing organization supported the option of providing nutrition information for the major cuts through point-of-purchase materials. According to one trade association, their retailer customers believe nutrition labeling for meat is more efficiently displayed via point-of-purchase materials than on the product.

Response: As FSIS proposed, this final rule 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. FSIS agrees that the final rule will produce health benefits, including projected 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 final rule.

FSIS agrees with the individual that stated that most retailers do not participate at a significant level when labeling is voluntary. In the two most recent surveys from 1996 and 1999, FSIS found that significant participation in the voluntary nutrition labeling program did not exist (see 66 FR 4973, January 18, 2001; 74 FR 67736–67737, December 18, 2009). In addition, since the surveys were conducted, FSIS's LPDD has not seen an increase in the number of labels that include nutrition

information for the major cuts of single-ingredient, raw meat and poultry products. Further, FSIS's OPEER also has not seen an increase in the number of packages of the major cuts of single-ingredient, raw meat and poultry products that have nutrition facts panels on their labels at retail or an increase in the availability of point-of-purchase materials that provide nutrition information for such products at retail since the last compliance surveys were conducted. These observations do not constitute survey data but provide additional meaningful information based on the experience of FSIS's LPDD and OPEER. No evidence has been submitted to FSIS that significant participation in the voluntary program now exists.

FSIS agrees that many consumers cannot accurately assess the nutritional content of the major cuts of single-ingredient, raw products; however, we continue to believe that point-of-purchase nutritional information is appropriate for these products.

While consumers cannot accurately assess the nutritional content of the major cuts of single-ingredient, raw products, their ability to do so is greater than in the case of ground products. Ground products are processed in such a way that fat content is very difficult to visually ascertain. Internal marbling, attached fat, and whether the product has skin gives consumers some rough indication of the fat content of the major cuts of single-ingredient, raw products, which leads FSIS to believe that the benefits of on-package labeling may be slightly less than with ground product. FSIS notes, however, that consumers still need nutrition information on point-of-purchase materials for the major cuts because consumers cannot assess precise levels of fat (e.g., 10 grams vs. 20 grams of fat per serving) and cannot know the levels of calories or other specific nutrients, such as saturated fat, in these products.

Based on comments received and the Supplemental Proposed Rule Regulatory Impact Analysis, FSIS believes that requiring on-package labeling for the major cuts of single-ingredient, raw products is also likely to be significantly more costly than for ground products because it would require on-package labeling on a larger volume of product. In the Supplemental Proposed Rule Regulatory Impact Analysis, FSIS estimated that the annualized average present value of the costs of requiring nutrition labels on the major cuts of single-ingredient, raw meat and poultry products would be \$16.48 million more than the annualized average present value of the costs of requiring nutrition

labels on all ground or chopped products, without taking into account the current level of voluntary compliance (74 FR 67789).

As discussed in the proposed rule and in the supplemental proposed rule, FSIS believes it will be relatively easy to prepare point-of-purchase materials for the major cuts because 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) (74 FR 67737, December 18, 2009). To ensure that this is the case, FSIS is making available nutrition labeling materials that can be used at point-of-purchase over the Internet free of charge.

FSIS acknowledges the concern expressed by an individual and by the consumer organization about the location of point-of-purchase materials, but believes that it is currently addressed in the regulations (9 CFR 317.345(a)(3) and 381.445(a)(3)) which require that point-of-purchase materials be made available in close proximity to the food. In addition, FSIS personnel will also visit stores to verify that they are following this and the other requirements.

In response to the comment 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 that 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. If individuals in a household have certain nutrition practices and needs, the person who purchases food for the household would likely take other household members' needs and preferences into account. In this case, the entire household would ultimately receive the benefits of the nutrition information. Further, other household members besides the primary food purchaser will be able to obtain nutrition information for the major cuts on the Internet on FSIS's Web site, ARS's Web site, and FMI's Web site.

FSIS agrees that consumers cannot accurately judge the nutritional content of the major cuts of single-ingredient, raw products, and that the mandatory provision of this information to consumers is warranted and

appropriate. However, for the reasons described above, we believe that point-of-purchase information is appropriate for these products.

Comment: Several individuals and trade associations, one food marketing organization, and an industry commenter opposed the proposed rule to require nutrition information for the major cuts, either on their label or at their point-of-purchase. These trade associations and the food marketing organization stated that FSIS should maintain its existing voluntary program. One trade association and the food marketing organization advocated that the USDA should conduct a new compliance survey because it is likely that the level of participation in the voluntary nutrition labeling program has increased beyond the “significant participation” threshold because of changes in the composition of the retail sector over the past decade, and because of efforts by FMI to encourage the widespread use and dissemination of Nutri-Facts materials. These organizations stated that the last USDA survey for compliance is outdated because it was conducted in 1999, and should not be the basis for promulgating the rule. The food marketing organization noted that the regulations that require FSIS to evaluate the level of participation in the voluntary nutrition labeling program every two years remain in effect. One trade association stated that maintaining the voluntary program will be less costly and will help the industry. According to this trade association, FSIS could increase voluntary compliance by making the same updated nutrition information available free of charge to retailers as it planned to make available under the proposed rule. Several trade associations stated that if individual consumers wanted more specific nutrition information about a particular product, they could access it through other sources like the Internet. An industry commenter noted that if there was sufficient consumer demand for more nutrition information, then retailers would have an economic incentive to voluntarily supply it.

One trade association did not agree with FSIS’s position that major cuts of single-ingredient raw, meat and poultry products that do not bear nutrition information on their labels or on point-of-purchase materials are misbranded. Another trade association believed that there were few significant differences in the nutritional values among the various brands of young chicken, and that nutrition information for single-ingredient chicken is not that useful because most people add ingredients to

it during cooking that alter the calories, fat, and protein. For those reasons, the poultry trade association stated that there is no need to mandate nutrition labeling for the major cuts, and FSIS should maintain its existing voluntary nutrition labeling program for the major cuts. Several individuals stated that consumers already have a general idea of the average nutritional value of major cuts of meat and poultry products.

Response: FSIS encouraged participation in the voluntary nutrition labeling program through meetings with industry. Additionally, 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 that consumers received this necessary nutrition information. By making the guidelines for the voluntary nutrition labeling program mandatory, FSIS will ensure that consumers are provided with sufficient information to assess the nutrient content of the major cuts and enable them to select foods that fit into a healthy diet that meets their individual needs.

FSIS’s regulations provide that the Agency would evaluate significant participation every 2 years (§§ 317.343(e) and 381.443(e)). Although FSIS did not conduct the surveys precisely 2 years apart, the Agency did conduct the surveys approximately every two years until 1999 (74 FR 67748, December 18, 2009), and the surveys failed to show significant participation. Because significant participation did not exist, FSIS proceeded with rulemaking.

Under § 317.4, FSIS’s LPDD reviews labels on meat and poultry products that have been submitted for approval. Based on its label review, FSIS has not seen an increase in nutrition labeling of the major cuts of single-ingredient raw, meat and poultry products since the surveys were conducted. Compliance investigators in FSIS’s OPEER also have not seen an increase in the number of packages of the major cuts of single-ingredient, raw meat and poultry products that have nutrition facts panels on their labels at retail or an increase in the availability of point-of-purchase materials that provide nutrition information for such products at retail since the last compliance surveys were conducted. Because (i) the most recent surveys showed that significant participation in the voluntary nutrition

labeling program did not exist, (ii) FSIS’s LPDD has not seen an increase in nutrition labeling of the major cuts of single-ingredient raw, meat and poultry products and ground or chopped meat and poultry products since the surveys were conducted, (iii) FSIS’s OPPER has not seen an increase in nutrition labeling of the major cuts of single-ingredient raw, meat and poultry products at retail or an increase in the availability of point-of-purchase materials that provide nutrition information for the major cuts at retail since the last compliance surveys were conducted, and (iv) no other evidence has been submitted to FSIS that significant participation in the voluntary program now exists, FSIS has concluded that this final rule is necessary.

In response to the comment that maintaining the voluntary program will be less costly and will help the industry, this final rule makes the guidelines for the voluntary nutrition labeling program mandatory, so the costs for the industry should not increase for stores that are following the guidelines.

In response to the statement that if there was sufficient consumer demand for more nutrition information, then retailers would have an economic incentive to voluntarily supply 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. However, as is explained above, FSIS believes that consumers can generally estimate the fat content of the major cuts of meat and poultry products, but nonetheless, they need more precise information about the nutrient content of the major cuts in order to make a fully informed comparative judgment about the various cuts.

FSIS has concluded that without nutrition information for the major cuts of single-ingredient, raw meat and poultry products, these products will be misbranded under the FMIA and the PPIA (21 U.S.C. 601(n)(1) and 453(h)(1)). Without nutrition information on their labeling, FSIS has concluded that the labeling of these products will be false or misleading because it will not provide consumers with sufficient information to assess the nutrient content of the major cuts and will not enable consumers to select major cuts that fit into a healthy diet that meets their individual needs.

In response to the comment that nutrition information for single-ingredient chicken is not that useful because most people add ingredients to

it during cooking that alter the calories, fat, and protein, the final rule allows nutrition information to be declared on either an “as packaged” basis or an “as consumed” basis. The point-of-purchase materials and the labels clearly inform consumers whether the nutrition information provided is “as packaged” or “as consumed.” 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)).

Comment: Several trade associations asserted that the list of major cuts needs to be updated. One trade association stated that, according to The National Pork Board meat scanner data, pork whole loin, pork shoulder picnic, pork shoulder Boston butt, pork sirloin chop, pork center chop, and pork rib roast should be added to the list of major cuts. One trade association stated that FSIS should review the list of major cuts based on market share and availability because there are still cuts on the list of major cuts for which data reflective of trim levels sold at retail is not currently available. One trade association was concerned that if the USDA does not update the list, but rather makes a change to the list later, then retailers will incur the \$5.67 million cost to purchase and install posters again.

Response: 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. FSIS acknowledges that the codified list of major cuts may need to be updated. FSIS intends to assess the need to update the list and to update it as necessary when resources permit. Establishments or retail facilities may choose to provide nutrition information for the non-major cuts, either at point-of-purchase, in accordance with § 317.345 or § 381.445, or on their label, in accordance with § 317.309 or § 381.409.

Comment: The consumer organization argued that the number of servings should be required on all major cuts. This organization stated that many retailers now have the ability to calculate the number of servings in a package. As an example, this organization suggested that companies could determine the number of servings for the major cuts based on the number of pieces of meat in the package and

their average weights. According to this organization, the number of servings reminds consumers that a package has multiple servings, and that if someone eats more than one serving, the nutrients consumed will increase. This commenter stated that most consumers eat more than the USDA standard serving size of 4 oz. of meat or poultry, and single-serving packages of meat or poultry contain more than 4 oz. This commenter also stated that nutrition facts should be provided for the entire package if the single serving package exceeds 4 oz. Alternatively, the commenter stated that the package should be required to include a disclaimer such as: “Nutrition Facts are based on a 4 oz. serving. This package may contain a serving larger than 4 oz.” Finally, the commenter stated that the USDA also needs to update its standard serving size upward to reflect actual consumption.

Response: The number of servings per container is not necessary information on the nutrition labels or point-of-purchase materials of the major cuts or non-major 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 because the weight statement is applied at retail. The weight of such products varies from package to package (§§ 317.309(b)(10)(iii), 381.409(b)(10)(iii), 317.2(h)(9) and 381.121(c)(9)) (74 FR 67747, December 18, 2009).

The request to change and update USDA’s standard serving size is outside the scope of this regulation.

Comment: One individual and a trade association were concerned that consumers would not understand that the nutrition information for the major cuts will be based on averages of nutrient content data for that cut of meat or poultry. The trade association questioned whether there should be an explanation on the package regarding the potential variation from the average, so consumers will not be misled. The individual suggested that there should be a disclaimer on the label regarding the potential variation from the average.

Response: FSIS does not believe an explanation regarding potential variability of nutrition information is necessary for single-ingredient cuts. All nutrition information is based on average values. Compliance requirements in 9 CFR 317.309 and 381.409 allow for a twenty percent variation before regulatory action is taken against products.

Comment: The consumer organization stated that nutrition facts should be provided on an “as packaged” basis rather than on an “as consumed basis” because consumers may alter the product in ways that could affect the nutrient content before eating.

Response: As proposed, for the major cuts and non-major cuts of single-ingredient, raw products, this final rule will allow nutrition information on the label or on point-of-purchase materials to be declared on either an “as packaged” basis or an “as consumed” basis because most of these products will not be subject to FSIS nutrient analysis. 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)) (74 FR 67747, December 18, 2009).

Mandatory Nutrition Labeling for Ground or Chopped Products

Comment: Many individuals, several trade associations, a city health department, an industry commenter, and a perishable items tracking company supported mandatory on-package nutrition labeling for ground or chopped products. Several of those trade associations and the city health department specifically supported FSIS’s proposal to require on-package labeling as opposed to allowing for nutrition information at point-of-purchase. One of these trade associations stated that on-package labeling is needed because fat content is difficult to see in ground products. Two of the trade associations noted that plants produce ground meats at specific lean/fat ratios, and that the amount of fat is easy to control. One trade association stated that plants provide nutritional data to retailers, and that data can easily be added to a nutrition facts panel.

Two trade associations and the city health department believed that on-package labeling is the most beneficial for consumers. One of the trade associations questioned whether consumers actually use point-of-purchase materials for ground or

chopped products and questioned the feasibility of developing point-of-purchase materials for such products. The city health department argued that point-of-purchase materials for ground or chopped products are not an effective means of communication because their success depends on external factors such as the retailer's placement of the point-of-purchase materials and layout limitations in small stores. One trade association stated that point-of-purchase materials increase redundancy and cost because most retailers have nutrition data that can be easily distributed among retailers and added to a nutrition facts panel.

Several trade associations and the food marketing organization supported the option to provide nutrition information for ground and chopped products at point-of-purchase. One of the trade associations believed that point-of-purchase materials allow consumers to make more informed choices concerning the purchase of ground or chopped products because they are consistently displayed and more efficient than on-package labeling. This commenter stated that retailers are limited because of the small number of meat case staff and the available space on ground or chopped product packages. According to the food marketing organization, point-of-purchase materials allow consumers to easily compare products. The organization also was concerned that consumers would not be able to visually inspect the product because of the large label required to be able to list the nutrition information, food safety information, and cooking instructions. This organization also suggested that important food safety information would not be as prominent once nutrition information is added to the label.

One trade association and the food marketing organization asserted that allowing the use of point-of-purchase materials will reduce the financial burden on retailers and benefit consumers. These commenters stated that FSIS underestimated the cost of providing nutrition labels on ground and chopped products. According to these commenters, FSIS did not account for the number of retailers that would have to buy new printer or scale systems at the store level. Additionally, one trade association stated that retailers that provide on-site custom services would have to increase prices or only sell case-ready meat because of the increased costs. The food marketing organization was concerned that retailers may be forced to eliminate some of their product choices because of

the cost of testing and verifying the nutrient values for each nutrition label.

The food marketing organization claimed that effective point-of-purchase materials for ground and chopped products could be developed. One trade association suggested that there could be standardized posters for other ground or chopped products, similar to the ones currently used for ground beef. An industry commenter noted that producers supply retailers with ground products based on established finished lean/fat ratios, which do not differ among retailers. The industry commenter suggested that nutrition information for these lean/fat ratios could be used on point-of-purchase materials, and consumers could match the lean/fat ratio on their ground product with the nutrition information for that lean/fat ratio on the point-of-purchase materials. The commenter also stated that if a retailer uses a different lean/fat ratio than is provided on the point-of-purchase materials, it would have to put the nutrition information on the individual package.

A trade association, an industry commenter, and the food marketing organization stated that FSIS should maintain its existing voluntary program for nutrition labeling of ground or chopped products. The food marketing organization believed that there was no need to require mandatory on-package labeling for ground and chopped products.

Response: 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 above. Because there are numerous formulations of ground or chopped products, as a practical matter, 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 required to provide such a statement and will not be required to provide such a statement when this rule becomes

effective (74 FR 67750, December 18, 2009).

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. Based on a Beef Sales Survey at retail markets in the United States over 52 weeks ending March 23, 2010, ground beef sales were about \$5.6 billion for about 2.1 billion pounds, excluding the "other" category of ground beef for chili, meatloaf, meat balls, and trim (source: FreshLook Marketing, available at <http://beefretail.org/GroundBeefCategoryBreakdown.aspx>). According to the summary of results on the National Cattlemen's Beef Association Web site, ground beef accounts for about 66 percent of all fresh beef eatings (servings) in-home (source: NPD National Eating Trends (NET) Research, Two Years Rolling August 2009, available at <http://beefretail.org/individualpenetrationbybeefcut.aspx>). Additional information about the nutrient values of ground or chopped meat and poultry products will enable consumers to make informed decisions about including these products in their diets and will, therefore, help consumers to construct healthy diets (74 FR 67750, December 18, 2009).

Thus, this final rule will require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. 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 understanding of the nutritional quality of these products (74 FR 67750, December 18, 2009).

Many grocers and manufacturers 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 (74 FR 67750, December 18, 2009). FSIS disagrees with the comment that consumers will not be able to visually inspect the product because of the large label required to list the nutrition information, food safety information, and cooking instructions. As with the Safe Handling Instructions (SHI) and cooking instructions, nutrition labeling information can appear off the principal display panel (PDP). Many retailers place SHI on the bottom or side panels of packages to allow consumers to visually inspect the largest amount of product. There should be sufficient space available on these panels for nutrition facts information to appear off the PDP.

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)) (74 FR 67750, December 18, 2009).

Moreover, an exemption from the nutrition labeling requirements, which is provided in this final rule, should alleviate any concerns that nutrition labeling requirements will discourage retailers from grinding product based on customers' requests. This final rule provides 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 (74 FR 67750, December 18, 2009).

If a 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 (74 FR 67750, December 18, 2009). Moreover, the product selected may already be the subject of nutrition labeling as a raw, single ingredient product.

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. Finally, the requirements for on-package nutrition labeling for ground or chopped products will not be effective until January 1, 2012 (74 FR 67753, December 18, 2009).

In response to the comments that FSIS underestimated the costs of developing and providing nutrition labels for ground and chopped products, FSIS does not believe that it has underestimated the costs. Since the Supplemental Proposed Rule Regulatory Impact Analysis was done, the total costs of labeling may have even decreased because of more cost-effective technology, such as less expensive computerized flexography and scale-label printers. The additional costs of labeling would be relatively low for the affected businesses. In addition, this final rule exempts small businesses that produce ground or chopped product from nutrition labeling requirements.

Comment: The consumer organization argued that nutrition labels for ground meats should list the number of servings in the package. In the alternative, the commenter stated that the package should be required to include a disclaimer such as: "Nutrition Facts are based on a 4 oz. serving. This package may contain two or more servings, some or all of which exceed 4 oz."

Response: As discussed above, FSIS is not requiring that the number of servings per container be declared for the major cuts of single-ingredient, raw meat and poultry products because all of these products are random weight products, and the number of servings is not required on random weight products (see §§ 317.309(b)(10)(iii) and 381.409(b)(10)(iii)) (66 FR 4974, January 18, 2001). FSIS is not requiring that the number of servings per container be declared for ground or chopped meat and poultry products because these are also random weight products. Even though the number of servings per container are not declared on ground or chopped products, FSIS believes that on-package nutrition information is still meaningful to consumers because it is based on a stated serving size and allows consumers to make comparisons among products.

Comment: One trade association opposed requiring nutrition labels on multi-ingredient ground beef retail processed products or ready-to-eat-retail packaged products.

Response: FSIS believes that all ground beef and hamburger products, unless an exemption applies, should be required to include nutrition facts information. If multi-ingredient ground beef products were permitted an exemption, it would encourage firms to add seasoning to ground beef and hamburger products as a way to avoid providing nutrition facts information. Seasonings often include substances, such as salt and sugar, that can significantly alter the nutritional profile. Thus, there is a need for nutrition labeling information on such products.

Comment: One industry commenter noted that there is no significant change in calcium and iron values for finished ground products that contain common industry levels of AMR or low temperature rendered product from that of finished ground products that do not contain these products. This commenter asserted that additional testing should not be required for products that contain AMR or LTR products.

Response: No additional testing will be required for products that contain meat derived from advance meat recovery systems or low temperature rendered products, such as finely textured beef (FTB) or lean finely textured beef (LFTB). 9 CFR 318.24(c) limits the calcium and iron content of meat derived from AMR systems. In comparison, meat trimmings only need a minimum of 12% lean tissue to be considered "meat," and the standard of identity for ground beef and hamburger (9 CFR 319.15(a) and (b), respectively) limit the fat content to no more than 30%. There is also no upper regulatory limit on the use of meat derived from AMR systems or the use of FTB or LFTB in ground beef. Therefore, a wide range of possible formulations for ground beef and hamburger exist that could result in significant differences in the fat content. These facts support the need for nutrition labeling.

Comment: One farmer did not believe FSIS should treat ground or chopped beef as a "single ingredient" product because it normally comes from a large number of animals. According to the commenter, if FSIS continues to treat ground or chopped beef as a "single ingredient" product, then the label should be required to indicate the sources of each and all animals contained in the package.

Response: Ground beef production does typically involve multiple animals. However, all animals are from the same

species. Previous regulations defined certain ground beef products as major cuts of single-ingredient raw products (9 CFR 317.344). FSIS is not re-defining ground beef products that do not include ingredients in addition to ground beef as multi-ingredient products. However, as is explained in this preamble, FSIS considers ground beef products to be formulated products.

No Requirements for Non-Major Cuts

Comment: Several trade associations supported the proposal not to require nutrition labeling on non-major cuts that are not ground or chopped. One of those trade associations questioned whether it would be misleading for consumers to see nutrition information about one product, but no nutrition information on another product within the same retail case. Additionally, one individual and the city health department argued that nutrition labeling should be mandatory for all products, including meat and poultry products.

Response: At this time, FSIS is not requiring that nutrition information be provided for non-major cuts of single-ingredient, raw products that are not ground or chopped. The Agency has concluded that it is not necessary to do so at this time. 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 considered to be major cuts (66 FR 4974, January 18, 2001). FSIS still intends to conduct this assessment. Once this rule is effective, FSIS will examine and assess the adequacy of the nutrition information provided for the major cuts and will also determine whether and to what extent nutrition information is being made available for the non-major cuts and whether it is necessary to consider a rule requiring such information be provided.

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

Comment: The majority of commenters on this issue supported the proposal to permit the use of the 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." According to several consumer survey results provided by trade associations, consumers use both lean and fat percentages to determine the type of product to buy. Several trade associations stated that consumers need the lean and fat percentages to quickly

determine whether the product is suitable for their needs. An industry commenter and the food marketing organization noted that recipes, child nutrition programs, and health and dietary requirements identify and refer to ground products by their lean percentage. The food marketing organization believed lean statements were complementary, not redundant. A trade association believed that not allowing lean percentage statements will omit key information. According to one trade association, the industry would be unlikely to use only a fat percentage statement because the majority of beef is sold using lean/fat ratios.

One trade association stated that, based on a consumer survey, consumers are not misled by %lean/%fat statements. An industry commenter stated that consumers were confused in 1993 when FSIS's nutrition labeling regulation did not allow %lean to be used on ground products that did not meet the regulatory criteria for "low fat." Also, a trade association noted that %lean/%fat ratios are needed on the label to avoid confusion with %lean claims, which are defined differently and used for other products. Additionally, the food marketing organization argued that consumers may purchase products higher in fat because they would be provided with less information if only "low fat" products could have lean/fat percentages. Moreover, a trade association stated that consumers benefit from consistent labeling and purchasing options.

One individual argued that if lean percentages are maintained, they should follow the fat percentages in a smaller letter size to reduce consumer confusion. Also, the individual noted that this labeling would ensure that people do not focus on only the lean percentage statement without regard to the fat percentage statement. According to this individual, all of the examples of nutrition labels in the **Federal Register** begin with the fat percentage. However, one trade association suggested that the use of %fat/%lean claims be an option for manufacturers, not a regulatory requirement.

A poultry trade association and the consumer organization 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." These commenters stated that the use of a lean statement is misleading to consumers if the product does not also qualify as "low fat." According to the consumer organization, FSIS's policy would be inconsistent with FDA's policy that

prohibits the term "percent fat free" on all foods that are not low in fat to prevent consumers from being misled. The trade association stated that FSIS should maintain a consistent policy for use of the phrase "low fat" and similar statements.

One individual and the consumer organization argued that lean percentage statements should not be permitted on labels or labeling of ground or chopped products because they are redundant and misleading. According to the consumer organization and its consumer survey data, percent lean claims are misleading because they imply that the product is low in fat and leaner than other meat and poultry products. This consumer organization noted that the use of fat percent claims with lean percent claims does not prevent consumers from being misled. According to the commenter, consumers cannot compare lean and fat percentage statements on ground products to other food products because only milk products use percent fat statements. This consumer organization believed that if lean percent claims are used, many people will only look at them and will not look at the nutrition facts panel. This consumer organization stated that consumers do not need lean percent claims because they can get all the necessary information from the fat percent claims.

Response: The final regulations 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 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. The regulations permit the use of %lean/%fat statements or %fat/%lean statements on the label or in the labeling of ground or chopped meat and poultry products. (74 FR 67752, December 18, 2009).

Trade associations presented information from consumer surveys that showed that consumers understood the meaning of statements of lean and fat percentages on ground beef and supported the use of these statements. Based on the survey information provided, the majority of consumers believe %lean/%fat designations are important information and use them when choosing which ground beef products to purchase.

Producers, according to industry, have been using lean percentage statements on the labeling of ground beef and hamburger products for over 30 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, even if they are used on products that do not qualify as "low fat" under the regulatory criteria (74 FR 67752, December 18, 2009).

Lean/fat ratios allow consumers to readily identify and differentiate between all ground or chopped meat and poultry products and will assist consumers in selecting leaner versions of these products and will provide an incentive for manufacturers to market products lower in fat (66 FR 4972, January 18, 2001).

As one trade association stated, producers may include a percent fat statement on the label or in labeling of ground products without including a percent lean statement, though unlikely. A percent fat statement on ground or chopped products would be an acceptable alternative to a statement of lean and fat percentage. 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 (74 FR 67752, December 18, 2009).

Comment: A trade association and the food marketing organization supported the proposal that small businesses that produce ground or chopped product and include a statement of lean percentage and fat percentage on the product's label or in the labeling would not be required to include nutrition information on the product label, unless they include other nutrition claims or information on the product label. The food marketing organization stated that the flexibility for small businesses should be maintained. Otherwise, according to the commenter, an undue economic hardship on small businesses could result in a competitive disadvantage for small businesses. This food marketing organization also did not believe this proposed exemption from nutrition labeling requirements would mislead consumers.

Several trade associations and an industry commenter stated that nutrition information should be required on the labels of any ground or chopped product for which a lean percentage and a fat percentage statement is provided on the label or in the labeling, regardless of the size of the business making the product. The industry commenter also believed that

all ground or chopped products should be labeled with a percent lean statement because consumers need consistent information to compare products and make informed decisions. One trade association argued that there is no need for a small business exemption because small businesses purchase raw materials from larger businesses, which provide nutrition labeling in the proper format for all fat contents of bulk coarse or fine ground products to any store that purchases their products. According to this trade association, the labels are provided for use at point-of-purchase at no cost to the retailer or distributor. Another trade association expressed concern because small businesses can produce a significant quantity of meat and poultry products per year. This trade association believed there should only be exemptions for very, very small companies that receive Federal inspection and market to a local customer base.

Response: This final rule maintains that 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. As discussed in the supplemental proposed rule, based on the National Cattlemen's Beef Association (NCBA) National Meat Case Study in 2004, 93 percent of ground beef packages had statements of lean or fat percentages (74 FR 67741). Sixty-eight percent of packages with such statements had nutrition facts panels and 25 percent did not have nutrition facts panels but had lean or fat percentages (74 FR 67741). Seven percent did not have any statements of lean or fat percentages. Because about 95 percent of grinders are small businesses, FSIS concluded that many of the 25 percent of packages that included lean or fat percentage statements without nutrition facts panels were produced by small businesses. Therefore, FSIS believes many small businesses include statements of lean or fat percentage on the label of their ground products but not the nutrition facts panel. Also, 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 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 (74 FR 67741). Many consumers have become accustomed to this labeling on ground beef products, and FSIS believes that this labeling provides a quick, simple, and accurate means of comparing ground or chopped meat and poultry products. Based on the survey information provided, the majority of consumers believe %lean/%fat designations are important information and use them when choosing which ground beef products to purchase. Therefore under the final rule, small businesses that use statements of percent fat and percent lean on the label of ground products, provided they include no other nutrition claims or nutrition information on the product labels or labeling, are exempted from the nutrition labeling requirements.

To qualify for the small business exemption from the nutrition labeling requirements under §§ 317.400(a)(1) and 381.500(a)(1), a meat or poultry product must be produced by a single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than 100,000 pounds of the product annually, provided that the label for the product bears no nutrition claims or nutrition information. In response to the comment that small businesses can produce a significant amount of meat and poultry products per year, if a small business produces more than 100,000 pounds of a particular product, then the small business no longer qualifies for the exemption from nutrition labeling requirements for that product. In connection with the 1993 final rule on nutrition labeling of meat and poultry products, FSIS evaluated several options in establishing a poundage limit for the small business exemption (58 FR 633). Based on that evaluation, FSIS continues to believe that an annual production poundage level of 100,000 pounds sets the limit high enough so that the risk that any small business would have to close would be minimal, and sets the limit low enough so that the maximum volume of total production would bear nutrition labeling (see 58 FR 633, 638 for more discussion of the analysis of the poundage limits). The limit on the number of employees at a firm is set at 500 or fewer employees, which is the Small Business Administration's definition of a small meat or poultry processing firm. This approach allows the Small Business Administration to assist in determining which firms would qualify for the small business exemption based on the number of employees (58 FR 638).

Comment: One trade association stated that %lean/%fat claims should

only be allowed on ground products, and that %Lean, Lean, and Extra Lean claims should be applied across all meat and poultry products.

Response: Current regulations address the use of these claims (9 CFR 317.362(b)(6) and 381.462(b)(6)). An exemption is being included for ground species and ground (kind) to allow for the %lean/%fat declarations on ground species and ground (kind) that do not meet the regulatory criteria for "low fat" because of the long and successful history of the use of %lean/%fat declarations in the ground beef industry. The %lean/%fat declaration has been used historically by consumers wishing to make quick purchase decisions based on the fat level of the ground products. However, in most cases the nutrition facts information is necessary for consumers to take into account additional nutrients in formulating healthy diets.

Comment: The consumer organization argued that the USDA should prohibit misleading health and structure/function claims and require that nutrient content claims bear disclosure statements similar to the FDA requirements. This consumer organization also stated that the USDA should create a list of permissible structure/function claims to ensure that they do not undermine the mandatory disclosure of nutrition information.

Response: This comment is outside the scope of the regulation.

Exemptions for Nutrition Labeling

Comment: One individual supported all of the exemptions in the proposed rule because he believed they ensure that the rule will not be unduly burdensome.

One trade association stated that the small business exemption should apply to all products for nutrition labeling purposes because excluding single-ingredient raw products that are not ground or chopped confuses small businesses that have to comply with the different requirements. According to this trade association, small businesses that increase prices in order to provide nutrition facts on the label will be at a disadvantage against their competitors that do not provide the nutrition information on the labels. This commenter supported a small business exemption from the nutrition labeling requirements for the major cuts because of the time necessary for small businesses to access and display the free nutrition information.

One trade association believed the small business exemption pound limit should be increased to 150,000 pounds. According to this trade association, if

the limit remains at 100,000 pounds, only retailers who sell fewer than 700 packages of each product a week will be exempt (based on USDA's estimate that the average ground product package weighs 2.7 pounds). This commenter stated that small businesses that only sell a limited variety of popular products would likely not be exempt under the current proposal.

One individual stated that small businesses should not be exempt from the proposed rule.

Response: As discussed above, FSIS believes an exemption for ground or chopped products produced by small businesses is necessary because the burden of mandatory nutrition labeling may force some small firms to stop producing the product because of the cost of nutrition labeling and eventually force some small firms out of business. FSIS believes it would not be feasible for some small businesses to incur the additional costs of nutrition labeling because of their low volume of sales or low volume of ground product. FSIS believes it is feasible for larger businesses to incur the additional costs of nutrition labeling because of their higher volume of sales or larger levels of production of ground product. This final rule, with an exemption for ground or chopped products that qualify for the small business exemption in §§ 317.400(a)(1) and 381.500(a)(1), provides nutrition labeling on the maximum volume of ground or chopped product while assuring that small businesses producing low volumes of product are not at risk of going out of business or materially reducing the variety of products they deliver to their customers. Further, as discussed above, FSIS believes that the relatively small additional benefits of requiring small businesses to put nutrition labels on all ground or chopped products are outweighed by the larger additional costs.

As explained in more detail above, even if the products produced by small businesses bear a %fat/%lean statement, they will still be exempt under the small business exemption. Consumers use these statements to identify their desired product and are not misled by these statements, even if small businesses do not include nutrition information on the products' labels.

To qualify for the exemption, a retail store must either be a single retail store that employs 500 or fewer people or a multi-retail store operation that employs 500 or fewer people and that produces no more than 100,000 pounds of each ground product per year. For an official establishment to qualify for the exemption, it must 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 produces 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; 74 FR 67753, December 18, 2009). As stated above and in the supplemental proposed rule, there is no small business exemption from the nutrition labeling requirements for the major cuts of single-ingredient, raw meat and poultry products because the requirements should not impose an economic hardship on small businesses (74 FR 67738). Nutrition information for the major cuts can be displayed either on the labels or on point-of-purchase materials. FSIS will make point-of-purchase materials available over the Internet free of charge. Therefore, small businesses will not incur significant costs to provide nutrition information for the major cuts of single-ingredient, raw meat and poultry products.

FSIS finds that the 100,000 pound limit in the small business exemption is appropriate because it has been successfully applied for over a decade for other nutrition labeling exemptions. Furthermore, the Agency received no compelling data to support raising the limit to 150,000 pounds for this exemption. A consistent poundage limit will be easier to apply across all meat and poultry products.

Comment: Two trade associations stated that it was necessary to provide outreach resources to the industry through meetings and materials such as compliance guidelines. One of the trade associations noted that many small businesses do not have Internet access, so FSIS's Office of Outreach, Employee Education and Training (OOEET) will need to develop hard copy materials.

Response: If retailers cannot obtain the point-of-purchase materials over the Internet, FSIS personnel will have copies of the information to provide to retailers. FSIS personnel will also conduct meetings on the final rule. For retailers that have access to the Internet, FSIS will conduct Webinars on the final rule.

Comment: The city health department asserted that nutrition labeling should be mandatory for all meat and poultry products that are sold to the food service sector to enable restaurants and food service companies to make more healthful choices, which will ultimately benefit consumer health.

Response: Existing regulations provide that products intended for further processing and products not for sale to consumers are exempt from nutrition labeling requirements (9 CFR § 317.400). Such products are exempt from nutrition labeling requirements because consumers do not see the nutrition information on products used for further processing or products that are not for sale to consumers.

Enforcement & Compliance

Comment: Several trade associations stated that there should be some flexibility in variations from estimated nutritional values in sampling and in nutrient analysis if the nutrition labeling information is based on the most current USDA National Nutrient Data Bank or the USDA National Nutrient Database for Standard Reference. One trade association questioned whether reliance on the USDA National Nutrient Database for Standard Reference or the Agricultural Research Service (ARS) calculator is considered a valid response to USDA nutrition test results. Another trade association believed that the use of the Nutrient Database for Standard Reference should be acceptable for providing nutritional values for all products. Further, the commenter stated that the nutritional values should be based on the analyzed fat content because it would minimize the number and costs of expensive analysis required.

One trade association stated that all entries in the Nutrient Database for Standard Reference that are added or removed should go through the rule-making process to ensure that all groups using these entries are considered. For example, this trade association stated that commodity type cuts and items with more than $\frac{1}{8}$ inch fat need to be added to the Nutrient Database for Standard Reference because these products are still sold through food service channels, and it is costly for producers to provide nutrition information via nutrient analysis to commodity type customers.

One trade association stated that the ARS calculator should be updated to provide nutrition information for turkey, pork, and chicken.

One trade association suggested that the Nutrient Database for Standard Reference be split into two databases, one for retail type products and one for commodity type products. One trade association questioned how enforcement of nutrition labeling requirements will work at retail establishments and farmer's markets. The trade association further questioned

whether there will be fines for non-compliance. Additionally, in order to prevent inconsistent Agency enforcement actions, the commenter stated that FSIS needs to ensure all businesses are in compliance.

Response: 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). As FSIS explained in the supplemental proposed rule, the procedures set forth for FSIS product sampling and nutrient analysis in 9 CFR 317.309(h)(1)-(8) and 381.409(h)(1)-(8) will be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. 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 other nutrient values in the product. (74 FR 67754, December 18, 2009).

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 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. FSIS will treat ground or chopped products in this way because the fat content of these products can vary significantly. 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. For example, FSIS 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) (74 FR 67755, December 18, 2009). 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 likely

find the product's label in compliance with nutrition labeling requirements, unless the product's source materials contain a significant amount of AMR product or product from low temperature rendering (74 FR 67755, December 18, 2009).

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 will not sample and conduct a nutrient analysis of the products. The preamble to the supplemental proposed rule 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).

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. One trade association comment to the supplemental proposed rule stated that nutritional tables will be sufficient for retailers to create nutrition labels for ground pork.

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. ARS also has published nutrient values for ground turkey with fat levels of 0%, 7%, and 15%. Most ground poultry products are produced and labeled at Federal establishments rather than at retail.

Commodity products are exempt from nutrition labeling requirements under 9 CFR 317.400 and 381.500 because they are not offered for sale. If commodity products bear nutrition claims or information, then they will be subject to the nutrition labeling requirements. Producers that sell product at farmers markets would typically be exempt from nutrition labeling requirements under the small business exemption.

FSIS will explore its regulatory options, including seeking criminal penalties, if it discovers a violation of the nutrition labeling requirements. FSIS is not authorized to impose civil penalties, including fines, under the FMIA or PPIA. For more discussion of possible enforcement actions following implementation of the rule, see the supplemental proposed rule (74 FR 67754, December 18, 2009).

Effective Date

Comment: Several trade associations stated that the requirements for major cuts of single-ingredient, raw meat and poultry products and ground or chopped products should become effective on the uniform compliance date, January 1, 2012. One of the trade associations believed that different implementation dates for the two types of products would be confusing to consumers and may require two outreach programs. The other trade association argued that establishments need as much time as possible to understand the new requirements and develop new labels and point-of-purchase materials before the requirements become effective. The food marketing organization agreed that there should be additional time prior to implementation of the nutrition labeling requirements for the major cuts because of the burden on the retailers.

One trade association stated that an 18–24 month period was needed for implementation.

The food marketing organization argued that the final rule should include a provision allowing an extension of the effective dates of up to six months if there is evidence of difficulties with compliance. One trade association agreed with a six month or a twelve month extension period before the effective date of the rule.

Response: As FSIS stated in the supplemental proposed rule,

requirements for ground or chopped products will become effective on January 1, 2012, the uniform compliance date for new food labeling regulations that are issued between January 1, 2009, and December 31, 2010, to minimize costs associated with on-package labels. In the supplemental proposed rule, FSIS proposed that the labeling requirements for the major cuts be effective one year from the date of publication of the final rule because the final rule allows for the presentation of nutrition information for the major cuts of single-ingredient, raw meat and poultry products at their point-of-purchase and will not require changes to product labels (74 FR 67741, December 18, 2009). But, because one year from the date of publication will only be a few days before the effective date for ground and chopped products, January 1, 2012, FSIS is also establishing January 1, 2012, as the effective date for the labeling requirements for the major cuts.

Costs and Benefits

Comment: One trade association stated that the proposed rule was discriminatory because it would have a disproportionate effect on retailers with service meat departments. This trade association also noted that under this rule, retailers will have a more costly burden compared to restaurant competitors.

One trade association argued that FSIS should finalize the regulation with the least amount of economic impact on the meat industry.

Several individuals and an industry commenter were concerned that the rule would increase costs to producers and consumers and increase taxes.

Response: The Regulatory Flexibility Act requires Federal Agencies to consider the effect of regulations on small entities in developing regulations (74 FR 67757, December 18, 2009). However, FSIS has sought to make this rule as fair and equitable as possible, regardless of the size of the company involved.

Thus, to minimize the burden on small businesses, the final rule provides a small business exemption. In addition, the final rule provides 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 will also 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>. (74 FR 67757, December 18, 2009).

As FSIS explained in the proposed rule, restaurant menus generally do not fall within the scope of the nutrition labeling regulations. See 9 CFR 317.400(b) and 381.500(b). 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. (66 FR 4979, January 18, 2001).

FSIS does not believe that it has underestimated the costs of the final rule. Since the Supplemental Proposed Rule Regulatory Impact Analysis was done, the total costs of labeling may have even decreased because of more cost-effective technology, such as less expensive computerized flexography and scale-label printers. The additional costs of labeling would be relatively low for the affected businesses. Furthermore, the final rule will exempt small businesses that produce ground or chopped product from nutrition labeling requirements. As FSIS explained in the proposed rule and supplemental proposed rule, this rule will not significantly increase costs to affected producers and retailers because the additional cost of this rule is a relatively small proportion of the total costs of production or retail marketing of affected businesses. The estimated cost of the rule on a per pound basis is about \$0.006, for ground or chopped products. This increase in cost should not affect consumer costs or purchases.

Comment: According to a case study, one individual stated that the proposed rule may produce benefits of \$62 to \$125 million annually.

Response: FSIS projected that the annualized average present value of the benefit of the final rule is about \$75.5 million, after accounting for assumed levels of current compliance. For a discussion of the methodology used to estimate the benefits of the final rule, please see the Final Regulatory Impact Analysis below.

Other Comments

Comment: The consumer organization believed nutrition labels should be required to indicate the amount of trans fat in the product similar to the FDA's policy. According to the consumer organization, the trans fat in beef and dairy products has the same harmful

impact on LDL cholesterol as the trans fat in partially hydrogenated oils.

Response: FSIS does not require the mandatory labeling of trans fats as required by FDA. However, through routine label approval, FSIS estimates 75% to 80% of FSIS nutrition labels do voluntarily include trans fat in the nutrition facts information. FSIS anticipates many companies will voluntarily include trans fat in the nutrition facts information on single-ingredient and ground products.

Comment: The city health department stated that nutrition labels for meat and poultry products should be consistent with the Nutrition Labeling and Education Act and the majority of packaged foods.

Response: Products under FSIS jurisdiction are not subject to the Nutrition Labeling and Education Act (74 FR 67754, December 18, 2009). But, FSIS believes that the requirements of this final rule are consistent with the Nutrition Labeling and Education Act.

Comments: FSIS also received comments on issues outside the scope of these regulations. One trade association stated that all nutrition labels should specify all the nutrients found in meat products. One individual suggested that approximate cook times for chicken and pork products should be placed on their labels. One individual stated that meat and poultry product labels should include information such as date butchered, date preserved/frozen, any hormones or antibiotics in the product, and genetic engineering used in the creation of the product. One perishable items tracking company argued that tracers like radio frequency identification tags should be mandated in all meat and poultry shipping containers to record the shipping times and ensure the products were kept at safe temperatures similar to the TEDSBOX system. Further, the tracing information should be provided on all product labels.

Section II

Executive Order 12866—Final Rule Regulatory Impact Analysis (FRIA) and Final Regulatory Flexibility Act (RFA) Assessment

This action has been reviewed for compliance with Executive Order 12866. This rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 and was determined to be significant.

¹ National Cattlemen's Beef Association, 2004. National Meat Case Study.

² U.S. Department of Agriculture, October 1999. Nutrition Labeling/Safety Handling Information Study—Raw Meat and Poultry. Prepared by Retail

In this FRIA, FSIS is adopting the compliance adjusted analysis (*i.e.*, accounting for assumed levels of current compliance with the final rule) presented in Table 1 below and in Table 30c and Appendix C of the supplemental Preliminary Regulatory Impact Analysis (PRIA) and the supplemental initial Regulatory Flexibility Act (RFA) assessment as final. This FRIA and final RFA assessment do not finalize the supplemental PRIA or the supplemental initial RFA. The PRIA used both a baseline before considering existing compliance (*i.e.*, assuming no compliance) and a baseline after considering an assumed compliance to the rule. Then, in the supplemental PRIA, FSIS compared the analyses that used the two cases of different baselines of compliance. FSIS used the analysis that accounted for the assumed levels of nutrition labeling in compliance with this final rule here because FSIS thinks that this baseline would best represent the current state of the use of nutrition labeling of these products before FSIS implements the final rule.

The supplemental PRIA overestimated the amounts of ground or chopped products and major cuts that would be impacted by the final rule by not taking into account the assumed level of voluntary compliance with the nutrition labeling regulations that currently exists—the 68 percent compliance rate of voluntary nutrition labeling of ground or chopped products.¹ and 54.8 percent level of voluntary compliance of stores that provide nutrition labeling for major cuts.² Thus, the averages and ranges of benefits and costs used in the FRIA reflect the supplemental PRIA baseline that considered the assumed levels of compliance.

OMB designated the supplemental proposed rule economically significant based on annual benefits that did not take into account current benefits that result from nutrition labeling information that is currently available; costs in the supplemental PRIA did not reach the threshold for economically significant regulations. In this FRIA, after accounting for existing levels of compliance, the additional benefits were only “significant,” as were the additional costs. The complete supplemental PRIA and the complete final RFA assessment can be found online through the FSIS Web page

located at http://www.fsis.usda.gov/Regulations_Policies/2009_Proposed_Rules_Index/index.asp.

A. Costs and Benefits of the Final Rule

The FRIA assumes that some establishments or retail facilities have incurred costs associated with the requirements of this regulation prior to its effective date, and many firms have already been providing the information that is being required.³ Hence, the discounted average present value of the total costs, over a 20-year period, are estimated to be about \$115.4 million using a 7 percent discount rate and about \$156.7 million using a 3 percent discount rate. The corresponding annualized present values of the average total costs are \$10.9 million, using a 7 percent discount rate, and \$10.5 million, using a 3 percent discount rate (see Table 1). For point-of-purchase (POP) nutrition information for major cuts of single ingredient, raw products, the annualized present values of the average total costs are \$1.32 million, using a 7 percent discount rate, and \$1.30 million, using a 3 percent discount rate. For on-package nutrition labels for ground or chopped products, the annualized present values of the average total costs are \$9.6 million, using a 7 percent discount rate, and 9.2 million, using a 3 percent discount rate. For POP nutrition information for major cuts of single ingredient, raw products, the estimated additional annual cost of the rule on a per pound basis is about \$0.0002 (\$1.3 million/7,548 million pounds). For ground or chopped products, the estimated additional annual cost of the rule on a per pound basis is about \$0.006 (\$9.6 million/1,568 million pounds). However, the additional cost of nutrition labeling for ground or chopped products may be overstated because firms can use their existing stock of labels before incurring additional costs of new labeling, under the Uniform Compliance Date for Food Labeling Regulations.

The average present values of the benefits are about \$800 million and about \$1,358 million, using 7 and 3 percent discount rates, respectively. The corresponding annualized average present values of the benefits are about \$75.5 million and about \$91.3 million, using 7 and 3 percent discount rates, respectively. Table 1 provides a summary of these annualized net present values of costs and benefits.

Diagnostic, Inc., Oradell, New Jersey. Final Report 2000.

³ 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) are included in this RIA of the Final Rule.

TABLE 1—SUMMARY OF ANNUALIZED NET PRESENT VALUES OF COSTS AND BENEFITS, AFTER ACCOUNTING FOR ASSUMED LEVELS OF CURRENT COMPLIANCE TO THE FINAL RULE.

[\$million/year]

Category	Primary or average estimate	Low estimate	High estimate	UNITS		
				Year dollars	Discount	Period covered
<i>Benefits:</i>						
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	<i>Consumers might also choose to use nutritional information to enhance enjoyment of food, and not just to raise their health status.</i>					
<i>Costs:</i>						
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 assumed levels 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

The projected annualized average net present values of costs of the rule's nutrition labeling requirements appear to be justified by the larger projected annualized average net present values of benefits.

B. Regulatory Flexibility Act (RFA)—Assessment

This final Regulatory Flexibility Act (RFA) assessment is not changed from the supplemental preliminary RFA assessment that was published in the supplemental proposed rule on 18 December 2009.

Based on the cost analysis, FSIS certifies that this final 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).

FSIS does not believe that any very small processing operations (grinding firms) would 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.

Small retail stores would incur the additional cost of providing POP nutrition information for the major cuts of single-ingredient, raw products. There are about 47,422 small retail firms that own about 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 would 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 the retail stores, including small and very small businesses would incur these additional costs in either the first year, if the store is not currently providing POP nutrition information for the major cuts of single-ingredient, raw products, or in the third year, if the store is currently providing this information. FSIS believes that these additional costs are not significant even for very small businesses.

Retail stores would also incur additional costs related to required nutrition labels for ground or chopped products. A total of 74,910 stores owned by 47,688 firms could be affected. However, 23,479 stores 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, in the worst case scenario, as many as 51,431 small establishments owned by 47,422 firms could be affected.⁴

FSIS estimates that using a 7 percent discount rate the sum of the annualized average cost to each retail store that is not currently providing nutrition information for the major cuts or ground or chopped products would 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. For a store that is not currently providing nutrition information for the major cuts or ground

or chopped product, the annualized total cost over 20 years, using a 7 percent discount rate, would be about \$1,537, per store. In summary, FSIS concludes that this final rule would not have a significant impact on a substantial number of small entities.

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 affected that is not currently providing nutrition information for ground or chopped products, the additional annualized average total cost is about \$1,402. Then, for each such processing (grinding) establishment, additional annualized average total 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. Additional annualized total 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.

⁴ 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 all small for purposes of the Regulatory Flexibility Act and that they will not qualify for the small business exemption.

The exemption for small businesses affects about 1.238 billion pounds of meat or poultry product affected by the final rule.

Executive Order 12988

This final 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.

This final rule does not 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

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB). This information collection request is at OMB awaiting approval. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Ave., SW., Room 60853 South Building, Washington, DC 20250–3700; (202) 720–0345.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation

and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, *etc.*) should contact USDA's Target Center at 202–720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

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 final rule, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_and_policies/2010_Interim_and_Final_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.

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 amending 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) Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except 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, unless the product is exempted under § 317.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials, except as exempted under § 317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in § 317.301, nutrition labeling must be provided in accordance with the provisions of § 317.309, except as exempted under § 317.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and that are not major cuts of single-ingredient, raw meat products identified

in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials.

- 3. A new § 317.301 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. Amend paragraph (b)(10) 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. Amend paragraph (b)(11) 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. Amend paragraph (d)(3)(ii) 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. Amend paragraph (e)(3) 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”; and

- f. Amend paragraph (h)(9) 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 [Removed]

- 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. Revise the section heading and paragraphs (a) and (c);
 - b. Amend paragraph (d) by removing “should” and adding, in its place, “for products covered in paragraphs (a)(1) and (a)(2) must”;
 - c. Amend paragraph (e) 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. Amend paragraph (f) by adding “provided” after “nutrition information is”; and
 - e. Amend paragraph (g) 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).

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

- b. Amending paragraph (a)(1)(ii) 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. Amending paragraph (a)(7)(i) 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. Amending paragraph (a)(7)(ii) 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. Adding a new paragraph (a)(7)(iii); and

■ 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 additions 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.

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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) Nutrition labeling must be provided for all poultry products intended for human consumption and offered for sale, except 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, unless the product is exempted under § 381.500. 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. Amend paragraph (b)(10) 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. Amend paragraph (b)(11) 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. Amend paragraph (d)(3)(ii) 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. Amend paragraph (e)(3) 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”; and

■ f. Amend paragraph (h)(9) 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.

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§ 381.443 [Removed]

■ 14. Section 381.443 is removed.
 ■ 15. Section 381.445 is amended as follows:
 ■ a. Revise the section heading and paragraph (a) and (c);

- b. Amend paragraph (d) by removing “should” and adding, in its place, “for products covered in paragraphs (a)(1) and (a)(2) must”;
- c. Amend paragraph (e) 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
- d. Amend paragraph (f) 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. Amending paragraph (a)(1)(ii) 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. Amending paragraph (a)(7)(i) 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. Amending paragraph (a)(7)(ii) 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. Adding a new paragraph (a)(7)(iii); and

- f. Amending paragraph (d)(1) 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 additions read 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,

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(7) * * *

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

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Done in Washington, DC on December 21, 2010.

**Alfred V. Almanza,
Administrator.**

[FR Doc. 2010-32485 Filed 12-28-10; 8:45 am]

BILLING CODE 3410-DM-P