(1) Send the producer a maturity notice letter before MAL maturity.

(2) Maintain the MAL or LDP documents according to FSA requirements.

(3) Transmit the necessary funds to repay the MAL to FSA.

(b) FSA shall process the CCC release of paper receipts or EWR's where such a release is appropriate.

§ 1421.422 Inspections and reviews.

The books, documents, papers, and records of the DMA and parent company shall be maintained for six years after the applicable crop year and shall be made available to CCC for inspection and examination at all reasonable times. At any time after an application is received, CCC shall have the right to examine all books, documents, papers, and determine whether the DMA is operating or has operated in accordance with the regulations in this part, any articles of incorporation, articles of association, partnership documents, agreements with producers, the representations made by the DMA in its application for approval, and, where applicable, its agreements with CCC. If the DMA is determined to be not complying with this part or any of its agreements, CCC will take appropriate action as provided in elsewhere in this subpart or other action CCC determines appropriate.

§ 1421.423 Appeals.

Parts 11 and 780 of this title apply to this subpart.

Signed in Washington, DC, on May 25, 2005.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 05–11505 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 04–091–2]

Addition of Malaysia To List of Regions in Which Highly Pathogenic Avian Influenza Subtype H5N1 Is Considered To Exist

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the regulations concerning the importation of animals and animal products by adding Malaysia to the list of regions in which highly pathogenic avian influenza (HPAI) subtype H5N1 is considered to exist. We took that action to prevent the introduction of HPAI subtype H5N1 in the United States.

DATES: The interim rule became effective on August 7, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Julie Garnier, Staff Veterinarian, Technical Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–5677.

SUPPLEMENTARY INFORMATION:

Background

Highly pathogenic avian influenza (HPAI) is an extremely infectious and fatal disease of poultry and a wide variety of other birds. HPAI can strike poultry quickly without any infection warning signs and, once established, the disease can spread rapidly from flock to flock. In some instances, strains of HPAI viruses can be infectious to people. Human infections with AI viruses under natural conditions have been documented in recent years. Particularly alarming is the HPAI strain of most of these outbreaks, H5N1, which has crossed the species barrier and caused severe disease, with high mortality, in humans. Recent outbreaks of HPAI in Southeast Asia have caused significant concern among health authorities worldwide because of the potential for the human and avian flu viruses to swap genes, creating a new virus to which humans would have little or no immunity.

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, and 95 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including HPAI subtype H5N1.

In an interim rule effective August 7, 2004, and published in the **Federal Register** on February 1, 2005 (70 FR 5043–5044, Docket No. 04–091–1), we amended the regulations in part 94 by adding Malaysia to the list of regions in § 94.6(d) where HPAI subtype H5N1 exists.

Comments on the interim rule were required to be received on or before April 4, 2005. We received one comment by that date, from a private citizen. The commenter supported the interim rule.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule without change.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Order 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 70 FR 5043–5044 on February 1, 2005.

Done in Washington, DC, this 6th day of June 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–11504 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 319 and 381

[Docket No. 92–024F]

Rin 0583–AC82

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to establish a general definition and standard of identity for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names. These products will be identified by an expressed nutrient content claim, such as ''fat free,'' ''low fat,'' and ''light,'' in conjunction with an appropriate standardized term, *e.g.*, ''low fat bologna.'' FSIS is taking this action to: Assist consumers in maintaining healthy dietary practices by providing for modified versions of standardized meat and poultry products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium; increase regulatory flexibility and support product innovation, and provide consumers with an informative nutrition labeling system.

DATES: This final rule will be effective January 1, 2008, the uniform compliance date for all meat and poultry products subject to labeling regulations issued by FSIS between January 1, 2005 and December 31, 2006. However, establishments may begin to produce meat and poultry products in compliance with this final rule anytime before the effective date.

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

SUPPLEMENTARY INFORMATION:

Background

On December 29, 1995, FSIS published a proposed rule in the **Federal Register** to amend the Federal meat and poultry products inspection regulations to establish a general definition and standard of identity (the ''general standard'') for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names (60 FR 67474). Under the proposed general standard, meat and poultry products with a regulatory standard of identity or composition in 9 CFR Parts 319 and 381, subpart P, would be permitted to be formulated and processed with ingredients otherwise not provided for, or in amounts greater than, that allowed by the standard in order to qualify for certain expressed nutrient content claims permitted in 9 CFR 317 subpart B and 381, subpart Y, such as ''fat free,'' ''low fat,'' and ''light.'' Instead of being identified as ''substitute'' standardized meat and poultry products, as required by the current regulations (9 CFR 317.313(d) and 381.413(d)), standardized meat and poultry products formulated or processed in accordance with the proposed general standard could be identified by an expressed nutrient content claim in conjunction with the standardized term.

To allow modified versions of standardized meat and poultry products that have been formulated to reduce their fat content to be marketed without having to be labeled as ''substitutes,'' FSIS issued Policy Memo 123, ''Modified Breakfast Sausage, Cooked Sausage, and Fermented Sausage Products Identified by a Nutrient Content Claim and a Standardized or Traditional Name,'' and Policy Memo 121B ''Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients,'' in January of 1995. These policy memoranda stated, among other things, that these products are permitted to be identified by a nutrient content claim that reflects the reduction in fat content in the product in conjunction with the appropriate standardized product name, *e.g.*, ''Fat Free Bologna,'' ''Low Fat Pepperoni,'' or ''Low Fat Hamburger, Water, and Carrageenan Product.'' Both Policy Memo 121B and Policy Memo 123 were issued as interim measures until such time that rulemaking could be completed. Both of these policy memoranda will be rescinded by this final rule.

In this final rule, FSIS is establishing a general definition and standard of identity for modified versions of meat and poultry products that substitute for meat and poultry products defined by a regulatory standard of identity or composition in 9 CFR Part 319 and 381, subpart P, *i.e.*, ''substitute standardized products.'' This rule is needed to facilitate the development and availability of substitute standardized meat and poultry products that have reductions in constituents that are of health concern to some people, *e.g.*, fat, cholesterol, and sodium. The rule allows FSIS to rely more on labeling requirements and less on restrictive recipe-type standards to carry out its mandate to ensure that the labels of meat and poultry products are truthful and not misleading to consumers.

Comments and Agency Response

FSIS received 56 comments in response to the proposed rule from members of the meat and poultry processing industry, industry trade associations, members of the flavoring and ingredients industry, members of the soybean industry, academia, health professionals, governmental entities, consumer advocacy groups, and individual consultants. In general, the comments submitted in response to the proposed rule were favorable. Most commenters agreed that FSIS should establish a regulatory general standard for substitute standardized products that are lower in fat, cholesterol, or sodium.

One commenter opposed the rule because the commenter believed it did not go far enough in providing flexibility to industry. This commenter stated that, rather than converting FSIS Policy Memo 123 into regulation, FSIS should create a new standard for substitute standardized meat and poultry products to allow the use of non-traditional ingredients in all products, not just versions of products that are identified by a nutrient content claim and a standardized product name.

Response: FSIS recognizes the need to explore this and other issues concerning reform of the meat and poultry product standards. However, expanding the use of non-traditional ingredients for all standardized products is an issue that is outside the scope of this rulemaking. The Agency is, however, exploring this and other related issues in a separate rulemaking to modernize meat and poultry product standards. This rulemaking is discussed in greater detail later in this document.

Policy Memo 123 and Policy Memo 121B

Comment: A few commenters felt that FSIS Policy Memo 121B and Policy Memo 123 should remain in effect once this final rule becomes effective so that products produced under these policies can continue to be manufactured. Other commenters stated that the general standard defined in the proposed rule should apply to food products whose standards are documented in the FSIS Food Standards and Labeling Policy Book (the Policy Book), as well as those products whose standards of identity and composition are codified in Parts 319 and 381, subpart P. The commenters noted that the wording in proposed 9 CFR 319.10(a) and 381.172(a) does not specifically include the standards described in the Policy Book, while FSIS Policy Memo 123 does. They were concerned that once the rule is in place, and Policy Memo 123 is rescinded, certain products, such as ''Low Fat Pepperoni,'' would no longer be permitted because pepperoni

does not have a standard of identity codified in the regulations.

Response: The policy embodied in the proposed general standard will also apply to the informal standards for products, such as pepperoni, that are described in the Policy Book. Thus, Policy Memo 121B and Policy Memo 123 will not remain in effect once the proposed rule becomes final. FSIS issued both Policy Memo 121B and Policy 123 as interim measures to accommodate certain lower fat substitute meat and poultry products until such time that rulemaking was completed. This final rule incorporates, expands, and codifies the intent of these policy memoranda. Thus, rescinding Policy Memo 121B and Policy Memo 123 will not preclude the production of products that have been made under those policies. The Agency intends to clarify this point in a policy bulletin, which is a more appropriate document for addressing the informal standards described in the Policy Book.

Nutrient Content Claims That Emphasize the Presence of an Ingredient

Comment: Some commenters disagreed with the Agency's proposal to permit only expressed nutrient content claims that relate to reductions in constituents such as fat, cholesterol, or sodium, in conjunction with the standardized name of the substitute product. These commenters felt that nutrient content claims, such as ''high in'' and ''good source of,'' that emphasize the presence of an ingredient, should also be permitted to be used as part of the substitute standardized product's name, provided that the product qualifies for these claims under 9 CFR part 317 subpart B or 9 CFR 381 subpart Y.

Response: Under the current regulations, meat and poultry products that satisfy the criteria for use of nutrient content claims defined in 9 CFR part 317 subpart B and 9 CFR 381 subpart Y are permitted to make claims, such as ''high in'' or ''good source of,'' that emphasize the presence of a nutrient. The ability to make these kinds of nutrient content claims is not affected by this rulemaking.

In the preamble to the proposed rule, FSIS noted that the meat and poultry product standards did not appear to preclude the making and marketing of standardized products that qualify for the use of claims such as ''high in'' and ''good source of.'' Therefore, in the proposed regulation, the Agency did not expressly provide for these types of nutrient content claims in the general standard. However, in the proposal, FSIS did solicit comments on whether current regulatory standards prevent the distribution of products with nutrient content claims other than those that reflect a reduction in the level of a nutrient.

None of the comments received suggested that the existing meat and poultry product standards preclude the making and marketing of standardized products that qualify for the use of claims such as ''high in'' or ''good source of.'' Furthermore, because of the FSIS policy that precludes direct nutrient fortification of meat and poultry products, standardized meat and poultry products are not permitted to be modified to qualify to use a nutrient content claim by adding nutrients to the product. Therefore, FSIS has decided not to modify the scope of coverage in this final rule to permit nutrient content claims other than those that reflect a reduction of constituents that are of health concern to some people, *e.g.*, fat, cholesterol, and sodium, to be used as part of the product name. Products that qualify for ''high in'' and ''good source of'' nutrient content claims may continue to highlight these claims as provided in 9 CFR 317.354 and 9 CFR 381.454.

Nutrient Fortification

Comment: Four commenters suggested that FSIS reexamine its policy precluding direct nutrient fortification of meat and poultry products. Two of these commenters suggested that FSIS allow selective nutrient fortification in meat and poultry products to permit standardized products to be modified so that they qualify to use nutrient content claims, such as ''high in Vitamin A,'' as part of the product name. One of these commenters requested that FSIS modify the language in proposed 9 CFR 319.10(a) to delete the following italicized words ''* * * because of a *compositional* deviation that *results from reduction of a constituent that* is described by an expressed nutrient content claim * * *''

Another commenter suggested that FSIS permit selective protein fortification in substitute standardize products so that they may use claims such as ''High in Protein'' and ''Good Source of Protein'' as part of the product name. This commenter recommended that FSIS continue to require substitute standardized products to meet the same basic minimum meat and poultry content requirements contained in the existing meat and poultry product standards, but that the overall protein level in these products should be allowed to be fortified using ingredients such as soy protein. Another commenter that expressed support for permitting direct nutrient fortification of meat and poultry products felt that, because the over-consumption of protein in the American diet, that protein fortification should not be permitted.

Two other commenters requested that FSIS allow fortification to replace vitamins and minerals that may be lost due to formulation adjustments to produce nutrient-modified foods. These commenters also requested that FSIS exempt substitute standardized products subject to the general standard from the minimum meat and poultry content requirements imposed by the existing meat and poultry product standards. Both commenters suggested that for these substitute products, FSIS should focus on nutritional equivalency to the traditional standardized product rather than meat content equivalency, and permit reductions in the meat and poultry content for purposes of reducing the product's fat content. The commenters stated that if FSIS were to permit such reductions in the meat and poultry content, fortification might be necessary to replace lost nutrients.

One commenter suggested that, while existing FDA regulations state that the FDA does not consider it appropriate to fortify meat and poultry products (21 CFR 104.20(a)), the FDA regulations appear to make an exception for fortification of foods that replace traditional foods when fortification is necessary to avoid nutritional inferiority.

Response: The comments requesting that FSIS reexamine its policy on nutrient fortification raise some interesting points, particularly with respect to the issues concerning nutritional equivalency versus meat content equivalency. However, the decision to allow fortification of meat and poultry products involves several complex issues, many of which are outside the scope of this rulemaking.

FSIS'' fortification policy is derived from FDA's policy statement on nutrient fortification codified at 21 CFR part 104, subpart B, which states, in part, that the FDA ''* * * does not consider it appropriate to fortify fresh produce; meat, poultry, or fish products * * * (21 CFR 104.20(a)). The fundamental objective of FDA's fortification policy is ''* * * to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to food'(21 CFR 104.20(a)). As stated in its policy, FDA determined that, ''* * * random fortification of foods could result in over-or under-fortification in consumer diets and create nutrient imbalances in the food supply'' (21 CFR 104.20(a)).

FSIS has a long history of prohibiting direct fortification of meat and poultry products, which is supported by the codified FDA fortification policy. Thus, when determining whether to revise its nutrient fortification policy for meat and poultry products, FSIS must consider the issues in relationship to the codified FDA policy statement on fortification. Furthermore, in order to maintain consistent policies regarding nutrient fortification between the two agencies, any effort by FSIS to revise its prohibition on direct nutrient fortification of meat and poultry products should include FDA participation and involve the scientific community (*e.g.*, the National Academy of Sciences, Institute of Medicine). FSIS, FDA, and the scientific community need to first consider the guiding scientific principles that form the basis for establishing a public health need for fortifying meat and poultry with nutrients. Only after these principles are applied could there be consideration of revising the current fortification policy.[1] Obviously, this type of effort is outside the intended purpose and scope of this rulemaking. It would be more appropriate to consider this matter in a separate rulemaking where the Agency can receive the benefit of an open and thorough review of all issues related to the fortification of meat and poultry products.

Furthermore, FSIS believes that the formulation adjustments needed to produce substitute standardized products with reductions in constituents such as fat, cholesterol, and sodium, will not result in a product that is nutritionally inferior to the product for which it is a substitute. Important nutrients, such as iron, zinc, B vitamins, and protein, are associated with the lean muscle portion of meat and poultry tissue, not the fat. Because the minimum meat and poultry requirement for substitute standardized products is not changed by this rule, reductions in the fat content should not affect the levels of nutrients associated with the lean muscle portion of these products. Therefore, nutrient fortification is not necessary to prevent the products subject to the general standard defined by this rule from being nutritionally inferior to the standardized products for which they are a substitute.

[1] See report: Institute of Medicine, National Academy of Science, 2003. Dietary Reference Intakes, Guiding Principles for Nutrition Labeling and Fortification. The National Academies Press, Washington, DC.

Differences in Performance Characteristics

Comment: The proposed regulation stated that a substitute standardized product with performance characteristics, *e.g.*, cooking quality, freezing quality, spreadability of product, and shelf-life, that materially limit the use of the product must include a disclaimer on the product's label adjacent to the product name informing the consumer of such differences.

Most commenters agreed that limitations in a product's performance characteristics should be disclosed on the product label, and be conspicuous and readable. A number of commenters stated that the disclaimer should be adjacent to the most prominent claim on the label. One commenter, although in agreement with the disclaimer requirement, felt that disclosure on the label, not necessarily adjacent to the product name as provided in the proposed rule, was sufficient to inform the consumer of performance differences. This same commenter recommended that FSIS harmonize the requirement for labeling of performance differences with a similar FDA rule, which requires a disclaimer adjacent to the most prominent claim on the label (21 CFR, 101.13(d)). Another commenter stated that the disclaimer should be adjacent to the most prominent claim and should most likely appear on the principal display panel.

Response: In the preamble to the proposed rule, FSIS stated that ''if there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim in accordance with 9 CFR 317.313(d)(1) and (2) and 9 CFR 381.413(d)(1) and (2), informing the consumer of such difference'' (60 FR 67480). However, in the text of the proposed rule, FSIS stated that the label must include, ''adjacent to the product name,'' a statement in accordance with 9 CFR 317.313(d)(1) and (2) and 9 CFR 381.413(d)(1) and (2) informing the consumer of differences in performance characteristics (60 FR 67486, 67487). Thus, the preamble and the text of the proposed rule differed in that the preamble did not mention that the disclaimer must be ''adjacent to the product name.'' The regulations referenced by both the preamble and the text of the proposed rule, 9 CFR 317.313(d)(1) and 9 CFR 381.413(d)(1), require that differences in performance characteristics that materially limit the performance of a substitute product be disclosed adjacent to the most prominent claim on the product label.

FSIS is resolving the discrepancy regarding placement of the disclaimer. FSIS agrees with the comment that disclosure on the label, not necessarily adjacent to the product name, is sufficient to inform the consumer of performance differences. Therefore, in this final rule, FSIS is not requiring that the disclaimer be placed adjacent to the product name. As in FDA regulations 21 CFR 130.10 and 101.13(d), a disclaimer for differences in performance characteristics shall be placed adjacent to the most prominent claim on the label. To reflect this decision, FSIS is removing the phrase ''adjacent to the product name'' from proposed §§ 319.10(b)and 381.172(b).

Comment: Two commenters disagreed with the need for the proposed disclaimer requirement and suggested that disclosure of any limitations in the performance characteristics of a substitute standardized product be voluntary. One of these commenters stated that disclaimers on a product's labeling informing consumers of performance characteristics that materially limit the use of the product need not be required by regulations because a substitute standardized product produced under the general standard will succeed or fail in the market place based on consumer expectations associated with the product's performance. This commenter stated that businesses would voluntarily place disclaimers on a product's label in the absence of a regulation requiring that they do so because it would be good business to inform consumers that a product they are purchasing can not be used in a traditional application.

The other commenter agreed that, in practice, poorly formulated products would fail in the marketplace long before any regulatory system could determine that they did not meet the specific performance characteristics they would be expected to have. However, this commenter acknowledged that requiring a disclaimer informing consumers of limitations in a product's performance characteristics, when they exist, will require manufacturers of substitute standardized products to monitor performance characteristics during product development and may help ensure that new low- and reduced-fat standardized products are formulated well from the beginning. The commenter went on to state that consumers are also more likely to accept this category of substitute products if they are well formulated from the beginning.

Response: FSIS disagrees with the commenters' suggestion that disclosure of performance characteristics that materially limit the use of a substitute standardized product compared to the use of the traditional standardized product should be voluntary. The FMIA and the PPIA require that the labeling of a meat or poultry product must be truthful and not misleading, and that such labeling accurately disclose to consumers what they are buying when they purchase any meat or poultry product. Information disclosing differences in performance characteristics that affect the use of a substitute standardized product (*e.g.*, cooking quality, freezing quality, spreadability of product, and shelf life) is a material fact that must be disclosed on the labeling of these products. Without such labeling, consumers would be misled about significant characteristics and uses the product has compared to the standardized product for which it substitutes. Accordingly, this information must be communicated to consumers on the product's label, or the label will be misleading and the product will be misbranded under the FMIA or PPIA.

Moreover, FSIS agrees with the commenter who suggested that processors are more likely to monitor the performance characteristics of substitute standardized products during product development when limitations in the product's performance characteristics are required to be disclosed on the product's labeling. FSIS also agrees that if substitute standardized products are well formulated from the beginning, it will promote consumer acceptance of this category of meat and poultry products.

Comment: One commenter pointed out that it may be possible for performance characteristics to be introduced into a substitute standardized product that improve upon the performance characteristics of the traditional standardized product. The commenter suggested that the Agency consider substituting the term ''not inferior'' for ''similar'' in proposed 9 CFR 319.10(b).

Response: FSIS did not intend to prohibit improvements in the performance characteristics of substitute products when it proposed that substitute standardized products subject to the general standard perform similarly to the traditional standardized products for which they substitute. However, FSIS disagrees that it should require that substitute standardized products have performance characteristics that are ''not inferior to'' rather than ''similar to'' the traditional standardized products as suggested by the commenter. As proposed, §§ 319.10(b) and 381.172(b) permit products subject to the general standard to have limitations in performance characteristics provided that such limitations are properly disclosed on the product's labeling. The Agency believes that requiring disclosure of any performance limitations on the labeling of products subject to the general standard provides sufficient incentive for manufacturers of these products to market products that are not inferior to the traditional standardized products. Furthermore, proposed 9 CFR 319.10(b) and 9 CFR 381.172(b) require a disclaimer for performance characteristics that ''materially limit'' the use of a substitute standardized product, not for characteristics that improve the performance of the product. Thus, the disclaimer requirement contained in proposed 9 CFR 319.10(b) and 9 CFR 381.172(b) will not discourage manufacturers from making improvements to the performance characteristics of substitute products when it is possible to do so.

Enforcement

Comment: Two commenters questioned FSIS's ability to enforce and ensure uniform compliance with the performance characteristics requirements proposed in 9 CFR 319.10(b) and 381.172(b). One commenter asked how FSIS intends to determine differences in performance characteristics. The commenter went on to state that the proposed performance characteristics requirements seem to be ''command and control'' regulations that are not related to product safety. The other commenter stated that, in practice, poorly formulated products would fail in the marketplace long before any regulatory system could determine that they did not meet the specific performance characteristics discussed in the proposal.

Response: FSIS expects that substitute standardized products that are produced under the general standard will conform to the performance characteristics requirements set forth in proposed 9 CFR 319.10(b) and 381.172(b). To ensure that there is compliance, FSIS will examine the performance characteristics and product quality of substitute products as it would other types of products, through scientific review and experimental investigations. In addition, FSIS will use traditional methods available to the Agency, such as sample analysis, inspections, surveys, and follow-up investigations of consumer and trade complaints to identify products that do not comply with the new regulations in order to enforce this regulation as the need arises.

Furthermore, FSIS disagrees with the comment that the proposed performance characteristics requirements are ''command and control'' regulations. Under §§ 319.10(b) and 381.172(b), FSIS is not establishing specific criteria for determining similarities in performance characteristics. FSIS believes that judgments about similarity are best left to product developers, who have the incentive to market a product that resembles the traditional standardized product as closely as possible and to disclose product performance limitations to ensure that there is consumer satisfaction with the substitute standardized product.

Safe and Suitable Ingredients

Comment: There was general agreement among the commenters that the ingredients used in a substitute standardized product produced under the general standard should be those ingredients provided by the traditional standard, with the exception of ''safe and suitable ingredients,'' as defined in (former) 9 CFR 318.7 and 381.147, at the minimum level necessary to improve texture and prevent syneresis. However, several commenters requested clarification and expansion of the ingredients permitted under this provision.

Three commenters stated that allowances for ingredients should be broadened to include any safe and suitable ingredients to replace functional characteristics. These commenters all noted that the FSIS proposal limits ingredient usage to achieve textural improvement and to prevent syneresis. They felt that FSIS should build additional flexibility into the final rule to allow for a wider use of safe and suitable ingredients to replace functional characteristics that may be lost when a formulation is adjusted to meet a claim requirement. These commenters mentioned that the comparable FDA regulation allows the use of safe and suitable ingredients ''* * * to add flavor, extend shelf life, improve appearance, or add sweetness'' (21 CFR 130.10(d)). One commenter suggested that any ingredient that is generally recognized as safe (GRAS) or that is an approved additive should be permitted to be used as desired by the manufacturer. Another commenter stated that limiting the use of safe and suitable ingredients to the minimum level necessary to improve texture and to prevent syneresis severely limits the ability to produce a consumer-acceptable meat or poultry product. One

commenter specifically requested that FSIS clarify the acceptability of flavorings, especially meat flavorings, as safe and suitable ingredients in substitute standardized products.

Response: For purposes of clarification, since it published the general standard proposal, FSIS issued the final rule ''Food Ingredients and Sources of Radiation Listed or Approved for Use in Meat and Poultry Products'' (64 FR 72168, December 23, 1999). The rule is intended to improve the efficiency of the procedures used by FSIS and FDA to review and approve the use of food ingredients and sources of radiation in the production of meat and poultry products. Under the new regulations, rather than listing substances approved for use in the production of meat and poultry products in the chart of substances contained in former 9 CFR 318.7(c)(4) and former 9 CFR 381.147(f)(4), FDA now lists food ingredients and sources of radiation that are safe for specific use in the production of meat and poultry products in its regulations in title 21 of the CFR. In the final rule, FSIS also created a list of food ingredients approved for use in the production of meat and poultry products by combining the listing contained in former section 318.7(c)(4) with the listing contained in former section 381.147(f)(4) and moving the combined listing to section 424.21(c). The final rule became effective on January 24, 2000.

FSIS did not include ingredients that would affect flavor, shelf life, or sweetness because these kinds of ingredients do not affect the ability of a manufacturer to modify a meat or poultry product to reduce fat, cholesterol, or sodium, which was the focus of this rulemaking. Thus, §§ 319.10 and 381.172 provide only for increased amounts of safe and suitable ingredients that are needed to achieve the effect of replacing fat, *i.e.*, binders, texturizers, and emulsifiers.

As for the acceptability of flavorings in substitute standardized products, manufacturers will not be limited by §§ 319.10 or 381.172 in their ability to use ingredients that impart flavor. This final rule does not limit a manufacturer's ability to use safe and suitable meat and poultry flavorings.

''Fat Replacing'' Binders

Comment: In the preamble to the proposed rule, FSIS provided a list of ''fat replacing'' binders to assist meat and poultry processors to understand the types of ingredients that are permitted to be used to achieve the effects of fat in making substitute standardized products under the general standard. However, the list was not intended to be all-inclusive. One commenter supported the use of ingredients not identified in the preamble as part of a fat replacement system and requested that FSIS clarify whether other fat replacers, such as milk protein concentrates, would be permitted in substitute standardized products, given this substance's similarities to the listed substances. The commenter also requested that the preamble to the final rule specifically note that milk protein concentrates and egg whites are acceptable substances in fat replacement systems.

Three commenters agreed that the ingredients listed in the preamble are appropriate for use in a substitute version of a standardized product but felt that the list should be broadened to include other safe and suitable ingredients that have a demonstrated ability to function as a fat replacement system. One of these commenters requested that if the list provided within the context of the preamble is not meant to be all-inclusive, FSIS should state that fact. The commenters also encouraged FSIS to include a list of criteria for evaluating fat replacing binders not on the list to determine whether they qualify as acceptable binders.

Response: The list of ''fat-replacing binders'' presented in the preamble to the proposed rule represents examples of ingredients or additives historically classified as binders by food scientists and ingredient technologists. This list is not intended to be all encompassing, and other safe and suitable ingredients historically recognized as binders are permitted to be used in ''fat replacement'' systems for substitute standardized products produced under the general standard.

In general, a safe and suitable ingredient qualifies for use as a fat replacing binder under this final rule if it is only used for its functional properties and does not impart other characterizing qualities, such as taste and nutritional value, to the standardized product when used in the product formulation. FSIS will evaluate whether safe and suitable ingredients that were not listed in the preamble to the proposal qualify as fat replacing ingredients on a case-by-case basis.

As a point of clarification, milk protein concentrates have historically been used by meat and poultry product manufacturers as binding ingredients in meat and poultry products and therefore, under the general standard, FSIS will permit milk protein concentrates to be used as binders in fat replacement systems for substitute standardized products.

Regarding the use of egg whites as a fat replacing binder, egg whites are considered an egg product and as such function as an individual food product that is consumed for its own taste and nutritional value. Thus, FSIS considers the use of egg whites in the formulation of a meat or poultry product to be sufficiently characterizing so as to result in a product that is not a substitute standardized product, but one that is a non-standardized product, *e.g.*, identified with a true product name, such as ''Low Fat Pork Sausage made with Egg Whites.''

Although FSIS is not providing an all inclusive list of suitable fat replacing binders in this final rule, the Agency did provide an extensive listing of binders in the preamble to the proposed rule to convey the intent of the rule (see 60 FR 67481). Persons interested in determining whether an ingredient is an appropriate fat replacing binder may refer to this original listing.Furthermore, safe and suitable ingredients that meet the general criteria outlined above, *i.e.*, have historically been classified as binders, are only used for their functional properties, and do not impart other characterizing qualities when used in the formulation of substitute products, will also qualify as acceptable fat replacing binders under this final rule.

Textured Vegetable Protein (TVP) as a ''Fat Replacer''

Comment: In the preamble to the proposed rule, FSIS stated that the Agency views TVP as a ''meat or poultry replacer,'' and that the use of TVP as a fat replacing ingredient in a substitute standardized product subject to the general standard would be inappropriate. At the time that the proposal was published, FSIS had determined that the use of TVP in a substitute standardized product would change the nature of the product to such an extent that it would no longer be a substitute product within the parameters of the proposed rule. This view, in part, was based on the belief that TVP was used as a ''meat replacing'' ingredient in foods considered ''meat replacing products,'' such as ''veggie-burgers,'' which are primarily TVP with water, flavorings, and seasonings.

FSIS received numerous comments expressing strong disagreement with FSIS's historic views. Forty-three commenters submitted statements in support of allowing TVP as a fat replacer in substitute standardized meat and poultry products subject to the

general standard so that these products may be identified by a nutrient content claim. Many of these commenters provided supporting studies on the health and nutritional benefits of soy protein, along with data on consumer awareness and acceptance of products containing TVP. Many commenters felt that not permitting TVP as a fat replacing ingredient would greatly limit the ability of the industry to develop substitute standardized meat and poultry products that are lower in fat. These commenters stated that the use of TVP as a fat replacer is important in expanding the flexibility of the meat and poultry industry to create and market an increased variety of healthful substitute meat and poultry products. Some commenters specifically mentioned that prohibiting TVP would limit product development in areas of coarse ground cooked and fermented sausage.

Several commenters stated that TVP should be permitted as a fat replacer so long as its use conforms to the requirements of the general standard. These commenters stated that TVP should be permitted as part of a ''fat replacement system'' in substitute standardized meat and poultry products so long as: (1) Its use does not substantially change the nature of the finished product; (2) it is not used to replace the meat or poultry content required by the traditional standard; and (3) it is used only at the minimum level necessary in a fat replacement system to qualify for use of the nutrient content claim.

A number of commenters stated that TVP should be regulated on the basis of its functional properties rather than on its physical form. Many of these commenters pointed out that, while in the past TVP was used as a ''filler'' or ''substitute'' for meat components in food, advancements in TVP technology have made TVP a highly functional ingredient that could now be used as part of a fat replacement system to improve the textural character and quality of a substitute standardized meat or poultry product. Many commenters noted that TVP, when used in combination with other water binders, provides improved product texture, visual appearance, performance, and storage characteristics. Data supporting this view were presented to the Agency.

Some commenters felt that TVP should be allowed as a fat replacer in all meat items where non-textured vegetable proteins are allowed. One commenter stated that texture is a matter of degree, and that forms of vegetable proteins range from fine powders, to small granules, to small flakes, to larger granules and flakes. This commenter stated that it is arbitrary to require that TVP be excluded as a ''fat replacer'' but not the powdered forms. One commenter questioned the logic of permitting soy flour, soy protein concentrate, and isolated soy protein in products because they replace fat, but prohibiting the use of TVP because it is inappropriately thought to replace meat. The commenter pointed out that the proposed rule does not permit a reduction in the meat or poultry content, and therefore, TVP could not be used as a meat replacer. Another commenter mentioned that other binders, such as carrageenan, can be texturized, and therefore, TVP is being singled out unfairly.

A number of commenters stated that, because the presence of TVP can be disclosed in product labeling, consumers should be allowed to decide for themselves whether to purchase a lower fat standardized product that contains TVP. Some commenters pointed out that the presence of TVP in a meat food product could be communicated to consumers in the same manner as any other ingredient, in the ingredient statement. The commenters asserted that appropriate product labeling required by the general standard would ensure that consumers would not be misled about the presence of TVP in substitute standardized products produced.

Some commenters stated that if TVP is permitted as a fat replacer in substitute standardized products, the substitute product should provide the same amount of animal protein as the traditional standardized product. One commenter stated that this approach would provide manufacturers with optimum flexibility, yet guarantees that the consumer receives a product that is at least as valuable as the unmodified product. Another commenter mentioned that consumers are interested in over-all nutrition, not in specific ingredients.

Some commenters expressed the view that TVP should not be considered as a ''food,'' because it is not consumed by itself as a food. These commenters stated that TVP is a functional food ingredient that can be used as part of a fat replacement system.

Response: FSIS has been persuaded by the comments, information, and other data submitted by commenters to permit the use of TVP as a part of a fat replacing system in substitute standardize products produced under the general standard. Accordingly, in this final rule, proposed §§ 319.10(c) and 381.172(c) have been modified to provide for the use of TVP, alone or in combination with other binders and water, as part of a fat replacement system.

The Agency will permit the use of TVP as a functional food ingredient that is used to replace fat. Like the other fat replacing ingredients permitted to be used under this final rule, the use of TVP as an ingredient in a substitute standardized product will be permitted only at the lowest level necessary to achieve the intended effect of replacing fat. When TVP is used to replace fat, the ingredients statement on the product label must alert the consumer to the fact that TVP is not permitted in the traditional standardized product or is used in excess of amounts permitted in the traditional standardized product. The labeling requirements will ensure that consumers will not be misled when TVP is used to replace fat in substitute standardized meat and poultry products subject to the general standard.

Under this final rule, TVP may not be used to replace the meat or poultry content of a product when a product standard specifies a minimum meat or poultry content requirement. However, if the formulation of a substitute product produced under the general standard contains the same amount of meat or poultry prescribed by the traditional standard, the fat component of the meat or poultry in the substitute product may be removed during processing and replaced with TVP, or any other safe and suitable binder, alone or in combination with water as part of a fat replacement system.

For example, the product standard for ''chili con carne'' provides that the product shall contain not less than 40% meat computed on the weight of the fresh meat (9 CFR 319.300). The product formulation for a substitute version of chili con carne produced under the general standard must contain 40% meat, but the fat content of the meat component may be replaced with TVP during processing.

According to information presented to the Agency, TVP is particularly useful in developing lower fat versions of cooked sausages and other comminuted meat and poultry products. Although the standards for these kinds of products generally do not prescribe a minimum meat or poultry content, most of these standards limit the amount of fat that is permitted in the product. For example, the standard for cooked sausages defined in 9 CFR 319.180 limits the fat content of these products to no more than 30% of the finished product, and the standard for ground beef defined in 9 CFR 319.15 limits the fat content in this product to no more than 30%. Thus, under this final rule, the amount of TVP permitted in such

products will be limited by both the requirement that fat replacing ingredients may be used only at the lowest level necessary to replace fat and by the minimum fat content requirement established by the product standard.

For example, a substitute cooked sausage produced under the general standard is permitted to contain up to 30% TVP, provided that the sole function of the TVP is to replace the fat. For purposes of this rule, FSIS does not consider replacing the fat component of a single ingredient standardized product, such as ground beef, as reducing the product's meat content, provided that the product complies with the manufacturing and labeling requirements prescribed in this final rule.

To eliminate the possibility of confusion, the phrases ''textured vegetable protein shall not replace meat'' and ''textured vegetable protein shall not replace poultry,'' which were used as examples in the regulatory text of proposed 9 CFR 319.10(c)(2) and 381.172(c)(2), will be removed in the final rule. These phrases are unnecessary because the regulation already prohibits reductions in the meat or poultry content required by a regulatory standard regardless of whether TVP is used in the product.

Other Foods as ''Fat Replacers''

Nine commenters indicated that in the final rule, FSIS should permit foods, such as bread, rice, potatoes, fruits, and vegetables to be used in substitute standardized meat and poultry products to reduce their fat content. Some of these commenters stated that these ingredients could serve the same role as the water and binder systems permitted as fat replacers in the proposed rule, but that food ingredients are more beneficial because they may contain some nutritional constituents, such as vitamins and minerals, that many binders do not. One commenter stated that food ingredients, when used at proper levels, help to provide consumers with substitute standardized products that perform similarly to traditional standardized products. Another commenter stated that the nutrition label would enable consumers to make informed purchase decisions based on the entire nutritional profile of the product. This commenter pointed out that many consumers would prefer the nutritional profile of substitute standardized products that use starchy vegetables and complex carbohydrates, such as rice and potatoes, rather than a combination of water and ingredients such as highly refined vegetable gums to lower the percentage of calories from fat. One commenter stated that it makes sense to allow other foods as fat replacers if the goal is to make more healthful products available to consumers. Another commenter suggested that consumers might be more interested in overall nutritional quality, taste, convenience, and performance of the product than in the specific ingredients present in the product.

Response: FSIS concedes that because foods such as bread, rice, potatoes, fruits, and vegetables, have little or no fat, their use as ingredients in standardized meat and poultry product could have the effect of reducing the fat content of such products. However, when foods are used as ingredients in a standardized product, the composition of the product may be altered to such an extent that the resulting product is not a substitute version of the traditional standardized product but a new and different product with a separate identity that reflects the combination of the individual foods. For example, because diced apples and rice are not specified as ingredients in the standardized product ''Pork Sausage,'' when they are added to ''Pork Sausage,'' the result is a new product, which, provided that it does not have a standard of identity or composition prescribed by 9 CFR part 319 or other established common or usual name, is required to bear a descriptive name, such as ''Pork Sausage with Diced Apples and Rice,'' that clearly identifies the product (see 9 CFR 317.2(c)(1) and (e) and 9 CFR 381.117(a)). Because the product ''Pork Sausage with Diced Apples and Rice'' is a new product and not a substitute version of the standardized product ''Pork Sausage,'' it is not the type of product that the general standard established by this final rule is intended to address.

As a point of clarification, this final rule does not prevent non-standardized meat and poultry products that use food ingredients to reduce their fat content from using a traditional nutrient content claim permitted under 9 CFR 317 subpart B and 381 subpart Y, provided they meet the requirements of the claim. For example, the product ''Pork Sausage with Diced Apples and Rice'' is permitted to bear the claim ''low fat'' on its label if it complies with § 317.362, and therefore, may be referred to as ''Low Fat Pork Sausage with Diced Apples and Rice.'' Consumers who prefer the nutritional profile of meat and poultry products that use other foods, rather than binders and water, or other functional food additives, to reduce their fat content will be able to identify these products by their descriptive product name and the traditional nutrient content claim on the product labeling. Furthermore, any benefits in the nutritional profile of products that use foods as ingredients to reduce their fat content will be reflected in the nutrition facts panel, as well, if appropriate, in other nutrient content claims.

Prohibited Ingredients

Comment: One commenter expressed agreement with the provision in proposed 9 CFR 319.10(c)(3) and 381.172(c)(3) that states that ingredients specifically prohibited for use in standardized meat and poultry products should also be prohibited for use in substitute standardized products subject to the general standard. However, the commenter felt that ingredients prohibited from use in all meat and poultry products should be based on safety considerations rather than quality considerations.

Response: The general standard allows for the use of any safe and suitable fat replacement ingredient, *e.g.*, binders and water. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), FDA is responsible for determining the safety of food ingredients for use in food in general. Under the authority of the FMIA and PPIA, FSIS acquiesces to FDA's safety judgments, but FSIS determines the suitability of ingredients determined to be safe by FDA for use in meat and poultry products. These responsibilities are fully described in the final rule ''Food Ingredient and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products,'' which was published in the December 23, 1999, **Federal Register** (64 FR 72168).

Thus, although it is the responsibility of the FDA to evaluate the safety of a substance for use in meat or poultry products, under the authority of the FMIA and PPIA, FSIS may preclude the use of a substance in meat or poultry products for reasons other than safety. There are instances in which the use of a substance, even if safe, may promote deception when used in a meat and poultry product, and, accordingly, such use would be prohibited by FSIS. For example, paprika is considered GRAS by FDA and is also listed for use as a color additive, but the FSIS regulations prohibit its use on fresh, uncooked meat products because such use adds color that may make the meat appear fresher than it actually is (9 CFR 424.23(a)(1)). Therefore, it is incumbent upon FSIS to consider suitability, as well as the safety, of ingredients for use in the production of meat and poultry

products in order to prevent these products from being adulterated or misbranded.

Processing Methods/Anatomical Location for Meat and Poultry Ingredients

Comment: One commenter stated that the provision in proposed §§ 319.10 and 381.172 that requires that the meat portion of a substitute standardized product undergo the same basic processing procedures as the traditional standardized product for which it is a substitute has the potential to limit the use of new technologies without producing any stated goal that would justify the limitation. The commenter stated, that as long as the substitute standardized product has performance characteristics that are similar to the traditional standardized product, and is produced only from authorized ingredients, additional restrictions on processing procedures are unnecessary and undesirable.

Another commenter stated that the general standard should permit substitute standardized products to contain different meat species and different kinds of poultry than those prescribed by the traditional standard, and that it should permit meat or poultry from different anatomical locations than the locations prescribed by the traditional standard, provided that the difference in species or anatomical location is stated in the product name. This commenter felt that a literal reading of the proposed regulation could be interpreted to mean that products such as ''Beef Bacon'' or ''Pork Shoulder Bacon'' would no longer be permitted to include the term ''Bacon'' in their product names if coupled with a nutrient content claim. The commenter went on to say that these kinds of products should continue to be permitted to be marketed under the same familiar names that have been used in the past, and that use of a nutrient content claim next to the product name should not change this.

Response: The intent of the general standard for substitute standardized products is to enable the meat and poultry industries to produce modified versions of standardized products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium, and to increase flexibility and support product innovation. Under this rule, deviations from the existing standards are not expected to result in a product that no longer resembles the original standardized product. Thus, the use of a different meat species or kind of poultry, or the use of meat or poultry from different anatomic locations from those specified in the standard, that results in a product that is so physically dissimilar from the traditional standardized product that it does not meet the definition of ''substitute'' set forth in 9 CFR 317.313(d) and 381.413(d) would be inconsistent with the intent of this rule. For these kinds of products to represent themselves as substitute standardized products would be false and misleading under the FMIA and PPIA.

As an illustration, the regulatory standard for ''Bacon'' under 9 CFR 319.107 requires that this product be prepared from cured, sliced pork bellies. Curing and slicing a cut of meat from a different livestock species or from a different anatomical location, or preparing sliced pork bellies using a method other than curing, would result in a product with physical characteristics so different from the standardized product ''Bacon'' that the resulting product could not be considered a ''substitute'' for bacon under 9 CFR 317.313(d) and 381.413(d). Thus, instead of being identified as a substitute product, the product would be identified by a descriptive term such as ''Beef Bacon'' or ''Pork Shoulder Bacon.''

However, FSIS will consider the types of changes requested by the commenters, such as amending a standard to permit the use of alternative processing methods, on a case-by-case basis. FSIS agrees that certain technologies used to prepare standardized foods may yield a product with the same physical, nutritional, and sensory characteristics as the food made in accordance with the traditional standards. To reflect this fact, instead of specifying that substitute standardized products must contain all ingredients specifically required by a standard of identity or composition, and that the meat or poultry portion of substitute products come from the same anatomical location, be of the same kind and amount, and undergo the same basic processing procedures as the standardized product as was proposed, FSIS is revising §§ 319.10(c)(4) and 381.172(c)(4) to require only that substitute standardized products comply with all other applicable standards of identity or composition.

Regarding the comment expressing concern that under the general standard, products such as ''Beef Bacon'' or ''Pork Shoulder Bacon'' would no longer be permitted to include ''Bacon'' in their product names if coupled with a nutrient content claim, as previously mentioned, FSIS intends to apply the principles embodied in the general standard established by this final rule to other products as appropriate. The Agency will clarify this fact in a policy bulletin after this final rule is published.

Thus, this final regulation will not prohibit the ''bacon-like'' products described in the Policy Book, such as ''Turkey Bacon-Cured Turkey Breast Meat-Chopped and Formed,'' from being modified to qualify to use a nutrient content claim as part of the product name. The modified version of this ''bacon-like'' product would be permitted to be identified as ''Low Fat Turkey Bacon-Cured Turkey Breast Meat-Chopped and Formed.'' FSIS reiterates that the intent of this rule is to provide a wider array of nutritionally improved substitute products that would provide consumers with more meat and poultry products from which to choose. The intent is not to diminish or interfere with markets providing innovative as well as traditional kinds of products to consumers.

Minimum Meat and Poultry Requirement

Comment: Several commenters submitted statements both for and against the proposed requirement that a substitute standardized product subject to the general standard rule maintain the same minimum meat or poultry requirement as the standardized product for which it is a substitute. Seven commenters agreed that substitute standardized products should be required to maintain the minimum meat and poultry requirement established by the traditional standard, while ten commenters expressed disagreement with this requirement.

Several commenters stated that the meat or poultry content of a standardized product often contains the highest concentration of fat, and, while it may be theoretically possible for manufacturers to use leaner meat to reduce fat, it is not economical. One of these commenters stated that fat-reduced products that meet the existing minimum meat or poultry content requirement would be prohibitively expensive. Another commenter stated that relying exclusively on leaner meat to reduce fat might also make products tougher in texture and less palatable. Another commenter stated that, without reducing the ''meat block'' (meat or poultry content), the proposed general standard can not deliver on its promise to encourage innovation and the production of nutritionally improved meat and poultry products.

Some commenters stated that minimum meat and poultry content requirements for substitute products are not necessary so long as the labeling of

the substitute standardized products provides sufficient information to distinguish these products from the traditional standardized products for which they substitute. One commenter submitted data showing that consumers do not mind if part of the meat block in a substitute product is replaced with another ingredient, so long as the labeling of the substitute standardized product discloses the presence of the replacing ingredient. Another commenter stated that trends in consumer behavior, which include reducing the amount of meat consumed in order to reduce fat intake, strongly support the argument that consumers will not be misled by nutrient-modified food products that contain less meat and poultry than is required by the traditional standardized form of the food. One commenter suggested that a substitute standardized product with reductions in its meat or poultry content should state on its label that, ''in order to reduce fat, this product contains less meat than the traditional standardized product.'' Some commenters stated that nutritional equivalency, rather than meat-content equivalency, should serve as the basis for defining requirements for the use of nutrient content claims. These commenters felt that FSIS should allow for necessary reductions in meat or poultry content to meet the requirements of the claim, with the reduction accomplished in such a manner that nutritional equivalency to the traditional standardized product is maintained. One commenter stated that meat replacers may be more desirable than some of the fat replacers, which hold water but contribute little in taste or nutritional value.

One commenter stated that it is widely recognized that the requirements for minimum meat content are based on the notion that meat and poultry represented the most valuable constituent of a meat or poultry product. This commenter claimed that meat and poultry are simply no longer the indisputable ''highest value'' components of food products. Another commenter mentioned that FDA regulations provide for marketing of products, such as reduced-fat peanut butter, which allows for reduction of the peanut content of the product below that required for the standardized product.

Those commenters that agreed with the requirement that substitute standardized products subject to the general standard maintain the same minimum meat and poultry requirement as the standardized product for which they are a substitute maintained that consumers have come to expect a certain amount of meat or poultry in products that bear a standardized term, and that the meat and poultry content of the product is still the most valued constituent.

Response: Because many consumers have come to expect a certain amount of meat or poultry in products that bear a standardized term, deviations in the prescribed meat or poultry content will not be permitted in this final rule. Moreover, while FSIS appreciates these comments, the Agency does not view this rulemaking as the appropriate vehicle for changing the specific meat and poultry content requirements of meat and poultry product standards. These issues will be considered in a separate rulemaking that will examine FSIS's overall regulatory approach to standardized meat and poultry products that was described in the ANPR ''Meat and Poultry Standards of Identity and Composition'' published in the September 9, 1996, edition of the **Federal Register** (61 FR 47453).

In response to that ANPR, FSIS and FDA are jointly working on a more comprehensive approach to modernizing food standards whose goal is to establish ''general principles'' that interested parties could follow in requesting changes to food standards. One change that interested parties may be able to pursue, if these principles are adopted, would be reductions in the meat or poultry content requirements of standardized products. FSIS and FDA expect to soon publish the joint proposed rule in the **Federal Register**.

Nomenclature-Labeling of Nutrient Content Claims

Comment: Of those who commented, all agreed that the name of a substitute standardized product subject to the general standard should be an expressed nutrient content claim in conjunction with (*i.e.*, next to) the appropriate standardized term, as provided in the proposal. However, several commenters did not agree with the provision in proposed 9 CFR 319.10(d) and 9 CFR 381.172(d) that states that the nutrient content claim and standardized term should be presented ''in the same style, color, and size of type on the product label.''

One commenter stated that it was unaware of any evidence that consumers are confused or misled by the labels currently in the marketplace on similar FDA-regulated products, which are not subject to a style, color, and size of type requirement. The commenter stated that the 3:1 type size requirement that generally applies to names on FSIS-regulated products should apply to foods that are marketed under the general standard rule.

Another commenter stated that some flexibility should be allowed for the type size of the nutrient content claim. The commenter stated that some product names are fairly lengthy, and therefore, FSIS's Policy Memo 87A , *Word Size in Labeling of Product Names and Fanciful Names*, states that the Agency will not object to a ⅓ type size flexibility between the largest letter and the smallest letter in a product name. The commenter also noted that the existing FSIS regulations for nutrient content claims allow a ½ type size flexibility to assure that nutrient claims are not disproportionately larger than the product's statement of identity.

Two commenters stated that the FDA regulation establishing a general standard for FDA-regulated substitute standardized products (21 CFR 130.10(e)) does not contain the same restrictions on the style, color, and size of type of the nutrient content claim that FSIS's proposed rule does. One of these commenters requested that FSIS consider modifying the proposed nomenclature for products subject to its general standard to make it similar in format to that prescribed by the FDA regulation. A similar comment suggested that FSIS delete the last clause from the nomenclature section, *i.e.*, '' * * * which shall be in the same style, color, and size of type,'' because it is unwarranted and unnecessary to inform consumers of the nature of the substitute product.

Response: FSIS agrees with the commenters' arguments and in this final rule has deleted the last clause from the nomenclature section (''* * * which shall be in the same style, color, and size of type''). FSIS has been persuaded by the arguments against requiring the nutrient content claim portion of the substitute standardized product's name to be presented in the same style, color, and size of type, as the standardized product term and agrees that this requirement is unnecessary for consumers to distinguish the substitute product from other products that bear nutrient content claims but that are not substitute products that meet the requirements of this final rule. Therefore, to harmonize, to the extent possible, its labeling requirements with the labeling requirements of FDA's corresponding regulations found in 21 CFR 130.10, FSIS will not require that the expressed nutrient content claim that is part of the product identity appear in ''the same style, color, and size of type'' as the standardized term. The product name on the principal display panel of the substitute product,

as well as its ingredients statement, are the pertinent labeling features that identify the differences between the traditional standardized product and the modified version bearing the standardized name.

Ingredient Labeling

Comment: Twenty commenters expressed agreement with the provision in proposed 9 CFR 319.10(e) and 381.172(e) that all safe and suitable ingredients not provided for by the traditional standard, as well as permitted ingredients added at a level in excess of those allowed by the traditional standard, must be appropriately identified as such with an asterisk in the ingredients statement. Three commenters disagreed.

Two commenters stated that because a nutrient content claim calls the consumer's attention to the fact that the product has been modified from the traditional standardized product, there is no need for asterisks to be included in the labeling information. These commenters believed that the product name with the appropriate nutrient content claim, along with the ingredients statement, is all that is necessary to adequately inform the consumer that the product has been modified from the traditional standard. One commenter stated that, in addition to adding to label clutter, the requirement to highlight ingredients present in amounts greater than in the standardized product could result in the ''ludicrous'' situation where a label indicates that the substitute product contains more meat than the traditional standardized product. The commenter felt that requiring an asterisks for particular ingredients will provide a disincentive for meat and poultry processors to make products using the new technologies in fat replacement products because they must market products with labels that are cluttered with additional statements.

One commenter expressed support for using an asterisk to identify ingredients not provided for, or used in excess of those levels provided for, by the traditional standard in so far as it provides parity with FDA's regulation but questioned the real value of this labeling feature to the consumer. The commenter suggested that this labeling requirement be applicable on a short-term basis, with provisions for its phase-out in no more than three years as consumer become more familiarly with nutritionally-modified foods.

Two commenters felt that FSIS should require more than just the identification of the substitute ingredients in the ingredients listing, as proposed by the Agency. These commenters suggested that FSIS also require that whenever ingredients are present in the substitute product that are not permitted by the traditional product standard, an appropriate disclosure (*e.g.* ''made with non-standard ingredients—see back panel for ingredient lists'') appear on the principal display panel. One of these commenters stated that such a disclosure would alert consumers to the fact that a substitute product is different from the standardized product and would direct them to specific information about the differences.

Several commenters requested that FSIS clarify whether the ingredient ''water'' or the added moisture not normally in or in excess of that permitted in a standardized product should be indicated with an asterisk.

Response: FSIS disagrees with the comment that ingredients not provided for by the traditional standard, as well as permitted ingredients added at a level in excess of those allowed by the traditional standard, need not be identified as such with an asterisk in the ingredients statement. Differences between the ingredients in a standardized product and a substitute standardized product identified in part by a nutrient content claim must be highlighted so that consumers will be able to differentiate between the traditional standardized product and the substitute version. Highlighting these ingredient differences also ensures that the labeling of the substitute product will not be misleading. Furthermore, as a point of clarification, when water or added moisture not found in or used in excess of that permitted in a traditional standardized product is added to a substitute standardized product, this fact must be highlighted with an asterisk as is required for all other safe and suitable ingredients not found in, or used in excess of, the amount permitted by the traditional standard.

FSIS disagrees with the comment that requiring an asterisks to highlight specific ingredients present in a substitute standardized product will provide a disincentive for meat and poultry processors to make and manufacture standardized products with reductions in their fat content. Similar labeling has been required on FDA-regulated products for several years and does not appear to have been a disincentive for industry to develop these kinds of products. FSIS also disagrees that labeling features in addition to those provided in the proposed rule are necessary to inform consumers of ingredient differences between a traditional standardized product and its nutritionally modified substitute. Highlighting ingredient differences with an asterisk in the ingredients statement, along with the product name on the principal display panel, are the pertinent labeling features that identify the differences between the traditional standardized product and the substitute version. Furthermore, to some consumers, statements such as ''made with non-standard ingredients'' may imply that the ingredients used in a substitute product are inferior or harmful to the ingredients used in the traditional standardized product. Such statements could be misleading because only ingredients that have been found to be safe and suitable for use in meat and poultry products are permitted to be used in formulating substitute standardized products.

Consumers who have purchased substitute standardized products manufactured pursuant to FDA's general standard codified at 21 CFR 130.10 are familiar with the labeling of such products through the use of asterisks and the statement referenced by the asterisks, which appear adjacent to the ingredient list. Thus, many consumers already look to the ingredient statement to determine differences in formulation between traditional standardized products and nutritionally modified versions of these products. Harmonizing labeling to the extent possible with that of the FDA benefits consumers by providing a more consistent food labeling system across all foods.

FSIS finds no merit in the comment that asterisks are unnecessary because they could lead to the ''ludicrous'' situation where an ingredients statement asterisk would indicate that more meat or poultry than required by the food standard has been used in the product. Because food standards for meat and poultry products generally require minimum amounts of meat and poultry and maximum amounts of fat and water, it has always been possible for manufacturers to include more meat or poultry than the minimum established by the food standard in the product formulation. This rule does not change that fact and there is no need to require an asterisk to highlight the fact that a manufacture chose to include more meat or poultry in a substitute product than the minimum required by the traditional standard.

Regarding the comment that the asterisk provision should be phased out at some point in the future, FSIS does not agree with this view because the ingredient statement is the primary feature where the differences between the standardized product and the substitute version can be made known to the consumer in labeling. As

described earlier, during the joint FSIS and FDA standards modernization activities, if appropriate, the agencies may revisit the issue of phasing out the asterisk requirement and consider it within the context of a more comprehensive approach to food standards modernization.

The Final Rule

In this final rule, FSIS is establishing a general definition and standard of identity for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names in conjunction with a standardized term. FSIS is adding new §§ 319.10 and 381.172 to the meat and poultry products regulations in title 9 of the CFR. As was proposed, §§ 319.10(a) and 381.172(a) describe the type of meat and poultry products that are defined by the general standard. These are products that substitute, in accordance with 9 CFR 317.313(d) or 381.413(d), for a standardized product, but that do not comply with the established standard because of a compositional deviation that results from reductions of a constituent that is described by an express nutrient content claim, such as ''low fat'' or ''fat free.''

As was proposed, §§ 319.10(b) and 381.172(b) require that a substitute standardized product subject to the general standard have similar performance characteristics to the traditional standardized product for which it is a substitute. However, if a substitute product has performance characteristics that materially limit the uses of the product compared to the uses of the traditional standardized product, §§ 319.10(b) and 381.172(b) require that a product's label include a disclaimer informing consumers of such differences, such as ''not suitable for grilling.'' In response to some of the comments and to be consistent with the existing definition of substitute products found in 9 CFR 317.313 and 381.413, FSIS is removing the provision in proposed §§ 319.10(b) and 381.172(b) that would have required the performance characteristics disclaimer to appear ''adjacent to the product name.'' Deleting this provision is also intended to provide consistency with 21 CFR 130.10 of the FDA regulations, which is the codified general standard of identity for substitute standardized products under FDA jurisdiction. As was proposed, §§ 319.10(b) and 381.172(b) will require that deviations in the ingredients in a substitute standardized product be the minimum necessary to qualify for the nutrient content claim.

Sections 319.10(c) and 381.172(c) prescribe the ingredients that must be used in, and the ingredients that are permitted to be used in, substitute standardized products under the general standard. As was proposed, §§ 319.10(c)(1) and 381.172(c)(1) require that the ingredients used in a substitute standardized product be those ingredients provided for by the traditional standard, except that in addition, safe and suitable ingredients may be used in the substitute product at the minimum level necessary to improve texture or prevent syneresis. The final rule replaces references to former §§ 318.7 and 381.147 with the phrase ''as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B,'' to reflect the issuance of the final rule ''Food Ingredients and Sources of Radiation Listed or Approved for Use in Meat and Poultry Products'' (64 FR 72168).

As was proposed, §§ 319.10(c)(2) and 381.172(c)(2) forbid substitute standardized products to replace or exchange ingredients required by the traditional standard with functionally similar ingredients from other sources not provided for in the traditional standard. In the final rule, FSIS is removing the phrases ''textured vegetable protein shall not replace meat'' and ''textured vegetable protein shall not replace poultry'' from proposed §§ 319.10 (c)(2) and 381.172(c)(2). These phrases are unnecessary and could potentially cause confusion since the final rule permits TVP to be used in limited amounts as a fat replacer, although it may not be used to replace meat. Reductions in the meat or poultry content required by the traditional standard are already prohibited by the final rule regardless of whether TVP is used in the product.

As was proposed, §§ 319.10(c)(3) and 381.172(c)(3) prohibit substitute standardized products from containing ingredients that are prohibited for use in traditional standardized products. Proposed §§ 319.10(c)(2) and(3), and 381.172(c)(2) and (3) use the phrase ''[a]n ingredient or component of an ingredient'' when describing the ingredients permitted and prohibited in substitute standardized products. In this final rule, FSIS is deleting the words ''or component of an ingredient'' because they are unnecessary and may cause confusion.

Proposed, §§ 319.10(c)(4) and 381.172(c)(4) required substitute standardized products to conform to certain aspects of the traditional standard, such as the meat or poultry content specified in the standard, the anatomic location and kind of meat or poultry specified in the standard, and the processing procedures specified in the standard. As previously mentioned, deviations from these types of requirements may result in a product that is so physically dissimilar from the traditional standardized product that it does not come within the established definition of a substitute product.

However, because certain technologies used to prepare standardized foods may yield a product with the same physical, nutritional, and sensory characteristics as the food made in accordance with the traditional standards, FSIS intends to consider certain deviations from product standards, such as alternative processing methods, on a case-by-case basis. As stated above, FSIS and FDA are jointly working on a more comprehensive approach to modernizing food standards to establish ''general principles'' that interested parties would follow in requesting changes to or creating new food standards. Therefore, FSIS is revising proposed §§ 319.10(c)(4) and 381.172(c)(4) to require that substitute standardized products comply with all other applicable standards of identity or composition unless otherwise specified in part 319 or part 381. The Agency is making this revision to accommodate changes to food standards that may result from the joint FSIS/FDA food standards modernization approach.

As was proposed, §§ 319.10(c)(5) and 381.172(c)(5) permit water and fat-replacing binders to be used to reduce the fat content in a substitute standardized product subject to the general standard. Based on the comments and data submitted in response to the proposal in support of using TVP as a ''fat replacer,'' FSIS will permit the use of TVP as a functional fat replacing ingredient in substitute standardized products defined by the general standard. FSIS is adding new language to the final rule that permits the use of TVP as part of a fat replacement system at the lowest level necessary to achieve the technical effect of replacing the characteristics of fat in the substitute product. This language is found in new §§ 319.10(c)(6) and 381.172(c)(6). Because §§ 319.10(c)(2) and 381.172(c)(2) of the final rule forbid reductions in the meat or poultry content of a substitute product where one is established by a standard, under the final rule, TVP may only be used to replace fat component and not to replace the lean meat or poultry content of the substitute standardized product.

Sections 319.10(d) and 381.172(d) prescribe the nomenclature for the substitute meat and poultry products that comply with the general standard. As was proposed, these products may be identified by the appropriate expressed nutrient content claim and the applicable standardized term (*e.g.*, ''Fat Free Bologna''). If a product meets the requirements of the general standard, it is itself a standardized product, and therefore, its name will not be required to contain the term ''substitute'' despite the fact that it does not meet all of the requirements of the traditional product standard.

This final rule removes the provisions in proposed §§ 319.10(d) and 381.172(d) that would have required that the expressed nutrient content claim part of the substitute standardized product's name appear in the ''same style, color and size type'' as the standardized term. This change is in response to public comments and to harmonize, to the extent possible, with similar FDA regulations.

As was proposed, §§ 319.10(e) and 381.172(e) require each of the ingredients used in the substitute product to be declared on the product label as required by the applicable FSIS regulations. 9 CFR parts 317 and 381, subpart N, require that all ingredients be listed by common or usual name in descending order of predominance by weight. As was proposed, §§ 319.10(e) and 381.172(e) also require that all safe and suitable ingredients not provided for by the traditional standard, as well as those used in excess of those permitted by the traditional standard, be identified as such with and asterisks in the ingredients statement.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined to be significant and therefore has been reviewed by OMB under EO 12866.

I. Need for the Rule

FSIS is issuing this rule to facilitate the development and availability of substitute standardized products that have reductions in certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium. This rule allows FSIS to rely more on labeling requirements and less on restrictive recipe-like standards in endeavoring to ensure that the labels of meat and poultry products are truthful and not misleading as well as to improve the public health. The names of products covered by the General Standard will be composed of an express nutrient content claim that reflects the modifications made in formulating and processing the product (so that it qualifies to bear the claim) and an established standardized term. FDA has already promulgated a corresponding General Standard for the products that it regulates (21 CFR 130.10). By harmonizing an FSIS labeling requirement with that of FDA, this final rule represents a significant step towards providing consumers with an informative and consistent food standard and labeling system. This final rule also promotes product innovation by encouraging the production of meat and poultry products that are low in constituents that are of health concern to some people.

II. Description of Affected Industry

FSIS regulations contain approximately 80 standards of identity or composition for meat and poultry products. Most of these standards are for processed products, including sliced, injected, smoked, fermented, heat-treated, and raw products. According to the Agency's Performance Based Inspection System Database, in the second quarter of 2003, there were approximately 6,600 Federal and State Establishments [2] that potentially will be affected by the final rule if they develop and make available substitute products for standardized products. Some of these establishments, however, are already producing sausage and other comminuted meat and poultry products under FSIS Policy Memo 121B and Policy Memo 123 which provide for the type of substitute products defined under this final rule. Thus, this rule is likely to have little or no impact on the processing establishments that are producing products in accordance with the policy memos.

Ingredient manufacturers who produce binders and textured (source) protein products (*e.g.*, textured soy or wheat protein) will be affected by the final rule because the rule will permit the increased use of these ingredients as fat replacing ingredients in some modified standardized products.

III. Costs

The decision to produce products subject to the General Standard established by this rule is voluntary. Therefore, only those manufacturers that choose to produce and market these products will incur the direct costs imposed by this rule. These costs include research and development, production and marketing, and labeling production. However, because the rule is voluntary, companies that choose to produce products covered by the General Standard will do so only if they determine that the benefits of producing and selling these products outweigh the costs of complying with the final rule. Furthermore, companies that are already producing and marketing products under Policy Memo 121B and Policy Memo 123 (*i.e.*, comminuted meat and poultry products) are likely to incur minimal or no costs as a result of this final rule.

Under most circumstances, companies are likely to charge a premium for substitute standardized product produced in compliance with this final rule because many consumers will be willing to pay a premium for products with improved nutritional profiles. They view these products as ''value added'' products.[3] Therefore, based on the experience of food companies that are operating under FDA's 21 CFR 130.10 regulations, *e.g.*, the manufacturers of fat-free ice cream and reduced fat cream cheese, any costs associated with producing and marketing substitute products most likely will be passed on to the consumer in the form of higher retail prices.

However, once this rule becomes effective, some companies that are not producing substitute meat and poultry products under Policy Memo 121B or Policy Memo 123 may begin to manufacture and market substitute standardized products in accordance with the General Standard because of the market value of using traditional product names. Their decision to do so could have the effect of increasing the supply of these types of products in the short run, which could translate into lower prices for consumers.

IV. Benefits

This rule will assist consumers in making dietary choices by providing for modified versions of standardized meat and poultry products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium. Therefore, there will be a greater opportunity for consumers to maintain or to initiate healthy dietary practices. In the United States, diets high in fat, cholesterol, and sodium are associated with chronic diseases such as coronary heart disease, cancer, stroke, and diabetes. In 2002, according to the Centers for Disease Control National Center for Chronic Disease Prevention and Health Promotion, 7 out of every 10 U.S. deaths and more than 60% of medical care expenditures are attributed to chronic diseases. In addition, the

[2] These establishments processed, froze, stored, or otherwise held meat and poultry products.

[3] Consumer purchasing trends.

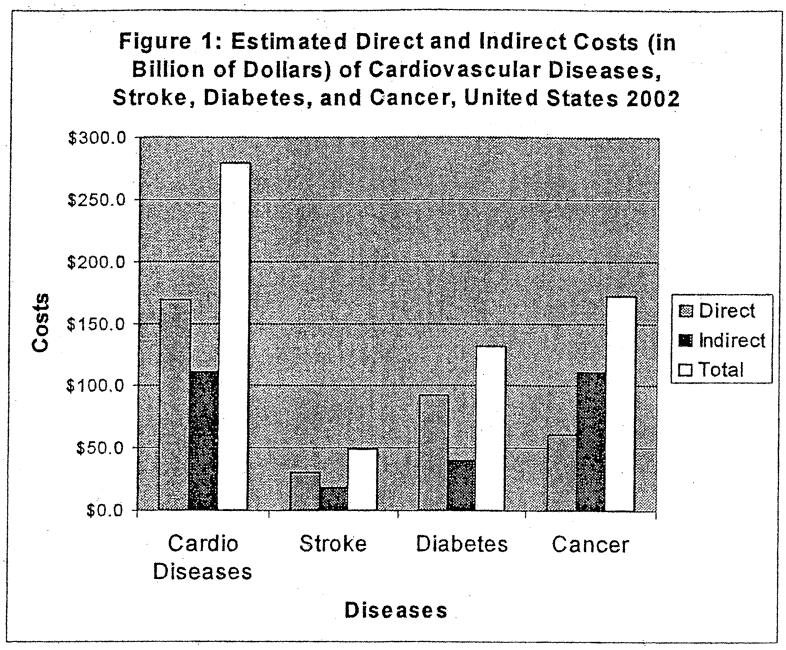
prolonged illness and disability associated with many chronic diseases decrease the quality of life for millions of consumers.

ESTIMATED DIRECT AND INDIRECT COSTS OF CARDIOVASCULAR DISEASES, STROKE, DIABETES, AND CANCER IN THE UNITED STATES—2002

[In Billion of Dollars]

Costs	Cardiovascular diseases	Stroke	Diabetes	Cancer
Direct	$168.7	$30.8	$92.0	$61.0
Indirect	111.1	18.6	40.0	111.0
Total	279.8	49.4	132.0	172.0

According to the 2002 Heart and Stroke Statistical Update published by the American Heart Association and the American Stroke Association, the total cost of cardiovascular diseases and strokes in the United States was estimated at $279.8 billion and $49.4 billion, respectively, as reflected in the above table and figure 1 below. Direct costs ($168.7 billion and $30.8 billion, respectively) consist of the cost of physicians and other health professionals, hospital and nursing home services, medication, home health care, and other medical durables. Indirect costs ($111.1 billion and 18.6 billion, respectively) consist of lost productivity resulting from morbidity and mortality.



The total cost in 2002 associated with diabetes was $132 billion of which $92 billion were direct costs and $40 billion were indirect costs.[4] The estimated total costs for all cancers in 2002 were $172 billion ($61 billion in direct costs and $110 billion in indirect costs) [5].

Most chronic diseases are preventable, or their onset can be delayed, through increased physical activity and healthy eating. There is research to support that practicing good nutrition lowers the risk of chronic diseases for many consumers.[6] The total estimated cost of chronic diseases to the consumer is $633.2 billion. The extent to which these costs might be reduced by an improved diet cannot be calculated precisely, but some researchers estimate that a balanced and healthful diet might forestall at least 20 percent of the annual deaths from heart disease, stroke, cancer, and diabetes.[7]

It is reasonably expected that the final rule could contribute to the reduction of these costs, but this contribution, too, cannot be calculated precisely. In the ''Economic Benefits of Nutrition Labeling: A Case Study for Fresh Meat and Poultry Products,'' the Agency estimated the potential benefits of reducing the incidence of coronary heart disease and three types of cancers at $61.8 million, (7 percent discount rate); and $125 million (3 percent discount rate).[8]

The results of the 2002 ''Trends'' survey'' conducted by the Food

[4] ''The Economic Costs of Diabetes in the U .S. 2002'', American Diabetes Association.

[5] Heart Disease and Stroke Statistics—2003 Update, American Heart Association.

[6] CDC National Center for Chronic Disease Prevention and Health Promotion, ''Physical Activity and Good Nutrition: Essential Elements to Prevent Chronic Diseases and Obesity.''

[7] ''The American Diet: A Costly Health Problem, Food Review.''

[8] The Agency estimated the potential benefit of an FSIS rule (2001). Nutrition Labeling of ground or chopped meat and poultry products and single-ingredient products. **Federal Register**, 66, 4969–4999.

Marketing Institute (*Trends in the United States, Consumer Attitudes and the Supermarket*) stated that 80 percent of consumers surveyed indicated that they had sought out and purchased products based on ''low-fat'' claims; 60 percent had purchased products because of ''low cholesterol'' claims; 59 percent purchased products because of ''natural'' claims; and 52 percent purchased products because of ''low salt'' claims. If this trend continues, and the final rule is promulgated, it is more than likely that the final rule will assist in the reduced incidence of chronic diseases by expanding the availability of meat and poultry products with lower levels of constituents such as fat, cholesterol, and sodium.

In conclusion, this final rule will assist consumers who want to reduce their dietary intake of fat, cholesterol, and sodium by encouraging the production of modified versions of traditional meat and poultry products that are formulated with fat, cholesterol, and sodium-replacing ingredient systems that reduce these constituents. The final rule will provide parity with FDA's regulations and will promote a unified approach to food standards and labeling. Most importantly, the final rule supports national efforts to reduce the expenditures for health care and the cost of morbidity and lost productivity by permitting the introduction of modified, substitute foods.

In terms of administrative benefits, the General Standard established by this final rule will permit industry to introduce modified, substitute versions of traditional standardized meat and poultry products without having to petition FSIS to establish new standards for products on a case-by-case basis. This will generate efficiency within the food standards system by saving time and resources that would have been expended by both the industry and FSIS to establish new or modified product standards. It will also permit companies to introduce standardized meat and poultry products with improved nutritional profiles into the marketplace in a timely manner, making such products more readily available to consumers.

V. Regulatory Flexibility Analysis

The FSIS Administrator has made a final determination that this rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

This final rule will not impose any new requirements on small entities. The decision to produce versions of standardized products that have been modified to qualify for use of an expressed nutrient content claim in conjunction with a traditional product name is voluntary. Therefore, the requirements of this final rule will only apply to those small manufacturers who choose to produce these types of products. Those small entities that choose to produce these products will be required to design new labels or to revise current labels to comply with this new rule, and thereby incur some costs. However, small entities who will be marketing these substitute products will most likely have anticipated that the revenues generated from the sale of these products will outweigh the costs of complying with the new regulation.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.320 through 590.370 must be exhausted before any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), FSIS will submit the information collection and recordkeeping requirements in this final rule to the Office of Management and Budget (OMB) for approval.

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

Type of collection: New.

Abstract: Under this final rule, FSIS is requiring that establishments that produce meat and poultry products in accordance with the definition and general standard of identity for substitute standardized products design new product labels and submit sketches of the new labeling to FSIS for approval. To receive approval of the labels, establishments must complete FSIS form 7234–1. FSIS employees review FSIS form 7234–1 to ensure that information on the labels complies with the regulations.

Estimate of burden: FSIS estimates that it will take 60 minutes to design and develop modified product labels in accordance with the final regulations and 15 minutes to prepare FSIS form 7234–1 and submit it, along with the label, to FSIS.

Respondents: Establishments that produce substitute standardized meat or poultry products in accordance with this final rule.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual Burden on Respondents: 625 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250. Comments are invited on (a) Whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected, ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 30 days of publication.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Interim_&_Final_Rules_Index/index.asp.* The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will

accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/*.

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, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an email subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. 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 account.

List of Subjects

9 CFR Part 319

Food grades and standards, Meat inspection.

9 CFR Part 381

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

■ For the reasons stated in the preamble, FSIS amends 9 CFR parts 319 and 381 as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 1. The authority citation for part 319 continues to read as follows:

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

■ 2. Part 319, subpart A is amended by adding a new § 319.10 to read as follows:

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

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

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the meat food product shall be similar to those of the standardized meat food product produced under this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in this part, the label shall include a statement in accordance with § 317.313(d)(1) and (2) of this subchapter that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in this part, except that safe and suitable ingredients permitted for use in meat food products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in this part shall not be replaced or exchanged with a similar ingredient from another source, for example, turnip chunks shall not replace potatoes in corned beef hash.

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

(4) Unless otherwise specified in this part, a substitute meat food product must meet all other requirements of the applicable standards of identity or composition.

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

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute meat food product that complies with all parts of this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute meat food product shall be declared on the label as required by this section and part 317 of this subchapter.

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

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

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

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

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

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

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the poultry product shall be similar to those of the standardized poultry product produced under subpart P of this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in subpart P of this part, the label shall include a statement in accordance with § 381.413(d)(1) and (2) of this part, that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in subpart P of this part, except that safe and suitable ingredients permitted for use in poultry products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in subpart P of this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in subpart P of this part shall not be replaced or exchanged with a similar ingredient from another source, for example, extruded turnips shall not replace noodles in poultry with noodles.

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

(4) Unless otherwise specified in this part, a substitute poultry product must meet all other requirements of the applicable standards of identity or composition.

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

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute poultry product that complies with this section is the appropriate expressed nutrient content claim and the applicable standardized term.

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

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

Done in Washington, DC, on June 6, 2005.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 05–11493 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150–AH61

Revision of Fee Schedules; Fee Recovery for FY 2005

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule appearing in the **Federal Register** on May 26, 2005 (70 FR 30526) concerning the licensing, inspection, and annual fees charged to NRC applicants and licensees in compliance with the Omnibus Budget Reconciliation Act of 1990, as amended. This action is necessary to correct typographical and printing errors.

EFFECTIVE DATE: July 25, 2005.

FOR FURTHER INFORMATION CONTACT: Tammy Croote, telephone 301–415–6041; Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

1. On page 30531, in the first column, under Response, in the fourteenth line, the word ''commenters?'' is corrected to read ''commenters.''

2. On page 30535, in the second column, under 4. *Charging Fees for Unlicensed Sites in Decommissioning*, in the eleventh line, the word ''licensees?'' is corrected to read ''licensees.''

3. On page 30537, in TABLE III.—REBASELINED ANNUAL FEES FOR FY 2005, the first number under the *FY 2005 Annual Fee* column ''$3,115,000'' is corrected to read ''$3,155,000.''

4. On page 30540, in the second column, in the fourth line of the continued paragraph under Table VIII, the number ''$2,966,000'' is corrected to read ''$2,996,000.'' Also, in the tenth line in the same paragraph, the number ''$3,115,000'' is corrected to read ''$3,155,000.''

PART 170—[AMENDED]

§ 170.31 [Corrected]

■ 5. On page 30547, in § 170.31, in the table entitled SCHEDULE OF MATERIALS FEES, the Category of materials licenses and type of fees column entry for 14.B. ''(insert date 1 year from effective date of final rule)'' is corrected to read ''July 25, 2006.''