

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

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

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

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

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

#### A. General Standard

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

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

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

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

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