

or "reduced fat turkey ham." Since the proposed product name of a substitute standardized product is intended to distinguish it from the standardized product based on its improved nutritional attribute, a nutrient content claim along with a standardized term must be used to name the substitute products in order for consumers to understand how the modified product differs from the standardized product. FSIS is proposing that only expressed nutrient content claims, i.e., claims that have been defined and are related to reductions in constituents having negative health implications, be permitted in conjunction with the standardized name, in the name of the substitute meat and poultry products provided for in this proposal. Because such products cannot be formulated under some existing regulatory standards, FSIS is proposing to allow additional flexibility for industry to manufacture meat and poultry products whose compositions has been modified to qualify for use of an expressed nutrient content claim that asserts that a constituent of a product, of health concern to some people, has been reduced in amount. Examples of the applicable nutrient content claims are: "low," "lower," "lite," "reduced," "lean," "extra lean," and "free," as defined in 9 CFR 317.313, 317.356, 317.361, 317.362, 381.413, 381.456, 381.461, and 381.462.

D. Performance Characteristics of Substitute Foods

FSIS believes that in order for a product that bears a standardized name to be considered to be accurately labeled it must not only resemble the traditional standardized meat and poultry food product but also must perform similarly to the traditional standardized products unless, the product is specifically labeled to show any significant performance usage differences it has, such as a frankfurter not being suitable for freezing. Unless this is done, consumers might assume that the substitute product could be used interchangeably with the traditional standardized food in all applications.

Therefore, in order not to mislead consumers, FSIS is proposing in 9 CFR 319.10(b) and 381.172(b) to require that a substitute standardized product that bears a standardized name have similar performance characteristics to the standardized meat and poultry food product defined in 9 CFR parts 319 and 381, subpart P for which it substitutes, except as discussed below. FSIS is proposing that the performance characteristics by which a substitute food be judged in terms of its similarity

include its physical properties (e.g., texture, cooking qualities, freezing qualities, its functional properties (e.g., body, spreadability), and shelf-life.

FSIS recognizes, however, that when a standardized product is modified so that its composition accurately supports the nutrient content claim intended to be made, it may not be possible, in all cases, to produce a substitute product that performs similarly in regard to all uses of the regulated standardized meat or poultry food product of which it is a modification. The product would be considered a substitute product allowed under this proposal if the limitation on use does not affect the fundamental nature of the product and is disclosed in labeling.

The FMIA and PPIA require that the label or labeling of a meat or poultry food product must be accurate and not misleading and that such labels and labeling must accurately disclose to consumers what they are buying when they purchase any meat and poultry food product. Information disclosing differences in use performance characteristics (e.g., cooking quality, freezing quality, spreadability of product, and shelf-life) of substitute standardized products is a fact FSIS believes should be specifically disclosed on labels of substitute products identified partially by a standardized term because without such labeling consumers would be misled about the uses the product has in comparison to the standardized product for which it substitutes. Accordingly, this information must be communicated to consumers on the product's label, or the label would be misleading, and the product would be misbranded under the FMIA and PPIA.

Therefore, the provision in proposed 9 CFR 319.10(d) and 381.172(d) that requires disclosure of material differences in uses in regard to the performance characteristics between the substitute product and the standardized product for which it is a substitute is fully consistent with FSIS statutory responsibility under the FMIA and PPIA to prevent false or misleading labeling. 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 381.413(d) (1) and (2), informing the consumer of such difference. The statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and

use, in accordance with requirements of 9 CFR 317.313(d) (1) and (2) and 381.413(d) (1) and (2).

For example, according to the provisions of this proposal, a product identified as a "fat free frankfurter" would have to meet the criteria for using the nutrient content claim "fat free" and would have to have similar performance characteristics to a "frankfurter," unless a statement of any difference(s) in uses appears on the label of the substitute frankfurter product; and if it does not, the product would be considered to be misbranded. A "frankfurter" produced according to the standard for frankfurters would be expected by consumers to have certain physical and functional characteristics, such as a "link" form, a cured pink color, a spongy texture, and the ability for refrigeration or freezing for an appropriate time period to keep the product wholesome. It would also be expected that it could be prepared in a variety of ways, i.e., by boiling, broiling, grilling, and frying.

When fat, however, in a frankfurter or another standardized product is replaced by one or more other ingredients, it may not be possible, in all cases, to produce substitute products that perform identically to the traditional standardized meat and poultry products. Successful fat reduction in meat and/or poultry products requires a firm understanding of the functions of fat in a product, i.e., to provide texture, flavor, and palatability, and how those functions can be replicated with nonfat ingredients. Fats exhibit unique physical properties in meat and poultry products, e.g., their ability to combine with protein to form emulsions and their ability to enhance tenderness. In order to make a substitute product that qualifies for a "fat free" nutrient content claim, it may be necessary to replace fat with water and binders (i.e., additives that hold water and protein) which may result in a substitute meat or poultry food product with limitations in performance related to product uses because water and binders may not provide all of the physical and functional properties related to product use that are associated with fat, e.g., ability to be stored frozen. In products such as frankfurters, the increase in moisture which may be a direct result of fat replacement, and the way water is held by binders and dispersed in the product, can lead to the formation of large ice crystals because a higher level of available moisture makes the product less stable when thawed from the frozen state, i.e., water leaks from the product. Therefore, if a "fat free frankfurter" does