

claim and standardized names, e.g., "Fat Free Ice Cream," "Low Fat Cheddar Cheese," and "Reduced Fat Egg Nog," because of allowable deviations from FDA food standards permitted by 21 CFR 130.10.

The FDA regulation requires that the performance characteristics of the substitute standardized food be similar to those of the standardized food, except as discussed below. Performance characteristics are the physical properties (e.g., the ability to freeze), flavor, functional properties (e.g., spreadability), and shelf-life (i.e., the time the product exists in a wholesome condition under acceptable handling practices) of a food. If, however, there are any significant differences in the performance characteristics of the modified version of the standardized food that materially limit the uses of the food, as compared to the uses of the standardized food, these must be disclosed on the product's labeling. For example, if a "Fat Free Cream Cheese" cannot be used in baking, that fact must be stated on the product's labeling, e.g., "not recommended for baking."

The FDA regulation also provides that the ingredients used in the substitute food product must be those ingredients provided for by the standard, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food. The FDA regulation also requires that ingredients not provided for, and ingredients used in excess of those levels provided for by the standards, must be identified by an asterisk in the ingredients statement of a product and the meaning of the asterisk must be explained immediately following the ingredients statement.

The FDA regulation facilitated new markets and new opportunities for FDA-regulated food companies to develop modified versions of standardized foods. Although 21 CFR 130.10 addressed only FDA-regulated foods, meat and poultry food manufacturers were quick to respond to the potential market for modified standardized meat and poultry products. According to the meat and poultry industries, they intensified their research and development activities in order to be able to respond to potential consumer demands for meat and poultry products with reductions in various constituents, such as fat and cholesterol, where current standards may limit the marketing of such products. Technological developments and new ingredient uses now allow the industry

to develop new meat and poultry products, including substitute standardized products with decreased amounts of fat, such as, "Fat Free Bologna."

Manufacturers of these new meat and poultry products wanted to market them without labeling them by what they considered to be pejorative terms such as "alternative," "replacement," and "substitute." The manufacturers indicated that such products were not of lesser value compared to their traditional standardized counterparts. They asserted that these products, including new lower fat products, were better and should be allowed to be identified with an appropriate nutrient content descriptor and a commonly understood standardized name that would be familiar to consumers. They requested that FSIS allow labeling for these products similar to that provided for in FDA's general standard of identity in 21 CFR 130.10 for modified standardized products.

FSIS responded to this request by issuing Policy Memo 123³ (dated January 20, 1995) as an interim policy to allow some standardized or traditional meat and poultry food products that have been formulated to reduce their fat content to enter the marketplace while appropriate regulatory actions related to the modernization of standards were developed. Policy Memo 123 allowed modified versions of cooked sausage (e.g., frankfurters), fermented sausages (e.g., pepperoni, salami) and breakfast sausage products to be identified by a nutrient content claim that reflected a reduction in fat content in conjunction with a standardized or traditional name, e.g., "Fat Free Bologna," "Low Fat Pepperoni." Policy Memo 123 included provisions for labeling which were similar to those established by FDA's general standard of identity in 21 CFR 130.10. In a prior related policy, on May 10, 1991, FSIS issued Policy Memo 121, "Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients." Policy Memo 121 allowed for such products to be named with a standardized name along with other descriptive labeling, e.g., "Low Fat Hamburger With a X% Solution of Water and Carrageenan" or "Low Fat Hamburger, Water and Carrageenan Product." Policy Memo 121 has been updated (See Policy Memo 121B, dated January 20, 1995)⁴ to reflect current

³ This paper is available for public inspection in the FSIS Docket Clerk's office.

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changes in nutrition labeling regulations.

Both Policy Memo 121B and Policy Memo 123 were issued as interim policies intended to accommodate certain lower fat substitute meat and poultry products until such time that rulemaking was completed. Both of these policy memoranda will be rescinded if provisions proposed in 9 CFR 319.10 and 381.172 become final rules.

FSIS is now, in this rulemaking, proposing to establish a general regulatory standard of identity for modified meat and poultry products which substitute for meat and poultry food products defined by a regulatory standard of identity or composition in 9 CFR parts 319 and 381, subpart P. FSIS believes that this general standard of identity will be beneficial to consumers because it will (1) assist consumers by providing for substitute versions of standardized processed meat and poultry products that have reductions of certain constituents that are of health concern to consumers, such as fat and cholesterol, and which bear accurate descriptive names that are meaningful to consumers, (2) increase regulatory flexibility and support product innovation in accord with Executive Orders 12861 and 12866 and with President Clinton's Memorandum to Heads of Departments and Agencies, entitled "Regulatory Reinvention Initiative," dated March 4, 1995, and (3) provide consumers with an informative nutrition labeling system that will parallel, to a significant extent, the nutrition food labeling initiatives of FDA. FSIS believes that this proposed general standard of identity is fully consistent with FSIS's statutory responsibilities under the FMIA and PPIA to assure that the labeling of meat and poultry products is accurate and truthful and not false or misleading. The substitute meat food and poultry food products covered by this proposal will be identified by familiar product names and will be labeled to inform consumers about their general compositional changes from standardized products by use of a nutrient content claim as part of the product's name.

IV. Discussion of Regulatory Proposal

FSIS is proposing to amend the Federal meat and poultry products inspection regulations to establish a definition and general standard of identity for modified versions of standardized meat and poultry food products, i.e., "substitute standardized products." These products will be formulated and processed with ingredients otherwise not in or in