

ingredients were designated in food standards. The standard simply provided for "safe and suitable batter and breading ingredients," without listing the names of the specific permitted ingredients. This departure from the traditional food standards concept provided manufacturers with considerably more flexibility in the selection of ingredients to be used in the food. Along with this provision, the agency also required that each such safe and suitable optional ingredient used in the food be declared on the label.

Since the establishment of this policy, the agency has revised most of its standards to provide for the use of safe and suitable ingredients, by category, that perform the needed technical effect in the food, e.g., safe and suitable emulsifiers. However, a few of the standards have not been so updated to increase flexibility in the manufacture of those foods. These standards include the standards of identity for certain cheese products (e.g., §§ 133.169, 133.173, 133.179, 133.187, and 133.188), which specify antimycotics by name (e.g., sorbic acid, potassium sorbate, sodium sorbate, calcium propionate, and sodium propionate) and the levels at which they may be used in the food, and the standards of identity for artificially sweetened fruit products (e.g., §§ 145.116, 145.126, 145.131, 145.136, 145.171, 145.176, and 145.181), which designate the specific artificial sweeteners (saccharin and sodium saccharin) that may be used.

b. *The 1990 amendments—i. Ingredient labeling.* In the 1990 amendments Congress amended the ingredient labeling provisions in section 403(i) of the act by removing the language that limited full ingredient labeling to nonstandardized foods. The 1990 amendments also amended section 403(i) to require that certified color additives be declared by their common or usual names, rather than by the collective term "colorings." The framers of the act in 1938 apparently believed that consumers would know what mandatory ingredients would be used in staple food products covered by standards of identity and, thus, only provided that the optional ingredients used in such food would need to be declared on the label. However, with advance in food product formulation and processing, the ingredients used in standardized foods in the 1990's are more varied, and many are less familiar to consumers than the ingredients that were being used in 1938. This fact, along with consumers' desire to know the nature of all ingredients used in foods, led to the amendment of section 403(i). In response, the agency amended

the food standards, as necessary, in parts 131 through 169 to require label declaration of each ingredient used in these foods (58 FR 2850 at 2876 through 2887; and 58 FR 2888 at 2890 through 2896, January 6, 1993).

ii. *The standard setting process.* The 1990 amendments removed most section 401 proceedings from the list of rulemakings in which formal rulemaking is required under section 701(e) of the act. As a result, proceedings to establish, amend, or repeal food standards are subject to the requirements of informal notice and comment rulemaking. The only exception to this change is for actions to amend or repeal standards of identity for dairy products.

iii. *Preemption.* The 1990 amendments added section 403A(a)(1) to the act (21 U.S.C. 343-1(a)(1)). Under this provision, a State may not establish or continue in effect a standard of identity for a food that is the subject of a standard of identity under section 401 of the act if the standard is not identical to the Federal standard. One of Congress' goals in passing this provision was to provide industry with some relief from State requirements that interfere with its ability to market products in all 50 States in an efficient and cost effective manner (statement of Rep. Madigan, 136 Congressional Record H12954 (October 26, 1990)). Thus, as a result of the 1990 amendments, FDA's food standards are preemptive of State standards.

iv. *Other changes.* In addition to these provisions that bear directly on food standards, Congress made a number of fundamental changes in how virtually all foods are labeled that bear directly on the issue of the continuing need for some or all food standards. The 1990 amendments require that virtually all foods bear nutrition labeling. This information, plus the full ingredient list that is now required, ensures that consumers will have vastly more information about the make-up of a particular food product than was available in 1938. This information should make it immediately apparent if a marketer is attempting to sell a debased or watered down food. Because the standards were originally intended to prevent this type of economic deception, the nutrition labeling requirement raises a question as to whether food standards are still necessary.

The 1990 amendments also provide authority for FDA to adopt regulations defining nutrient content claims, such as "reduced fat," "low fat," and "fat free" in § 101.62 (January 6, 1993, 58 FR 2302 at 2418). Having established

uniform definitions for these terms, the agency was able to establish a general definition and standard of identity in § 130.10, which permits the modification of a traditional standardized food to achieve a nutrition goal, such as a reduction in fat or calories. Such modified foods, complying with the requirements of § 130.10, may be named by the use of a nutrient content claim defined by FDA in part 101, such as "reduced fat," and a standardized term, such as "cheddar cheese" (i.e., reduced fat cheddar cheese).

This general definition and standard of identity requires that the modified food: (1) Not be nutritionally inferior to the traditional standardized food that it resembles and for which it substitutes, (2) possess performance characteristics that are similar to the reference food, (3) contain a significant amount of any mandatory ingredient that is required to be in the traditional standardized food, and (4) not contain an ingredient that is prohibited in the traditional standardized food. However, under § 130.10, safe and suitable ingredients not specifically provided for in the standard for the traditional food may be added to ensure that the modified food will not be inferior in performance characteristics (e.g., physical properties, flavor characteristics, and shelf life) when compared to those of the traditional food. This one standard (§ 130.10) has provided enormous flexibility in the manufacture of foods that deviate from the traditional standards and in providing many healthful and informatively labeled food products to consumers. It has also eliminated the need for use of complex alternative names for foods, as well as the need for the industry to request establishment of new standards or TMP's to deviate from existing standards to make new foods to meet consumers' needs and desires.

In the past, many dairy products were defined by the level of milkfat in the food. Milkfat was considered to be one of the valuable constituents in the food, and if the minimum established level for milkfat was not met in the finished food, the product was deemed to be misbranded under section 403(g) of the act and adulterated under section 402(b) of the act. However, with the increased concern about fat and cholesterol in the diet, many consumers view milkfat in some dairy products as a negative factor or a constituent to be avoided rather than one that is sought after or highly valued. Under the general standard in § 130.10, manufacturers are able to meet consumers demands for reduced fat dairy products. Many new foods, e.g.,