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FAT SUBSTITUTES: A Regulatory Perspective[1]

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INTRODUCTION

The term *fat substitute* implies that a substance, when used as a replacement for the traditional fat contained in a food, has certain desirable physical or organoleptic properties of the fat that it replaces while lacking undesirable properties of this fat. Usually, a fat substitute is not a fat; however, the term also has been used to refer to those lipids that, because of their structure or elevated melting point, are not digestible or only partially digestible when consumed by humans.

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Fats contribute favorably to the texture, flavor, and appearance of foods. Brief descriptions of the effects of fat on these three properties follow. A full description of these organoleptic attributes and their importance to perceived food quality as indicated by consumer acceptance would require substantial discussion and is not the purpose of this article; several reviews serve that need (8–10, 19). In-depth knowledge of the desirable properties of fats is necessary, however, for the successful development and use of fat substitutes (19). Fats differ substantially with regard to their effects on the organoleptic properties of foods, but the success of a fat substitute in providing desired functional properties largely dictates its potential use.

The amount of fat present in a food and the physical properties of that fat may determine many of the characteristics of the food. For example, the amount of fat in a food and the melting point of the fat will greatly affect the texture of the food. The texture of a food, in turn, helps determine "mouth feel" and other organoleptic characteristics that contribute to food acceptance. Fat content also affects the structure and color of a food. Finally, fats are important in determining the flavor or aromatic characteristics of some foods, because many flavor or aromatic components are fat-soluble. The effects of some flavor components may also be modified by the type and quantity of fat in the food.

The major impetus for the development of fat substitutes is that the nutritional properties of fat contribute to excessive energy intake and the development of disease. Not only do fats contain more than twice as many calories as other macronutrients in foods, but the dietary intake of total fat and specific fatty acids and lipids, such as cholesterol, is now considered a risk factor for some degenerative diseases. The Surgeon General's Report on Nutrition and Health (15), the National Academy of Sciences' Report on Diet and Health (13), and the National Cholesterol Education Program's Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (12) review these relationships and provide a comprehensive consensus on diet-disease relationships. The development of fat substitutes is in part a market response to the perceived health benefits of lower consumption of fat (11).

In theory, replacement of fat with fat substitutes that reduce calorie content and lower exposure to specific lipids that augment the risk of degenerative diseases should contribute to the nutritional quality of the food supply. In practical terms, the validity of this hypothesis depends on (*a*) the physical and biochemical properties of the fat substitutes, (*b*) the extent to which such fat substitutes replace fat in the diets of those population segments for which a reduction in fat intake would be beneficial while not affecting the fat intake of those segments of the population that may not require reduced fat intake, and (*c*) the extent to which their use does not result in adverse effects such as nutritional deficiencies, excesses, or imbalances.

Also, when considering the potential health effects of fat substitutes, it is important to note that specific fats (i.e. fatty acids) have specific metabolic effects that vary according to the ratio of specific dietary fats, genetic predisposition, developmental stage, or disease condition. These metabolic effects influence hepatic cholesterol metabolism and the many biological functions that are altered by eicosanoid production. Cell membrane function, which is altered by lipid components, may also be affected. Therefore, the potential influence of fat substitutes on dietary lipid intake and any relationship to risk of developing chronic diseases is not easily assessed.

Historically, dietary fats and oils have been considered a primary source of energy without regard to the health effects of their specific complement of fatty acids and sterols. Economic considerations related to availability, cost, and technical function in a food product largely determined the use of a fat or oil. Many processing techniques, such as hydrogenation and restructuring of lipids, have been developed to use fats and oils from a wide variety of sources for many technical and functional effects. The wide application of fat-processing technology coupled with the use of "and/or" labeling has provided flexibility in marketing similar products with different ingredient sources and fat composition. And/or labeling refers to the regulatory provision in ingredient labeling that allows a manufacturer to cite the use of alternate fats without requiring a label change.

Traditional safety concerns have been largely limited to standard toxic endpoints, such as myocarditis associated with the high erucic acid content in rapeseed oils. In some cases, standards of identity, which defined the composition of products, governed the specific lipid composition of items such as butter, ice cream, and certain cheeses. When alternative fat sources were substituted in standardized products, they were labeled pejoratively as imitation products. If a standardized product was manufactured with a substitute fat (e.g. ice cream with partially hydrogenated soybean oil), then the product was considered adulterated and it was prevented from being marketed. In response to the recommendations of the White House Conference on Food, Nutrition, and Health (18) the Food and Drug Administration (FDA) published regulations that permitted these foods to be called substitutes provided such foods were not nutritionally inferior to the traditional food (17). The regulatory requirements for nutritional equivalency are that the substitute food must have equal or greater amounts of all nutrients that are contained in the traditional food at levels of two percent or more of the US RDA.

In recent years the marketing of fats has changed dramatically. So-called "heart-healthy" fats and the potential health benefits of diets with altered lipid composition are an active area for research.

The FDA is now engaged in extensive rule-making to modify food labeling according to the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA) (14). Rule-making, as authorized by the Procedures Act,

provides for regulations to implement the requirements of a law. The procedures involve publishing a proposal in the *Federal Register* for the purpose of receiving comment by individuals, industry, or other interested groups; reviewing comments and considering their merits in fulfilling the intent of the law; and publishing a final regulation, which has the force of law. Under special circumstances, any person who will be adversely affected by a final regulation may file objections with the Secretary of the Department of Health and Human Services and request a public hearing. Such action, under some circumstances, can cause a regulation to be stayed until final action on such objections is taken, including the holding of a hearing by an administrative law judge. Under these procedures, proposals for fat labeling were issued by the FDA in November 1991. These proposals, which would allow health claims for fats, are discussed later in this chapter.

SAFETY REQUIREMENTS FOR FOODS

The Federal Food, Drug, and Cosmetic (FD&C) Act (2) and its implementing regulations require that foods be inherently safe to be offered to the public for sale. The 1938 FD&C Act prohibits traffic in food that is injurious to health and prohibits the addition of poisons to food.

The 1958 Food Additive Amendment to the FD&C Act established a petition procedure for premarket approval of food additives. The amendment stipulates that a food is deemed to be adulterated if it contains any unsafe food additive and specifies that an unapproved food additive is unsafe. The amendment also describes the type of data necessary to evaluate the safety of a food additive, and it provides criteria for determining the safety and the suitability of the food additive for approval. Of particular note is the need to consider:

> (*a*) The probable consumption of the additive and any substance formed in the food because of the use of the additive; (*b*) the cumulative effect of such additive in the diet . . ., taking into account any chemically or pharmacologically related substance or substances in such diet; and (*c*) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

The amendment also contains the Delaney Clause, which prohibits the approval of any food additive that is found to induce cancer when ingested by humans or animals. It provides administrative procedures for premarket evaluation and approval of a food additive and for judicial review of agency decisions. These procedures require that all critical data supporting an agency action are made publically available.

The Food Additive Amendment establishes that a food additive must be shown to be safe before it can be added to food; it stipulates that a food

additive must achieve some physical or functional effect in food; and it establishes criteria for relative safety rather than for absolute safety and directs the agency to set tolerance levels for use of a food additive. Notably absent from criteria is any mention of a potential health benefit from an additive in food.

Confusion in marketing products with a novel composition may occur when safety is determined by independent scientific experts outside the FDA. The 1958 Food Additive Amendment to the FD&C Act establishes, as part of the definition of a food additive, a category for substances that are generally recognized as safe (GRAS) for their intended use in food. General recognition of an additive's safety is accorded by "experts qualified by scientific training and experience to evaluate its safety." The general recognition of safety may be founded either on "experience based on common use in food" before the amendment was introduced in 1958 or on "scientific procedures," which are essentially the same as the FDA uses in approving a new food additive. New fat substitutes that are made by processing of common food components require a determination of the GRAS status of their new uses. To establish a food use as GRAS, the FDA must carefully review previous uses and data publically available in the scientific literature. An independent GRAS determination cannot be based on data that is not publically available and cannot be supported by usage and experimental data when each alone would be inadequate to document safety of use. When an independent GRAS determination is made, the full responsibility for the safety of the food product resides with the manufacturer. The FDA may challenge such a determination or may affirm GRAS status using rule-making procedures.

Approving new fat substitutes and meeting the requirements of the food additive amendment may involve complex decisions. Often it is difficult to estimate the probable consumption and the cumulative effect on the diet that new fat substitutes and related substances may have. Application of a significant safety factor extrapolated from animal data may not be possible. Approaches used to prove the safety of fat substitutes may differ from those used for most food ingredients because such substances potentially may constitute a large portion of the diet of an individual. In some diets 40% of the calories are from fat. Such diets consist of more than 20% fat on a weight basis. If half of the fat in such a diet were to be replaced by a fat substitute, then the diet would consist of more than 10% of the fat substitute by weight. At such high consumption, it would be impossible to achieve a large safety factor by conducting only traditional toxicology studies with animals.

A large safety factor has been the standard for most new food additive approvals. Thus, to establish use with a lesser safety factor, one would need to establish safety with data from clinical trials in which human subjects consume levels of the fat substitute at and preferably above the highest

expected exposure level to provide a margin of safety. Data from such studies must confirm and be consistent with safety data derived from animal studies. When inconsistencies occur, the data from the human study must demonstrate a high level of safety when compared with data from animal studies.

When using data from animal studies, one must consider whether an animal model is appropriate for determining health effects that are relevant to humans. Many traditional animal models are not interpretable in terms of human health effects causally related to altered gastrointestinal physiology or nutrient availability because of significant differences between animal and human dietary tolerances, nutrient requirements, absorption mechanisms, or effects on metabolism. The use of animal models to estimate adverse health effects of novel fat substitutes in human subpopulations with a potentially increased risk typically has not been possible because appropriate models have not been identified.

The FD&C Act [Section 409(i)] provides the FDA with authority to issue regulations to allow human investigational testing of unapproved food additives, but, to date, such regulations have not been proposed or promulgated. The development of regulations in this area could facilitate the evaluation of novel macronutrient replacement products by providing a uniform approach to human clinical testing for food additive safety evaluations.

New issues that may arise concerning the safety of use of fat substitutes include the theoretical long-term influences of novel macro food ingredients on nutritional status or on gastrointestinal physiology. A number of these issues may not be practical to investigate before marketing a product. Often, no surrogate measures can predict long-term effects on health outcome. Thus, in some cases it may be desirable to consider some form of postmarket surveillance to confirm the safety of long-term use. However, surveillance would be difficult to implement for food additives unless their use was very limited and surveillance was actively pursued. Also, the endpoints for safety evaluation would need to be anticipated and relatively discrete. Complex effects, such as those caused by multiple agents or those that result from interactions between dietary ingredients over time, are less likely to be uncovered by a postmarket surveillance system, particularly one that is passive.

Exposure Assessment

An important step in assuring the safety of new food ingredients, such as fat substitutes, is the calculation of the level of exposure to an individual if the product is approved for use. This step is frequently referred to as exposure assessment. A very simplified approach to exposure assessment is to estimate the amount of a new product that could be placed in the food supply for specific purposes and to divide that amount by the exposed population. This

method of estimating exposure is unacceptable for safety assessments, as it results in unrealistically low individual exposures. It is necessary to use an exposure assessment model that is based on food consumption data from national probability surveys. These surveys indicate both the frequency of consumption and the serving size of individual foods.

The exposure assessment model used by the FDA and other regulatory agencies permits estimation of the fraction of the population that would consume more than a given amount of the product under evaluation. Usually, regulatory agencies require that safety assessments be based on exposure assessments made for the 90th or 95th percentile level of consumption by individuals who use the product.

When estimated exposure levels prove to be higher than safety data would support, they can be lowered by limiting product content or the categories of food in which the product may be used. In such cases, approval of the product may be contingent on the manufacturer agreeing to provide actual exposure data obtained through postmarket surveillance. Postmarket exposure surveillance, as opposed to safety surveillance, can be effectively conducted.

For fat substitutes that are reduced in caloric content, one must also consider some expanded use for caloric compensation. In addition, where such ingredients will have preferential markets and will be selected for high use levels (e.g. for weight reduction programs or for individuals requiring diets low in saturated fat to lower the risk of coronary heart disease), such use must be taken into account when evaluating safety. In this regard, exposure assessments for fat substitutes cannot rely solely on exposures to products that they are replacing.

Approaches to Safety Testing

To assess the safety of new food ingredients such as fat substitutes, one must develop tests that can demonstrate that the substance is safe. Procedures considered appropriate for testing new products are outlined in the FDA monograph "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food," referred to as the Redbook (4). It is not our purpose here to discuss the detailed data requirements for approval of new ingredients. In the case of fat substitutes, however, discussion of some unusual nutritional considerations is appropriate.

As indicated above, a fat substitute could become a significant portion of the diet. If the substance is poorly digested or is not digested at all, the absorption of essential nutrients by an individual may be decreased if the substance (*a*) absorbs the nutrients on its surface (in the case of a fiber or fiber-like substance), (*b*) dissolves the nutrients (in the case of substances with lipid-like characteristics), or (*c*) alters the function of the digestive tract (e.g. alters transit times or microbial ecology). Another nutrition concern with

nondigestible fat substitutes is the effect on the total consumption of nutrients. Consideration must be given to the replacement of those nutrients associated with fats, such as essential fatty acids and fat-soluble vitamins. If nutrient interferences can occur, the FDA must have data to indicate that they are trivial in terms of public health or that they can be accurately estimated and safely corrected by fortifying products that contain the substitute.

There could also be an increase in the consumption of nutrients, such as proteins and some carbohydrates, that may be present in digestible form as components of fat substitutes. In this regard, current levels of dietary protein in the United States are high, and further increases are not recommended (13).

The potential effect of fat substitutes on the microflora in the gastrointestinal tract must also be considered. Some of these microflora are associated with the synthesis of nutrients, such as vitamin K, biotin, and volatile fatty acids. Alterations could also result in altered pathogenicity or long-term effects on bowel health.

General health concerns and populations with potentially increased risk must be considered in the approval process for new food ingredients when safety is predicted on nonabsorption. Consider, for example, a new ingredient that is not absorbed in healthy animals, does not affect the absorption or synthesis of essential nutrients by intestinal bacteria, does not have any toxic effect on the gastrointestinal tract, but does accumulate in body tissues or shows toxic effects when it is injected into animals. It may then be necessary to demonstrate that the ingredient would not cross the gastrointestinal tract wall in the event that the epithelial tissues were compromised by a disease or injury that is likely to occur in a subpopulation.

Ingredients that are unmodified during transit through the gastrointestinal tract may cause or contribute to the formation of intestinal blockage. Substances that have a tendency to clump when changes in hydration or pH occur are of special concern.

The laxative effects of ingredients that are not digested may also be of concern. The laxative effects of nondigested substances among individuals may vary. Some individuals have a low tolerance for nondigested substances, which results in frequent defecation or anal leakage. In either situation, a reduction in absorption of nutrients may occur. Generally, most adults can recognize an association between the occurrence of the laxation and the consumption of the nondigested ingredient, and they avoid such products. However, some adults and many children cannot make the association. Under such circumstances, a limitation on the maximum exposure or special labeling may be necessary.

The safety evaluation of food additives is based on a projected effect on the general population. Specific effects in subpopulations are usually addressed through the provision of appropriate label information that can (but usually

does not) consist of warning statements. In the case of novel fat substitutes, it may be difficult to predict the effect on subpopulations. Additional clinical trials may be necessary to define safety of use in subgroups at increased risk.

Safety and Nutritional Benefits of Prominent Fat Substitutes

In assessing the safety and long-term health effects of fat substitutes, one usually considers the origin of the substance and the degree of processing. In reality, each product must be evaluated on the basis of data on its chemistry, metabolism, and stability during processing and storage rather than on its origin. For discussion, however, it is convenient to group fat substitutes into categories based on their origins: (*a*) fat substitutes derived from traditional food sources, (*b*) fat substitutes produced through chemical synthesis, and (*c*) fat substitutes derived from novel food sources.

FAT SUBSTITUTES FROM TRADITIONAL FOOD SOURCES

The fat substitutes derived from traditional food sources are primarily carbohydrates, proteins, or combinations of both. Gums such as alginates, guar, carrageenan, and xanthan are widely used in substitute cream toppings and certain candies. Proteins such as gelatin or whey have often been used to provide stability and improve mouth feel. Although these gums have been used safely for some time in limited amounts, assessment of expanded use of these substances has in many cases not been made nor has a recent exposure assessment been made for consumers of these products. In addition to gums, several water-soluble bulking agents derived from hemicellulose and other soluble fibers may be used to replace some of the fat that is traditionally added to foods. Although many of these substances have been affirmed as GRAS for functional uses, they have not been assessed for safety of expanded use for the purpose of replacing macronutrients, such as fat. Responsibility for the safety of increased use of these products as fat substitutes rests with the manufacturers. The FDA will take action against such expanded uses when it has reason to believe that such uses are unsafe; however, expanded uses may occur without the agency's knowledge.

A number of ingredients have been derived from various sources of starches, such as potatoes, tapioca, and corn (1, 8, 9). These ingredients are derived through acid or enzymatic hydrolysis and consist of low molecular weight starches, dextrins, and maltodextrins that are readily digestible. These ingredients have been used in a variety of foods, including luncheon meats, salad dressings, frozen desserts, table spreads, dips, baked goods, and confections. Frequently, a specific ingredient can be used successfully in only a limited range of foods. High water-holding capacity and film-forming

capacities enable these products to replace a substantial amount of fat in foods. These carbohydrates are generally considered safe and can be used at moderate levels in the diet.

More recently, proteins have been microparticulated under carefully controlled conditions to form particles smaller than 2 μm. These protein particles can bind with water at the rate of one part protein to two parts water by weight, thus yielding a product with one third of the caloric content of protein by weight. This hydrated product has excellent mouth feel and is particularly useful for frozen or refrigerated products, but it breaks down with thermal processing and thus cannot be used for frying or baking. Because the proteins are not altered chemically, they are digested and metabolized like ordinary protein. The FDA determined that use of the microparticulated proteins was GRAS for use in reduced calorie frozen desserts (6). By limiting the use of these products to certain categories of food, the increase in protein added to the diet of the 90th percentile consumer can be kept within a prudent range.

FAT SUBSTITUTES PRODUCED BY CHEMICAL SYNTHESIS

Fat substitutes that are derived through chemical synthesis are designed to closely mimic the properties of traditional fats, except that they are partially or totally undigested. The processes associated with the synthesis of these fat substitutes range from routine hydrogenation to more complex synthesis involving esterification and condensation. Polydextrose, a polymer made from glucose, is known as a reduced calorie, partially digestible bulking agent but also has been promoted as a fat substitute. Polydextrose is made by a high-temperature polymerization process that provides a number of glycosidic bonds in a 1–6 linkage, similar to the linkage that occurs in dietary fiber. Polydextrose was approved by the FDA in 1981 for use in products in eight food categories (10). Use of polydextrose in some of the products in these eight categories results in substantial reductions in fat. The categories include confections, frostings, salad dressings, and frozen dairy desserts. For these products and other approved uses, there are no limits on the amount of polydextrose that may be used. If a single serving of food contains more than 15 g of polydextrose, however, a statement on the label must be included to advise consumers that a laxative effect may be caused by excessive consumption of the product.

Data submitted to the FDA on the metabolism of polydextrose indicate that only one fourth of the product is absorbed by humans. Therefore, the agency has authorized the use of the value of 1 calorie per gram for calorie calculations in conjunction with nutrition labeling and nutrition claims. Perhaps the

most important aspect of polydextrose from a nutrition perspective is the apparent lack of any effect on the absorption or metabolism of essential nutrients. The basic carbohydrate structure of polydextrose and its solubility in aqueous media reduce the probability that nutrients will be bound to the surface of the molecule.

Many fat substitutes derived through chemical synthesis are altered fats. For example, several attempts have been made to modify triglycerides to prevent or decrease the hydrolytic action of human lipase. One approach is to form a triglyceride composed of long-chain saturated fatty acids. Such triglycerides can be formed either by hydrogenating triglycerides containing long-chain unsaturated fats or through transesterification, with long-chain saturated fatty acids as the starting material. The resulting fats have high melting points, and they consequently pass through the gastrointestinal system mostly undigested (16). When significant amounts of high melting point fats are consumed, individuals may experience severe gastrointestinal disturbances and frequent defecation with nonformed stools. Another approach is to modify the ester linkage of a triglyceride, in a manner which would block the normal action of lipases because of steric hindrance. Whether the reduced absorption of either high melting point triglycerides or sterically modified triglycerides promotes reduced absorption of fat-soluble vitamins or other nutrients is not known.

The most intense research on the development of fat substitutes during the last two decades has been with carbohydrate fatty acid esters. These compounds are easy to synthesize by transesterification, with chemically active fatty acid forms, such as anhydrides, or by other organic chemistry techniques. By using a variety of fatty acids and carbohydrates, one can produce products with a wide range of physical and biological properties. The most investigated carbohydrate fatty acid esters for use as fat substitutes are derivatized monosaccharides and disaccharides.

The Procter and Gamble Company has petitioned the FDA for a food additive approval of an octa-fatty acid ester of sucrose, called sucrose polyester (SPE) (7). Early animal research showed that SPE was not hydrolyzed and there was no evidence of absorption, but early human testing revealed a problem of anal leakage. Extensive research on this product has improved its functional properties and eliminated anal leakage.

Extensive testing in animals and humans showed, however, that consumption of SPE lowered the absorption of some fat-soluble vitamins from the diet. Furthermore, at least for vitamin E, prolonged use of SPE has a negative effect on the body stores (7). Research has shown that vitamin supplements can be effective in maintaining animal body stores when the level of SPE consumption is maintained within certain limits. Data from clinical studies involving humans are currently being obtained and evaluated.

Another concern with SPE has been the absorption of lipophilic drugs. Preliminary data have been obtained through clinical studies on the most commonly used lipophilic drugs. At planned levels of use, no reductions in serum drug levels were observed. Should SPE be approved, however, drug manufacturers may have to perform tests on a broad range of current and future drugs to assure that absorption will not affect treatment.

The concern about substances such as SPE crossing the intestinal mucosa when compromised by disease or injury is being addressed. Researchers have shown that SPE injected into animals was accumulated primarily in the liver and was excreted slowly into the bile (7).

Other concepts for the development of fat substitutes through chemical synthesis have been proposed, including esters of polycarboxylic acids and the conversion of ester linkages of triglycerides to ethers. Although limited animal research has been reported for such fat substitutes, the approval of these products for human use is probably years away.

FATS DERIVED FROM NOVEL SOURCES

There has long been an interest in naturally occurring lipids that are partially or completely nondigested. Considerable research has been conducted on paraffins and mineral oils. In addition to promoting frequent defecations and anal leakage, these substances may be unsafe. Evidence indicates that consumption of mineral oils causes a decrease in absorption of fat-soluble vitamins because these vitamins dissolve in such oils. Furthermore, there is some evidence that mineral oils may be absorbed in small amounts and accumulate in tissues.

Oils from novel plant sources have also generated interest as potential fat substitutes. One such fat is jojoba oil. Jojoba oil is poorly digested and therefore may lower caloric intake, but little is known about its toxicological effects. Early indications are that its functional qualities in foods are marginally useful (9).

TOTAL DIET PERSPECTIVE

The FDA must maintain the safety and nutritional adequacy of the food supply when approving new food additives or affirming uses of ingredients as GRAS. Part of the strategy for carrying out this mission must be to maintain a total diet perspective. In an environment in which multiple new fat substitutes are being reviewed, the FDA must consider the cumulative effects that the substitutes may have. The combination of such substances may have significant additive or interactive effects on nutrient bioavailability, gastrointestinal tract disturbances, or general health. The existence of reduced or calorie-free

carbohydrate substitutes must also be considered. Theoretically, the approval of nondigestible fat and carbohydrate substitutes could result in the production of a number of nonnutrient foods, which, if incorporated into an individual's diet, could have serious health consequences (5).

To make informed decisions, the FDA needs data that are sometimes difficult to obtain. To protect proprietary information, the agency frequently cannot require manufacturers to account for other products also being reviewed for approval. The alternatives are to obtain needed data through in-house research or to restrict initial approval to levels that are consistent with all existing data.

LABELING OF FOOD CONTAINING FAT SUBSTITUTES

With the enactment of the Nutrition Labeling and Education Act (NLEA) of 1990 (14), the labeling of all foods is subject to new requirements. Nutrition labeling will be required on virtually all packaged foods except those that are not a meaningful source of nutrients and those produced by small businesses. The NLEA requires that nutrition labels include total calories and the amounts of total fat, saturated fat, protein, carbohydrates, and fiber. The new law also requires that all foods have ingredient statements and that claims for nutrient content and claims for diet-disease relationships be defined by regulation.

In response to the new law, the FDA has proposed to define nutrient content claims such as fat free, low fat, and reduced fat. Proposals have also been published to permit health claims for a relationship between the level of dietary fats and cardiovascular disease, as well as for a relationship between the level of dietary fats and cancer.

Although labeling regulations do not require a specific listing of fat substitutes or the nutrition panel, the amounts of fat substitutes added to foods will affect labeling information. Fat substitutes, like all other ingredients, must be listed in order of predominance in the list of ingredients. The number of calories listed in the nutrition label must equal the digestible calories contained in a serving of food. In the case of a nondigestible ingredient, the manufacturer must have data to demonstrate the level of digestible calories (e.g. polydextrose has 1 calorie per gram).

The amounts of nondigestible lipid substances would not be included in total fats, just as nondigestible carbohydrates are not included in total carbohydrates. Most nondigestible carbohydrates will, however, be included as part of the total dietary fiber. In this regard, the physiological effects of these substitutes are not known. The use of fat substitutes may qualify a food for the label of fat free, low fat, or reduced fat, provided that the product complies with established definitions. Similarly, reductions in total fat or saturated fat made possible by the use of fat substitutes may qualify a product to be labeled with an appropriate health claim.

SUMMARY

Fat substitutes, in theory, may provide special health benefits to certain population segments. The most probable benefits are a reduction in total fat intake and a subsequent reduction in intake of calories from fat. Whether individuals who consume high intakes of fat substitutes that are partially or totally nondigestible also benefit from lower calorie intake on a long-term basis is unknown. It is likely that many individuals will compensate by increasing total food intake to maintain calorie intake.

Consumption of fat substitutes presents nutrition problems. Those fat substitutes that are partially or totally nondigested may reduce the bioavailability of other nutrients. Similarly, fat substitutes may have adverse effects on normal gastrointestinal tract function or intestinal tract flora.

Unlike other functional food additives, fat substitutes can make up a significant portion of the total diet. For this reason, traditional safety factors cannot be applied. Consequently, more reliance on data from clinical studies involving human subjects and requirements for postmarket surveillance will be necessary as part of the approval process.

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