

conditions of use as are customary or usual (see § 1.21 (21 CFR 1.21)). Thus, the omission of certain material facts from the label or labeling of a food causes the product to be misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n).

In general, the agency believes the concept of "material fact" is one that must be applied on a case-by-case basis. The agency has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product. For example, although protein products intended for use in weight reduction are not inherently unsafe, FDA requires a warning statement for such products that states, in part, that very low calorie protein diets may cause serious illness or death. Another example of required information is the use of the term "milk derivative" following the ingredient declaration of sodium caseinate when used in a product labeled "non dairy" (21 CFR 101.4(d)).¹

Consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know—and the agency believes is material information that the reasonable consumer should know—the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and

the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat is still a "material fact" for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers "to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet" (section 2(b)(1)(A) of Public Law 101–535). Further, foods in which *trans* fat has replaced saturated fat would appear to be heart healthy based on the saturated fat grams listed on the nutrition facts panel, when, in fact, such foods may not be heart healthy due to the large contribution of *trans* fat to the total fat content. Consumers would be misled without having *trans* fat information available on the label. Thus, for the reasons set forth previously, FDA concludes that it is acting within its statutory authority under the act to require *trans* fat labeling.

Moreover, Congress provided the agency with the express authority to add to the list of nutrients on the label under section 403(q)(2)(A) of the act. As stated in section V.A of this document, section 403(q)(2)(A) gives FDA the authority to require that information on additional nutrients be included in nutrition labels if FDA determines that providing such information will assist consumers to maintain healthy dietary practices. Section IV of this document provides ample evidence of the heart unhealthy effects from consumption of *trans* fat over a range of intakes, information the agency believes is material information that the reasonable consumer should know. When scientific evidence supports such labeling, the agency has discretion to determine whether to require the addition of a particular nutrient to the label of food products. Thus, the agency is well within its statutory authority for requiring mandatory labeling of *trans* fat and is not limited to requiring such information only when certain claims are made or only when other fats are listed on the label.

Further, the agency disagrees with the comments that assert that mandatory *trans* fat labeling would not assist consumers to maintain healthy dietary practices, unless the label also carries a nutrient content or health claim or

information about other fats. The agency also disagrees with comments suggesting that there is no basis for concluding any health benefit can be expected from disclosure of *trans* fat if foods contain a trivial amount of *trans* fat or if *trans* fat is not present in amounts that have not been clinically shown to adversely affect human health.

The agency is exercising the discretion that Congress gave it in the 1990 amendments to include *trans* fat as a mandatory nutrient in food labeling, based on the state of the scientific evidence on the increased LDL–C levels from intake of *trans* fat (see section IV of this document). The scheme that Congress established would require all mandatory nutrients be listed on the food label, including those that the agency determines are necessary under section 403(q)(2)(A) of the act. Congress wanted one uniform statutory scheme for food labeling and discussed the importance of maintaining consistency in the format and content of the food label to "help all consumers to better understand and improve their eating habits by providing uniform information in a coherent and understandable format." (136 Cong. Rec. S 16607 at 16609 (statement of Senator Metzenbaum)). The statute does not require other mandatory nutrients to be listed, for example, saturated fat, only when monounsaturated and polyunsaturated fat are voluntarily listed. Mandatory nutrients are listed for each food that bears a nutrition facts panel. Food that bears a nutrition label must contain certain required nutrients as part of that label to not be misbranded.

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. Consumers would have information on the amount of *trans* fat in a product, along with other information about the amount of saturated fat and cholesterol. Consumers could use information about all three fats, not just saturated fat and

¹ FDA's regulation regarding the failure to reveal material facts (§ 1.21) states that "affirmative disclosure of material facts * * * may be required, among other appropriate regulatory procedures, by * * * regulations in this chapter promulgated pursuant to section 701(a) of the act; or direct court enforcement action (emphasis added)." Thus, establishing a requirement for mandatory *trans* fat labeling is consistent with § 1.21.