Some Food and Drug Administration perspectives of fat and fatty acids\textsuperscript{1,2}

\textit{F Edward Scarbrough}

\textbf{ABSTRACT} Because of public health concerns about the amount of fat in the American diet, the Food and Drug Administration and the US Department of Agriculture have emphasized use of the recently reformed food label to inform consumers about the fat and fatty acid contents of foods. The health effects of specific fatty acids continue to be the subject of much research, discussion, and debate. Issues that must be addressed to further improve the communication effectiveness of the food label include health effects of n–3 and n–6 fatty acids; appropriate labeling of trans fatty acids, stearic acid, and other non-cholesterol-raising fatty acids; partially absorbed fats; and label claims, especially health claims, for specific fatty acids and fatty acids of biotechnologically altered foods. \textit{Am J Clin Nutr} 1997;65(suppl):1578S–80S.

\textbf{KEY WORDS} Food labeling, Food and Drug Administration, US Department of Agriculture, n–3 fatty acid, n–6 fatty acid, fat, health claim, trans fatty acid, stearic acid

\textbf{CURRENT SITUATION}

One of the motivating forces behind the passage of the Nutrition Labeling and Education Act of 1990 (1) was widespread concern about the amount of fat in the American diet because diseases such as heart disease, cancer, and obesity have been linked to the consumption of excess fat (2, 3). From the beginning of the current food label reform initiative, the Food and Drug Administration (FDA) and the Food and Safety Inspection Service (FSIS) of the US Department of Agriculture have contended with the question of how best to inform consumers about the fat content of food in a way that is most relevant to public health concerns. Much of this deliberation centered around the definitions that should be used for labeling, that is, whether fatty acids should be grouped by their chemical structure or by some physiologic or metabolic endpoint. The agencies determined that chemical definitions should be used, in part because the health effects of specific fatty acids had not been definitively determined and were still the subject of much research, discussion, and debate. This remains the case.

Nutrition labeling is now on virtually all processed, packaged foods on the grocery shelf. Near the top of the nutrition facts panel is information on fat. Every label must list the amount of total fat and saturated fat per serving. \textit{Total fat} is defined as total lipid fatty acids, “expressed as triglycerides.” \textit{Saturated fat} is defined as the sum of all fatty acids containing no double bonds. A manufacturer may voluntarily list the amounts of monounsaturated fat and polyunsaturated fat found in a serving. \textit{Monounsaturated fat} is defined as the sum of all cis-monounsaturated fatty acids and \textit{polyunsaturated fat} is defined as cis,cis-methylene-interrupted polyunsaturated fatty acids. Currently, the FDA allows no other fatty acids or groupings of fatty acids to be listed in the nutrition facts panel. Furthermore, the FDA allows no claims about specific fatty acids or groups of fatty acids anywhere on the label.

The FSIS does permit the voluntary declaration of stearic acid content in the nutrition facts panel on meat and poultry products. This is one of several differences between FDA and FSIS labeling rules. A brief, informal survey revealed no other countries that routinely permit declarations of specific fatty acids, although Canada has recently provided for the use on some products of temporary labeling permits that address the absence of \textit{trans} fatty acids or the presence of n–3 fatty acids.

\textbf{ISSUES}

The issues surrounding fat and fatty acid labeling are not definitively settled and specific areas continue to be questioned and discussed within the FDA and the FSIS. Six such areas are n–3 and n–6 fatty acids, \textit{trans} fatty acids, stearic acid and other non-cholesterol-raising saturated fatty acids, partially absorbed fats, claims for specific fatty acids, and fatty acids of biotechnologically altered foods.

\textbf{n–3 and n–6 fatty acids}

During the development of the final labeling regulations, the FDA was urged to allow the declaration of n–3 and n–6 fatty acid contents within the nutrition panel. It was asserted that consumers need to be alerted to the dietary essentiality of these fatty acids and to the importance of consuming them in an appropriate ratio. The FDA acknowledged that it may be useful to assist interested consumers in selecting foods that provide these fatty acids and that the n–3 and n–6 labeling of vegetable oils might be particularly useful because of the wide variation in n–3 fatty acid content of vegetable oils. However, there was also a belief that currently few consumers would accurately use such information and that this additional infor-

\textsuperscript{1} From the Center for Food Safety and Applied Nutrition, US Food and Drug Administration, Washington, DC.

\textsuperscript{2} Address reprint requests to FE Scarbrough, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, 200 C Street SW (HFS-150), Washington, DC 20204. E-mail: fes@cfsan.fda.gov.

1578S

mation as part of the nutrition label would confuse consumers and hinder their understanding.

At that time the FDA also noted that in the National Academy of Science’s 10th edition of the recommended dietary allowances, the possible need to establish dietary allowances for n-6 and n-3 fatty acids was recognized (4). Such allowances have not yet been established; therefore, dietary standards appropriate for labeling have also not been determined.

The FDA has not provided for the declarations within the nutrition panel nor has it defined claims related to these fatty acids. The FDA did indicate in the final rules that there was a need to reexamine these issues in the near future. We anticipate that the Workshop on Individual Fatty Acids and Cardiovascular Disease will aid us in this reexamination. The FDA does, however, permit truthful statements about the quantitative amounts of these substances in food (eg, “Contains xx grams n-3 fatty acids”), if such statements appear outside the nutrition facts panel and do not attempt to characterize the amount of the fatty acids as either high or low or meeting any dietary recommendations.

**trans** Fatty acids

Under the labeling regulations, trans isomers are excluded from the definitions of polyunsaturated and monounsaturated fats. Although in the preamble to the final rules, the FDA acknowledged that research was continuing in this area, the FDA considered it premature to address the issue of trans fatty acid declarations on food labels. Since then a study was published that concluded that trans fatty acids raise low-density-lipoprotein (LDL) cholesterol but to a slightly lesser degree than do saturated fatty acids (5). Also, the FDA has received a citizen petition in favor of requiring that the food label declaration of saturated fat include the amount of trans fatty acids in food and establishing limits for the amount of trans fatty acids that can be present in products bearing saturated fat and cholesterol nutrient content claims.

The federal government has not yet made any final decisions concerning the labeling of trans fatty acids. The FDA is currently reviewing the recently completed studies and available food-composition data.

**Stearic acid and other non-cholesterol-raising saturated fatty acids**

Comments received by the FDA suggested that nutrition labeling regulations be established that distinguish fatty acids associated with increased blood total and LDL cholesterol from those not associated with increased cholesterol concentrations, ie, regulations that would specify “cholesterol-raising fatty acids.” The FDA did not establish such rules because the effects of most individual fatty acids on blood total and LDL cholesterol are not sufficiently defined or understood. Furthermore, the FDA is concerned that the use of such terms would be confusing to consumers.

Another approach that would allow for the differentiation of fatty acids on food labels would be to declare amounts of specific fatty acids (especially saturated fatty acids) with no references to the effects on blood cholesterol concentrations. Because stearic acid may be neutral relative to changes in blood cholesterol, there was considerable interest in allowing the declaration of stearic acid amounts in the nutrition facts panel. The FDA disallowed this declaration because other saturated fatty acids that also may not raise blood concentrations of cholesterol were not considered and because only risk factors associated with cardiovascular disease were addressed. Ongoing research in these areas indicates that this decision may need to be reexamined.

**Partially absorbed fats**

An area of interest that has come to the FDA’s attention since the publication of the final food labeling regulations is the suggestion that fat be declared on the basis of available or digestible fat. The FDA recently received a petition requesting the use of a digestibility factor in determining the quantity of fat declared on the nutrition label. This modification would permit nutrient content claims, such as “reduced fat,” to be based on the declared amount of fat. For example, there is a novel fat ingredient under consideration by the FDA that consists of structured triglycerides containing one or two long-chain fatty acids (primarily stearic) and one or two short-chain fatty acids (eg, acetic, propionic, and butyric) per molecule. If the petition to change the way fat is declared on the nutrition label is accepted, 9 g of this fat would be declared as 5 g on the food label because of a 5/9 digestibility factor.

This petition raises several important issues. First, the use of such novel fats complicates the FDA’s compliance verification. The compound is analyzed as fat with use of conventional methods. Without either knowledge of the formulation used in each food or additional analysis methods, the FDA will have difficulty in verifying a company’s claim of reduced fat. Second, the FDA regulations have no precedent for adjusting the declared quantitative amounts of a nutrient. In the case of carbohydrates, for example, insoluble fiber may be subtracted from total carbohydrates only for the purpose of calculating energy from carbohydrates. However, the amount of insoluble fiber is included in the quantitative declaration of total carbohydrates. Although availability is a consideration in determining available energy, such energy value determinations have an extensive history of research and experience on which they are based. The FDA has many as yet unanswered concerns regarding the widespread use of bioavailability in declaring nutrient quantitative amounts because the issues are inordinately complicated and quantitation depends on the form of the nutrient, the food matrix, preparation methods, and other components of the meal. Third, little information exists on the long-term health effects of these novel fats and, by extrapolation, of other novel foods and food ingredients. Dietary guidance for Americans, from all expert sources, refers only to total fat and saturated fat and does not make the distinctions that the petition is asking the FDA to make.

What would the ramifications for naturally occurring fats be if an availability approach were adopted? Several studies have shown that cocoa butter is <100% available. Would this mean that fat values in food-composition tables would have to be adjusted to account for availability and conditions with regard to matrices and preparation?

**Claims for specific fatty acids**

Particularly since the passage of the Dietary Supplement Health and Education Act (6), there have been increasing pressures on the FDA to permit the labels of conventional
foods to bear so-called structure-function claims about specific fatty acids, such as γ-linoleic acid. In most cases, the scientific evidence for these claims is preliminary and has not reached a state to be deemed a significant scientific agreement.

**Biotechnology**

Projects are already under way to create saturated-fat-free vegetable oils and to create functional replacements for the so-called tropical oils from less saturated sources. If health effects are attributed to a specific fatty acid, the obvious corollary would be to restructure conventional oils with increased amounts of that fatty acid. The FDA needs to be prepared scientifically to deal with this almost certain future.

**CONSIDERATIONS**

As we enter this brave new world of fat labeling, four points should be considered:

1) Should definitions be based on chemical structure or on physiologic endpoints? If fatty acids are to be classified according to physiologic endpoints, it may well be necessary to look beyond cardiovascular disease and consider that other potential physiologic endpoints need to be considered as factors within the equation.

2) Many studies have involved the experimentally controlled feeding of individual fatty acids or of specially structured triacylglycerols. However, people eat diets composed of a variety of foods with many different combinations of fatty acid and triacylglycerol structures. How do we accurately translate the information gained from controlled feeding studies into broader dietary advice?

3) When dietary advice and food labels become too confusing or too complicated for consumers, we run the risk of undoing what has been accomplished through public health and food labeling initiatives. In other words, we cannot allow the elegance of our advice to outdistance the consumers' comprehension and interest.

4) The food label will, by necessity, almost always lag behind the forefront of science. Changes in the label tend to occur only after the science has been well established. What is the impact of this ever-changing science and technology on updating the food label?

**REFERENCES**