

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

To Whom it May Concern:

Re: Docket Number 2003N-0076

The American Heart Association is pleased to have the opportunity to reaffirm its position on the importance of trans fatty acids in nutrition labeling. This has been confirmed by scientific studies conducted within the last decade that demonstrated both saturated fat and trans fat could raise the level of blood cholesterol, a risk factor for coronary heart disease. Trans fat raises low density cholesterol (LDL) without also raising high density cholesterol (HDL). Some investigators believe that it may also lower HDL, as opposed to saturated fat that raises HDL.

The following comments correspond to the order in which they were requested in the Food and Drug Administration's request for comment document.

1. Comment on the approach recommended in the 2003 report to estimate minimum trans fat intakes within a nutritionally adequate North American diet and use this value to establish a DV for trans fat.

The American Heart Association agrees with the use of food composition data, menu modeling, and nutritionally adequate and health-promoting diets for diverse populations as a means of estimating minimum intakes of trans fat. This approach allows for the selection of foods for a healthful eating pattern for a population diverse in age, ethnic backgrounds, and socio-economic backgrounds. It further allows for a reasonable estimate of minimum trans fat in an eating pattern without completely eliminating foods whose nutritional content outweigh the small amount of trans fat they contain, such as some peanut butters which are a good source of unsaturated fat, but may contain 1 to 2 percent partially hydrogenated oil to prevent oil separation. The resulting amount of trans fat in a 2 tablespoon serving would be negligible. Another example is spreads with plant stanol or stanol esters. They also contain partially hydrogenated oils, but they provide a LDL cholesterol lowering benefit. There are also small amounts of trans fat in beef and dairy products (trans fats are produced naturally by bacteria in the gastrointestinal tract of cattle).

2. Comment about the development of a joint DV for saturated and trans fat.

The American Heart Association supports the recommendation in the IOM/NAS 2003 report, "Dietary Reference Intakes; Guiding Principles for Nutrition Labeling and Fortification" for the development of a joint DV for saturated and trans fat.

Trans fats often exist together with saturated fat in baked goods and fast foods. The effects on blood cholesterol can be significant. Trans fats are often eaten with foods high in saturated fat' cream in coffee that accompanies the sweet roll, and the French fries served with the cheeseburger. While the configuration of a molecule of trans fat and saturated fat is different, they both can raise the level of LDL cholesterol, and this is a major risk factor for cardiovascular disease.

3. Comment about how either a DV for trans fat or a joint DV for saturated and trans fats may affect the qualifying criteria for trans fat in trans fat nutrient content claims and qualifying criteria for saturated fat and cholesterol, lean and extra lean claims and health claims that contain a message about cholesterol-raising lipids as well as disclosure and disqualifying criteria for saturated and trans fats to help consumers make healthy food choices.

The American Heart Association supports the approach that the disqualifying criteria for health claims should apply to a joint level for saturated fat and trans fat and the criteria should remain as those currently in place. Given the fact that the effects of saturated fat and trans fat in the diet are somewhat balanced in that saturated fat appears to have greater effects on LDL cholesterol than trans fat, but trans fats lower HDL cholesterol, which is protective against heart disease and saturated fat does not have this effect, there is no strong rationale for developing separate disqualifying criteria for saturated fat and trans fat. In fact, it would probably be confusing to the consumer.

4. Comment on whether a DV for trans fat or joint DV for saturated and trans fats would eliminate the necessity for considering a disclosure statement, in conjunction with nutrient or health claim, concerning levels of saturated fat, trans fat, or cholesterol in a food or a message about the role of such cholesterol raising lipids in increasing the risk of coronary heart disease.

The American Heart Association believes, that since the joint DV for saturated fat and and trans fat and the amounts of saturated fat and trans fat are shown on the nutrition label, there should be no need for a disclosure statement. The information needed by the consumer to evaluate the food for inclusion in his or her eating pattern and to compare it with another food is readily available.

5. Comment on whether a DV for trans fat or a joint DV for saturated fat and trans fat would eliminate the need for a footnote about trans fat, either alone or in combination with saturated fat and cholesterol.

The American Heart Association strongly supports the development of a joint DV for saturated fat and trans fat because this would make it possible for the simplest, most understandable message to be communicated to the public, and, thus obviate the need for a footnote which would be both confusing and virtually impossible to read.

The American Heart Association further stresses the importance of consumer education so that the full potential of trans fatty acids in nutrition labeling is realized by the consumer.