

intake was used in the regulatory impact section as one of several possible approaches for determining cost benefit ratios of *trans* fat labeling. The agency would have been remiss in evaluating the full range of possible cost/benefit relationships if it had failed to include this potential adverse effect from *trans* fatty acid intakes to CHD risk in these analyses.

The question of interpretation of LDL/HDL ratios is more difficult. For example, concurrent small changes in both LDL-C and HDL-C could result in a similar LDL/HDL ratio as would concurrent large changes in both LDL-C and HDL-C assuming the changes are in the same direction. Or, large changes in HDL-C with moderate changes in LDL-C could give similar LDL/HDL ratios as would moderate changes in HDL and small changes in LDL. However, it is likely that the magnitude of the change in the individual blood cholesterol levels is as, or more, important than is a change in the ratio of the two. Thus, interpretation of the LDL/HDL ratio is unclear and until there is evidence by which its meaning can be more precisely defined, use of this ratio requires considerable caution. However, even with these caveats, regardless of whether results are expressed as increased levels of LDL-C or as increases in LDL/HDL ratios, the conclusion is the same: *trans* fat intakes increase CHD risk.

(Comment 11) A number of comments emphasized that, in addition to HDL-C, *trans* fat has other adverse effects that may contribute to CHD risk but saturated fat does not. The comments mentioned that *trans* fat has adverse effects on various CHD risk factors including serum lipoprotein(a), serum triglycerides, insulin resistance and diabetes risk. These comments also stated that *trans* fat has adverse effects on aspects of lipid metabolism that may cause increased CHD risk, such as interference with metabolism of omega-3 fatty acids, interference with enzymes such as delta-6-desaturase, promotion of essential fatty acid insufficiency, and increase in free radical formation. Several of the comments argued that some of these CHD risk factors represent additional biological mechanisms related to *trans* fat that could account for the amount of CHD risk observed in prospective studies beyond that explained by changes in LDL-C and HDL-C.

Some comments stated that *trans* fat may have adverse effects on other health conditions, besides CHD. One of these comments requested that, in order to provide the full picture of health issues involved with *trans* fats, FDA review

trans fat effects on cancer, obesity, immunity, reproduction, development, and diabetes when publishing the final rule. Another comment characterized *trans* fatty acids as being atypical fatty acids with an insidious nature in disrupting lipid metabolism. Some comments identified potential adverse effects of *trans* fat on lowered birth weights and decreased visual acuity in infants exposed to high levels of *trans* fatty acids in utero or via breast milk. The comments suggested that FDA advise pregnant and lactating women to limit their *trans* fat intake.

FDA recognizes that the relationship of biomarkers, other than LDL-C, and to a lesser degree, HDL-C, with CHD risk is less well established and difficult to interpret. Moreover, at this time, the findings suggesting effects of *trans* fat on non-heart disease risks are preliminary. Therefore, FDA finds that its focus on LDL-C provides a sufficient basis for concluding that the labeling of *trans* fat levels in food products is warranted.

V. Nutrition Labeling of *Trans* Fats

In the November 1999 proposal, FDA proposed that when *trans* fats are present in a food, including dietary supplements, the declaration of saturated fat must include the combined quantitative amount by weight of both saturated and *trans* fats. Further, FDA proposed that when 0.5 or more grams per serving of *trans* fats are present, the declaration be followed by a symbol that refers to a footnote at the bottom of the nutrition label stating the number of grams of *trans* fat present in a serving of the product, i.e., "Includes ___ g *trans* fat." The agency also had discussed, in addition to the one proposed, several other options for declaring *trans* fat in the Nutrition Facts panel. These included: (1) Declaring the combined amount of both saturated fat and *trans* fat as "Saturated fat" without identifying the amount of *trans* fat, (2) declaring the combined amount of both saturated fat and *trans* fat as "Saturated + *trans* fats" without identifying the amount of *trans* fat, (3) declaring the combined amount of both saturated fat and *trans* fat as "Saturated + *trans* fats" with an explanatory footnote stating the amount of each fat separately, and (4) declaring the amount of *trans* fat as a separate line item under saturated fat. The agency proposed that with all of these options the term "*trans* fatty acids" and "*trans* fat" could be used interchangeably.

A. Voluntary v. Mandatory Declaration of *Trans* Fatty Acids in Nutrition Labeling

(Comment 12) The majority of the comments supported the November 1999 proposal, which required the mandatory declaration of *trans* fat in nutrition labeling when it is present in a food, including dietary supplements. An overwhelming majority of comments supporting the mandatory declaration of *trans* fat did so because of public health concerns. Some comments stated that the scientific evidence clearly demonstrates that consumption of *trans* fat contributes to increased LDL-C and, hence, increased risk of CHD. Several comments noted that consumers are increasingly aware of the relationship between dietary fat and chronic disease, especially CHD, and look to the nutrition label for information about "heart-unhealthy" fat. A few comments noted that another benefit of mandatory labeling of *trans* fat is that it may provide an incentive to manufacturers to reduce the *trans* fat content of their foods.

A few comments stated that mandatory labeling of *trans* fat was not warranted because the scientific data linking *trans* fat to CHD is weak and because the average intake of *trans* fat, estimated as 2.91 percent of energy in the proposal, is minimal. Other comments also opposed mandatory labeling stating that the effect of *trans* fat on LDL-C or CHD risk was not sufficient to establish public health risk at ordinary levels of intake.

Some comments stated that, although mandatory labeling of *trans* fat was not warranted, a requirement for label declaration of *trans* fat could be justified in certain circumstances. Several of these comments stated that required label declaration of *trans* fat was justified if it was needed to prevent the label from being misleading because of the level of *trans* fat in light of other information on the label about total fat or fatty acids. Several comments that opposed mandatory declaration of *trans* fat suggested that, in order to prevent consumer deception, *trans* fat declaration should be required when nutrient content claims or health claims are made about fatty acids or dietary cholesterol or when there is label declaration of monounsaturated and polyunsaturated fats. One comment stated that there is no evidence that *trans* fat declaration would assist consumers in following healthy dietary practices unless certain claims are made or unless monounsaturated and polyunsaturated fats are declared on the label. One comment stated that the