

included within the nutrition label.” Some of the nutrients listed are total fat, saturated fat, polyunsaturated fat (voluntary), and monounsaturated fat (voluntary). Prior to publication of this final rule *trans* fat was not included as either mandatory or voluntary, and therefore, no information about *trans* fat could have been included in the Nutrition Facts panel.

As explained in the November 1999 proposal and in section IV of this document, there is a scientifically established link between the consumption of *trans* fat and CHD. As described in table 1 of this document, for purposes of economic analysis, FDA estimated *trans* fat intake based on dietary intakes reported in a national food consumption survey. FDA estimates that average *trans* fat intake from partially hydrogenated fat is about 2.03 percent of energy, and average total *trans* fat intake, including *trans* fat of ruminant origin, is about 2.55 percent of energy. Because *trans* fat increases serum LDL-C (“bad” cholesterol), reducing *trans* fat intake reduces CHD risk. The amount of risk reduction depends on what replaces *trans* fat in the diet (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, reducing *trans* fat intake by 0.1 percent reduces CHD risk by 0.072 to 0.163 percent.¹ CHD is a common disease in the general U.S. population, with about 1.1 million heart attacks annually, 40 percent of them fatal (Ref. 134). Therefore, a small decrease in risk corresponds to a large number of heart attacks and deaths prevented. Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.05 percent), prevents approximately 600 heart attacks per year, including 200 fatal heart attacks. Preventing these heart attacks is valued at \$4.1 billion per year (present value discounted at 7 percent).

Although the effect of *trans* fat on LDL-C and CHD risk is the primary basis for *trans* fat labeling, *trans* fat may also increase CHD risk by lowering high-density lipoprotein cholesterol (HDL-C) (“good” cholesterol). In a second method for estimating the health benefits of *trans* fat labeling, the expected changes in LDL-C and HDL-C can be considered together (64 FR

62746 at 62768 to 62770). For example, as shown later in this section, each 0.1 percent of energy decrease in *trans* fat intake reduces CHD risk by 0.237 to 0.293 percent.² Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.1 percent), prevents approximately 1,200 heart attacks, including 480 fatal heart attacks, annually, valued at \$8.3 billion per year (present value discounted at 7 percent).

This final regulation is needed to amend existing regulations so that manufacturers will be able to provide important health-related information to consumers regarding the amount of *trans* fat in food products.

FDA believes that the requirements of this final rule will provide consumers with information they need so that they may consider the amount of *trans* fat in products in their food purchasing decisions. Increased consumer attention to *trans* fat content because of nutrition labeling may also provide an incentive to food manufacturers to reduce the amount of *trans* fat in their products.

B. Regulatory Alternatives

In the analysis of the proposed rule, FDA listed a number of regulatory alternatives regarding *trans* fat, including: (1) Take no new regulatory action; (2) take the proposed regulatory action; (3) propose to permit the voluntary labeling of *trans* fat and to permit *trans* fat nutrient content claims; (4) alter the proposed regulatory action—propose reporting of *trans* fat on a separate line below saturated fat; (5) alter the proposed regulatory action—propose to report *trans* fat differently than in the proposal; (6) expand the proposed regulatory action—propose “low *trans* fat” and “reduced *trans* fat” claims; (7) expand the proposed regulatory action—propose labeling at food service establishments. We evaluated these regulatory alternatives in the economic discussion of the proposed rule, although we lacked sufficient data to evaluate all of the options quantitatively. FDA received no comments on the economic discussion of these alternatives, so we do not include them in this document. In addition to the alternatives described in the proposed rule, FDA considered and

asked for comments on a proposed required footnote. Because the agency is withdrawing the proposed requirement for a footnote and intends to ask for comments in an ANPRM published elsewhere in this issue of the **Federal Register**, we will not estimate the costs and benefits of that option in this document.

C. Changes Resulting From This Rule

As stated in the analysis to the proposed rule (64 FR 62746 at 62764), to estimate the impacts of this rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

1. Changes in Existing Labeling Regulations

This final rule requires the mandatory declaration in the nutrition label of the amount of *trans* fat present in foods. According to this final rule, the amount of *trans* fat must be on a separate line immediately under the amount of saturated fat, but it will not include a % DV that is required for some of the other mandatory nutrients, such as saturated fat. These changes must be made within a period of 30 months. This change to the existing regulations will increase the information available to consumers that they can use to maintain a healthy diet. It will also change the constraints and incentives faced by producers of food.

The final rule will increase the information provided to consumers on food packages. This change in the nutrition label will reduce the cost to consumers of obtaining information on the *trans* fat content of food. FDA anticipates that, once the rule takes effect, consumers will use information on the Nutrition Facts panel to adjust their purchasing practices among foods, consistent with their consumption preferences.

The final rule will also change the incentives and constraints that food producers face in manufacturing and marketing their products. Because these provisions will not be effective until months after publication of the final rule, food manufacturers can use the time between publication of the final rule and its effective date to study the requirements of the rule and the

¹ Using Method 1 (LDL-C), described later in section IX.E, and the factors shown in tables 8 and 9 below, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.072 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat ($-0.1 \times 0.74 \times 0.7 \times 1.4 = -0.072$) and by 0.163 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat ($-0.1 \times 1.66 \times 0.7 \times 1.4 = -0.163$).

² Using Method 2 (LDL-C and HDL-C), replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.237 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat ($-0.1 \times -0.47 \times -2.5 \times 1.4 = -0.165$ and -0.072 plus $-0.165 = 0.237$) and by 0.293 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat ($-0.1 \times -0.37 \times -2.5 \times 1.4 = -0.130$ and -0.163 plus $-0.130 = -0.293$).