

10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between \$96 and \$184 million, or about \$9,300 to \$17,900 per entity.

XI. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses for rules that would cost more than \$100 million in 1 single year. The final rule qualifies as a significant rule under the statute. FDA has carried out the cost-benefit analysis in sections IX.C and IX.D of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following:

1. Future costs;
2. Particular regions, communities, or industrial sectors;
3. National productivity and economic growth;
4. Full employment and job creation; and,
5. Exports.

A. Future Costs

Most of the costs of this rule will be incurred during the compliance period. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

B. Particular Regions, Communities, or Industrial Sectors

The final rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long run increase in the costs of food production would largely be passed on to the entire population of consumers.

C. National Productivity and Economic Growth

The final rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be significant, both productivity and economic growth would be higher than in the absence of

the rule. In section IX.C.3 of this document, FDA estimated benefits from the reduction in functional disability associated with a reduction in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

D. Full Employment and Job Creation

The human resources devoted to producing certain foods would be redirected by the final rule. The final rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

E. Exports

Because the final rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the final rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain lower amounts of partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Products in Germany and certain other European countries, for example, currently use partially hydrogenated oils to a lesser degree than in the United States, so the final rule could make U.S. exports of margarine more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unreformulated products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

XII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 62746, November 17, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no

significant impact on the human environment and that an environmental impact statement is not required.

XIII. Paperwork Reduction Act

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the Nutrition Facts panel disclose information on the amounts of fat and certain fatty acids in the food product. This final rule establishes § 101.9(c)(2)(ii) to require that the Nutrition Facts panel disclose information on the amount of *trans* fat in the food product. Similarly, under the provisions of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b)(2) that specify the nutrition information that must be on the label or labeling of dietary supplements. This final rule establishes § 101.36(b)(2) (21 CFR 101.36(b)(2)) to specify that when nutrition information is declared on the label and in labeling, it must include the amount of *trans* fat.

The regulations set forth in this final rule require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows: