

is to protect the public health by providing consumers with information that will assist them in maintaining healthy dietary practices and by preventing misleading labeling by providing factual, truthful, and noncontroversial information.

Providing information to consumers about the *trans* fat content of foods on food labeling is reasonably related to the agency's interest of assisting consumers to maintain healthy dietary practices. As explained in section IV of this document, there is a relationship between the level of *trans* fat in the diet and risk of CHD. To reduce this risk, consumers need information about the level of *trans* fat in food products. The agency has evidence that consumers refer to product labels when purchasing food products and use labels to determine how much fat is in a product (Ref. 96). Thus, by requiring that *trans* fat information be on a food label, the agency will be assisting consumers in making food purchasing decisions that can result in a reduction in *trans* fat intake so that they can reduce their risk of CHD. Moreover, because the presence or absence of *trans* fat is a material fact under section 201(n) of the act, as explained earlier, mandatory labeling that provides information about the presence or absence of *trans* fat, and if present, at what levels, is a reasonable means for imparting full, factual information to consumers so that they will not be misled in purchasing decisions because they have no information about *trans* fat content and may not even be able to calculate it based on information on other fats on the label.

The agency has carefully considered the limitations imposed by the first amendment to avoid unjustified burdens and costs of food labeling where there is no genuine public health benefit from the rule that does not alleviate a harm of potential consumer deception. The agency did carefully calculate the costs and benefits of food labeling (see section IX of this document) and determined that the scope of mandatory *trans* fat labeling was in proportion to the government interest served. *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (stating that a regulation "should indicate that its proponent 'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition" (quoting *Fox*, 492 U.S. at 480)). Moreover, the agency has documented that there is a public health benefit to the final rule. To the extent that those who commented "believe that their money is not being well spent, 'does not mean

that they have first amendment complaint.'" *Glickman*, 521 U.S. at 472.

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One comment asserts that FDA must adopt regulations that are supported by the rulemaking record and that are not otherwise arbitrary and capricious in light of the statutory limitations on the agency's authority. This comment and another assert that the data do not support a basis for treating *trans* fat and saturated fat the same either chemically or for purposes of one's health, and that therefore, FDA is proposing to require food labels that provide false information. One comment said that to equate *trans* fat and saturated fat on the existing body of evidence would be arbitrary and capricious in violation of the APA. Another comment asserts that FDA did not account for legal and policy considerations that are necessary to construct an appropriate *trans* fat regulatory framework and thus, does not have a rulemaking record that satisfies the agency's burden of proof under the APA. The comment seemed to relate deficiencies in the record necessary to satisfy first amendment requirements to a failure to satisfy APA requirements. One comment asserts that the rulemaking record for FDA's proposal does not support the expansive scope of the mandatory *trans* fat labeling proposal, and therefore, fails to satisfy the requirements of the APA. The comment states that the body of scientific evidence did not establish a genuine "harm" from *trans* fat consumed at ordinary intake levels from foods that would be subject to the mandatory labeling requirements.

To the extent that comments were raising concerns about the agency going to a final rule based on including *trans* fat in the amount and % DV for saturated fat and that doing so would be the same as requiring false information on labels, those comments are now moot since the agency is requiring a separate line for labeling *trans* fat. FDA disagrees with the comment that suggests that FDA did not account for legal and policy considerations necessary to construct an appropriate *trans* fat regulatory framework, and that the rulemaking record does not support the scope of this rule. As stated previously, the agency is using the statutory framework that Congress provided in section 403(q)(2)(A) of the act to require mandatory *trans* fat labeling. Further, the agency has explained its rationale, based on the science, for why it believes that it is necessary for consumers to have information on the *trans* fat content of foods to maintain healthy dietary practices. To the extent that the

comments assert that the body of scientific evidence did not establish a "harm" from *trans* fat consumed at ordinary intake levels from foods, and thus, would preclude the agency from requiring mandatory *trans* fat labeling under the APA, the agency disagrees. The science supports adverse health effects from consumption of *trans* fat among a range of intakes that includes intakes at average intake levels among the U.S. population (see section IV of this document). That said, mandating the disclosure of this information does not require FDA to find that *trans* fatty acids actually cause CHD. In mandating the disclosure of this information, FDA need not meet the standard of proof required to establish causation in a private tort action (*Glastetter v. Novartis Pharmaceutical Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

"The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it is unfair to require an individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it * * *."

In re "Agent Orange" Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y.) 1984), *aff'd* 818 F. 2d 145 (2d Cir. 1987). In making its decision, the agency follows "the preventive perspective that agencies adopt in order to reduce public exposure to harmful substances." *Glastetter*, 252 F. 3d at 991, quoting *Hollander v. Sandoz Pharmaceuticals Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000). Accordingly, so long as we conclude that the consumer would reasonably expect this information to be disclosed and that it is scientifically justifiable to require its disclosure, we are justified in taking this action.

The agency has determined, based on this scientific evidence, that consumers need this information to maintain healthy dietary practices. Thus, the agency is not precluded under the APA, as the comment suggests, from issuing this final rule. In addition, the agency has discussed why it believes that this final rule comports with the first amendment, and thus, disagrees with the comment that suggests that because it did not meet its burdens under the first amendment, it did not satisfy the APA requirements.