

Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5662.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29517 at 29532), as part of its effort to make the food label more useful and understandable to consumers, FDA proposed standard serving sizes for 159 food product categories based on the amount of food commonly consumed per eating occasion by persons 4 years of age or older. For the category "salt, seasoning salt (e.g., garlic salt)," the agency proposed a serving size of 1 g.

On November 8, 1990, however, before FDA could issue a final rule in the serving size rulemaking, Congress passed the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This statute amended the Federal Food, Drug, and Cosmetic Act (the act) to require that virtually all foods bear nutrition information that is based on a serving size that reflects the amount of food that is customarily consumed and that is expressed in a common household measure that is appropriate to the food (section 403(q)(1)(A)(i) of the act (21 U.S.C. 343(q)(1)(A)(i))). The new law also directed FDA to adopt regulations that establish standards to define serving sizes (section 2(b)(1)(B) of the 1990 amendments (21 U.S.C. 343 note)).

In response to the new law, FDA, among other actions, issued a rep proposal on serving sizes (56 FR 60394, November 27, 1991). In that rep proposal, FDA carried forward the 1-g value for salt, although it called this amount the "reference amount customarily consumed" to reflect the requirements of the new law. FDA chose this amount based in part on its tentative determination to use weight-based amounts except in those instances in which it was demonstrably inappropriate to do so. The agency also included salt substitutes in the food category for salt and seasoning salts.

FDA received three comments on the proposed reference amount for salt (58 FR 2229 at 2260, January 6, 1993). One comment agreed with the proposed 1-g reference amount. The second comment also agreed with this amount, but it requested a voluntary declaration based on 1/4 tsp. The third comment argued that a weight-based reference amount was inappropriate for salt and requested that a volume-based reference amount be established. However, this comment did not include any data to support its assertions. Thus, in its final rule on

serving sizes, FDA concluded that, in the absence of evidence to support a different reference amount, 1 g was the appropriate reference amount for "salt, salt substitutes, seasoning salts (e.g., garlic salt)" (58 FR 2229 at 2297).

II. The Petition

On November 19, 1993, FDA received a petition from Akzo Salt, Inc., that requested that FDA change the reference amount for salt from 1 g to a density-adjusted reference amount to be listed as "x g-1/4 tsp." In support of its petition, the petitioner submitted the results of a consumer study of consumption patterns for salt and low-density salt and analytical data comparing the physical properties (including density) of salt and low-density salt. The company stated that the low-density salt product contains 33 percent less sodium by volume than regular table salt, that the consumer data demonstrate that equivalent volumes of low-density salt and regular salt are consumed, and that, therefore, consumers who use similar volumes of low-density and regular salt would consume 33 percent less sodium by using the low-density salt product rather than regular table salt. The company concluded that it should be permitted to communicate the benefits of its low-density salt product to consumers in a truthful manner, including making claims that would be prohibited under regulations established in response to the 1990 amendments.

On May 24, 1994, the petitioner amended its petition by submitting supplemental materials consisting of detailed information regarding the protocol, data tabulation, and results of the consumer study. The supplemental materials also included an independent evaluation of the results and conclusions of the consumer study.

On February 2, 1994, FDA received a comment that requested that the agency reject the petition and take no further action with regard to salt and salt products. The comment stated that amending the reference amount as requested by the petitioner would permit a comparative claim that would be contrary to the letter and intent of the 1990 amendments, which the comment claimed was to provide for comparison of two distinct foods and not two versions of the same food. The comment also argued that the proposed change would undermine the overall structure of FDA's regulation of nutrient content claims by acting as an incentive for manufacturers to extend their products with air or other nonnutritive substances in order to make claims. Finally, the comment asserted that the

consumer study data submitted in the petition were incorrect and insufficient. On April 14, 1994, FDA received a response by the petitioner to the various arguments made in this comment.

FDA has carefully considered the information in this petition, the supplemental submission, and the comments. Based on its review, FDA finds that the petitioner has made a prima-facie case that a volume-based reference amount of 1/4 tsp for salt is more appropriate than the reference amount that FDA adopted in 1993 (Ref. 1). Therefore, in accordance with 21 CFR 10.30(e)(2)(i), FDA is granting the petition and proposing to change the reference amount for "salt, salt substitutes, seasoning salts (e.g., garlic salt)" from 1 g to 1/4 tsp. A discussion of the basis for the agency's action on the petition and for the proposed change in the reference amount follows.

III. Basis for the Proposed Action

A. The Appropriateness of a Weight-Based Reference Amount

As stated above, in the final rule on serving sizes, FDA adopted a weight-based reference amount of 1 g for "salt, salt substitutes, seasoning salts (e.g., garlic salt)" based on the agency's determination to use weight-based reference amounts unless such amounts were shown to be demonstrably inappropriate (58 FR 2229 at 2238) and on the lack of data showing that a weight-based reference amount was inappropriate for salt.

In the final rule on serving sizes, however, FDA outlined the circumstances in which a weight-based reference amount would not adequately reflect the amount of food customarily consumed per eating occasion (see comment 20 in 58 FR 2229 at 2238). The agency stated that weight-based reference amounts are inappropriate when foods within a product category vary considerably in density, that is, there is a density difference of 25 percent or more among the products in the category (see § 101.12(e) (21 CFR 101.12(e))), and the customarily consumed amounts for different products are more uniform when expressed in volume than in weight. As an example, the agency explained that, although the reference amount for the category "Mixed Dishes: Measurable with cup, * * *" is 1 cup, the g weights of different types of products within the category differ widely from about 160 g for seafood with vegetables without sauce to about 250 g for seafood stew. The use of a weight-based reference amount for this product category would result in serving sizes too large for some