

petitioner in support of retaining the first-tier sodium levels is close to the recommended daily sodium intake set forth in the dietary guidelines (Ref. 9). FDA believes that minor adjustments, such as the lower sodium level the agency is proposing for "healthy" individual foods, would be sufficient to bring such a menu within dietary guidelines.

The 1997 FLAPS data (Ref. 4) did not contain any additional "healthy" claims for meal and main dish products that were not already identified in the marketplace data analysis. This further supports the contention that there are a limited number of "healthy" meal and main dish products in the marketplace.

Meal and main dish products make a major contribution to the total daily diet, and FDA believes that sodium requirements for these products should reflect this contribution, while remaining consistent with current dietary guidelines. For example, under § 101.13(l), a meal is defined as weighing at least 10 oz per labeled serving and containing not less than three-40 g portions of food, or combinations of foods, from two or more of the four food groups: (1) Bread, cereal, rice, and pasta; (2) fruits and vegetables; (3) milk, yogurt, and cheese; and (4) meat, poultry, fish, dry beans, eggs, and nuts. Under the first-tier sodium requirement, a "healthy" meal must fall within the 600 mg sodium level per serving size of not less than 10 oz (282 g), or approximately 2.1 mg sodium per g of food. A "healthy" main dish, under § 101.13(m), must contain not less than 40 g of food, or combinations of foods, from each of at least two of the four food groups, and must contain 600 mg or less sodium per serving size of 6 oz (170 g), or approximately 3.5 mg sodium per g of food.

By contrast, the first-tier sodium level for "healthy" meal and main dish products is more stringent than the sodium level of a meal consisting of "healthy" individual foods at the second-tier sodium level. For example, both fresh or frozen vegetables and cooked fish/shellfish have reference amounts of 85 g (§ 101.12(b), table 2, "Vegetables: All other vegetables without sauce: fresh, canned, or frozen" and "Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes: Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake"). Prepared fried potatoes have a reference amount of 70 g (§ 101.12(b), table 2, "Potatoes and Sweet Potatoes/Yams: French fries, hash browns, skins, or pancakes"). Under the second-tier sodium definition of "healthy,"

individual foods are limited to 360 mg sodium per reference amount and per serving size. The sodium levels under these requirements would be approximately 4.2 mg sodium per g of fish or vegetables and approximately 5.1 mg sodium per g of potato. These levels are more than 200 percent higher than the sodium level that "healthy" meals are required to meet at the first-tier sodium level (2.1 mg sodium per g of food) and 120 percent higher than the first-tier sodium level for "healthy" main dish products (3.5 mg sodium per g of food). These examples demonstrate that the first-tier sodium level for "healthy" meal and main dish products is already more stringent than the second-tier sodium level proposed for "healthy" individual foods typically included in such meals and main dishes.

Furthermore, the first-tier sodium level proposed for "healthy" meal and main dish products is proportionate to and adequately reflects their contribution to the total daily diet while remaining consistent with current dietary guidelines. If each meal or main dish product has a maximum of 600 mg sodium and if one meal or main dish product is consumed at each of three meals during a typical day, then this accounts for a total of 1,800 mg sodium from meal and main dish products. This is consistent with previous agency assumptions that daily food consumption patterns include three meals and a snack with about 25 percent of the daily intake contributed by each (final rule on nutrient content claims (58 FR 2302 at 2380, January 6, 1993)). The 1,800 mg sodium level is well below the suggested 2,400 mg recommendation (Ref. 1) and allows for flexibility in the rest of the daily diet (i.e., the snack).

A number of comments to the ANPRM addressed whether there is an acceptable salt substitute that could be used to replace salt in meal and main dish products. Most of those comments indicated that currently it is not technologically feasible to manufacture a "healthy" meal or main dish product that uses a salt substitute to help meet the second-tier sodium level. Many flavor manufacturers stated that although they have been working towards a flavor profile to replicate salt, an acceptable salt substitute is not yet available. The comments stated that some of the salt substitutes currently available are ammonium salt and potassium chloride. The comments further stated that these are not effective salt substitutes because they leave an off or bitter aftertaste and require a masking of that aftertaste that is not always

successful. One flavor manufacturer asserted that it is not necessary to change the sodium requirements for the definition of "healthy" because this manufacturer had created a salt substitute that is acceptable for use in most processed foods. However, the petitioner described working with that manufacturer and using that salt substitute to try to reduce sodium in their products (e.g., frozen entrées) without success.

It appears that technological advances have not yet yielded an acceptable salt substitute that would allow meal and main dish products to meet the second-tier sodium level for the definition of "healthy." Furthermore, the second-tier sodium levels have been stayed several times to give manufacturers more time to develop alternatives. Because of the apparent difficulty of producing an acceptable salt substitute, FDA is no longer convinced that providing additional time will lead to the development in the near future of a salt substitute that is acceptable to manufacturers and palatable to consumers.

FDA tentatively concludes that the first-tier sodium level for meal and main dish products allows a "healthy" definition that is neither too strictly nor too broadly defined. The first-tier sodium level will allow consumers to meet current dietary guidelines for sodium intake while still maintaining flexibility in the diet. Additionally, the agency believes that by retaining the first-tier sodium level, a reasonable number of "healthy" meal and main dish products will remain available to consumers. Therefore, the agency has tentatively concluded that the current first-tier level of 600 mg sodium per serving size should be retained as the sodium criterion for "healthy" meal and main dish products. Accordingly, the agency is proposing to eliminate the second-tier sodium level of 480 mg for meal and main dish products and to make the first-tier sodium level permanent for those products.

D. Conclusion

FDA is proposing to permit the previously-established, second-tier sodium level to take effect for "healthy" individual foods and to retain the first-tier sodium level for "healthy" meal and main dish products. FDA believes that this combination of actions is necessary to provide for a reasonable number of "healthy" products in the marketplace. The marketplace data analysis indicated that the number of "healthy" individual foods has been increasing while the number of "healthy" meal and main dish products has been decreasing.