

delicious and healthy fruit product, which contains no fat, very low sodium, and no cholesterol." Such statements are implied nutrient content claims for "healthy" that the marketplace data analysis did not identify because the term "healthy" was not part of the brand name of the product. This leads FDA to believe that there are individual foods in the market place bearing "healthy" claims in addition to those identified in the marketplace data analysis. As some "healthy" claims are not part of the brand name of the product and, therefore, were not captured in the marketplace data analysis, it is likely that the number of "healthy" individual foods included in that analysis underestimates the number of individual food products bearing "healthy" claims.

The agency notes that individual foods with reference amounts on the lower end of the scale are also less likely to be affected by adoption of the second-tier sodium level because they are able to claim the same 360 mg sodium level for a "healthy" product as other individual foods with larger reference amounts. For example, bread or rolls have a reference amount of 50 g (§ 101.12(b) (21 CFR 101.12(b)), table 2, "Bakery products: Breads (excluding sweet quick type), rolls"). A 50 g serving of bread or rolls typically contains less than 360 mg sodium (Ref. 3) and would meet the second-tier criterion. Contrast that with individual foods such as pasta or potato salad, which have a reference amount of 140 g (§ 101.12(b), table 2 "Salads: Pasta or potato salad"). Assuming other aspects of the "healthy" definition are met, 140 g of pasta or potato salad must contain no more than 360 mg sodium to be considered "healthy," although the reference amount for pasta or potato salad (140 g) is almost three times that of bread or rolls (50 g). Many other individual foods are similar to the bread and rolls, having a reference amount on the lower end of the scale, which allows those products more flexibility in their sodium level.

Additionally, the agency believes that some individual foods may be close to meeting the second-tier sodium level. If the second-tier sodium level goes into effect, manufacturers may choose to reformulate such products in order to retain a "healthy" claim.

The ConAgra petition and other comments identified a few specific categories of individual foods for which the ability to make "healthy" claims could be negatively affected by permitting the second-tier sodium levels to take effect (e.g., soups, cheeses, frankfurters, and luncheon meats). FDA examined the marketplace data analysis

for these specific food categories (Ref. 2).

The total number of "healthy" wet and dry soup products available in the marketplace increased during 1993 through 1999. In 1993, 104 "healthy" soup products were on the market. In 1999, over 20 more products were available, for a total of 126 "healthy" soup products in 1999. The number of "healthy" brands remained steady at six in both 1993 and 1999.

The petitioner indicated that its "healthy" soup products would not be able to meet the second-tier sodium level. The petitioner stated that it had expended numerous resources (e.g., consulting with experts in the field of food technology and conducting research and development programs with flavor companies) and was not able to find a satisfactory salt replacement for its "healthy" line of soups.

On the other hand, a comment by a major manufacturer of soups claimed that it has been able to reduce the sodium levels in its "healthy" soups and is currently able to meet the second-tier sodium level for "healthy" individual foods. The comment from this major soup manufacturer indicated that it was able to reformulate its "healthy" soup product line by modifying the flavor system with ingredient changes on a product by product basis. The comment also noted that reducing sodium in a product is technically difficult but not unsolvable and that the flavor profile of a product can be manipulated so that it maintains consumer appeal.

Because one major soup manufacturer has been able to develop a "healthy" soup line that meets the second-tier sodium level for "healthy" individual foods, FDA tentatively concludes that it is technologically feasible to produce a "healthy" soup product that meets the second-tier sodium level and is palatable to consumers. The petitioner also stated that cheese might not be able to meet the second-tier "healthy" sodium requirement because salt is required in the manufacturing process and cannot be reduced without jeopardizing taste and texture. The petitioner also contended that if FDA permits the second-tier sodium level to take effect for individual foods, there will be no "healthy" version of cheese in the marketplace.

Another comment stated that if it is not possible to manufacture a "healthy" cheese, then no exception should be made, and cheese products should be removed from the "healthy" marketplace until manufacturers are capable of producing a cheese that meets the "healthy" definition.

The petitioner's comments regarding cheese are reinforced by the trend seen by FDA in its marketplace data analysis (Ref. 2). For example, there has been a general decline in the number of "healthy" cheeses in the marketplace. In 1993, before the final rule defining "healthy" was issued, there were a total of 60 "healthy" cheese products with 3 different brands on the market; however, in 1999, the numbers dropped to 32 products with only 1 brand in the marketplace. Furthermore, in Spring 2001, FDA staff made an informal telephone inquiry to the customer service center of the only manufacturer of "healthy" cheese identified in the marketplace data analysis for 1999 (Ref. 5). The manufacturer indicated that its "healthy" line of cheese had been discontinued. To the best of the agency's knowledge, no new manufacturer has entered the "healthy" cheese market.

FDA agrees that cheese generally requires salt in the manufacturing process. Cheese is made from the coagulation of milk into curds and whey. The whey is drained off and salt (sodium chloride) is typically added to the curd to control microbial growth and enzyme activity, assist in curd synthesis (whey expression), and directly cause changes in cheese proteins that will influence cheese texture (Ref. 6). The agency requests comments on whether salt is the limiting element in achieving a "healthy" cheese and whether salt can be removed from the cheese-making process.

FDA notes that "healthy" cheeses may have been removed from the marketplace for reasons other than the sodium requirement. Some "healthy" cheeses (e.g., light mozzarella cheeses) were able to meet the proposed second-tier sodium level for "healthy" individual foods; nonetheless, those products were removed from the marketplace (Ref. 5). In addition to sodium, cheese also typically contains fat and saturated fat, which have been identified as nutrients to limit when constructing a "healthy" diet (Ref. 1). Because the "healthy" claim sets limits on all three nutrients, the multiple requirements may be the reason why "healthy" cheeses are no longer in the marketplace. FDA requests comments that would help clarify whether it is the sodium limit, the fat or saturated fat limits, the combination of limits, or some other factor or factors that have resulted in manufacturers discontinuing the manufacture and marketing of "healthy" cheeses.

Further, the agency is not persuaded that it is necessary to provide for