

“healthy” cheese since the lack of a “healthy” cheese product is not likely to prevent consumers from constructing a diet consistent with dietary guidelines. Although cheese contributes calcium to the diet (Ref. 1), consumers can obtain their reference daily intake (RDI) of calcium from many other sources such as low-fat milk, yogurt, and dark-green leafy vegetables, to name a few.

For consumers who choose to eat cheese, there are alternative cheese products such as “reduced fat” or “reduced sodium” cheeses. These claims accurately describe the specific attributes of the product without claiming that it conforms to the requirements for “healthy.”

FDA also is concerned that treating cheese differently from other foods could be misleading to consumers trying to construct a healthy diet. Cheese has a small reference amount (30 g) (§ 101.12(b), table 2, “Dairy Products and Substitutes: Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread”), and therefore, more than one serving can be consumed easily. In general, approximately 32 g to 46 g of cheese is consumed per eating occasion (Ref. 7). Because the actual amount consumed is typically larger than the reference amount (30 g), it appears that consumers will be better served if the second-tier sodium level applies to all foods, including cheese. Applying the second-tier sodium level to cheese will help maintain a reasonable sodium intake even for those people who consume larger amounts of cheese.

However, FDA invites comments on whether having no “healthy” cheeses may have a negative impact on consumers, and if so, whether the agency could establish a reasonable alternative sodium requirement for “healthy” cheese. Alternative methods might include: (1) Leaving cheese at the current first-tier sodium level for “healthy” individual foods (480 mg) or (2) establishing “healthy” sodium levels based on a percent reduction of market-basket norms.

The first alternative of leaving cheese at the current first-tier sodium level for “healthy” individual foods may encourage cheese manufacturers to reenter the marketplace, since they would no longer have to face uncertainty as to whether the sodium level would be reduced to the second-tier level. The marketplace data analysis showed that there were 32 “healthy” cheese products in 1999, demonstrating that manufacturers were capable of producing a “healthy” cheese at the current first-tier sodium level.

The second alternative of establishing a “healthy” sodium level based on a market-basket norm may not be practical for all individual foods but may be appropriate for cheese because of its special manufacturing process. To consider both alternatives, it would be helpful to have additional information, such as: (1) The sodium levels for various cheeses currently in the marketplace that do not bear the term “healthy” (i.e., the current market-basket norm) and what might be an achievable percent reduction for sodium from that market-basket norm; (2) the impact that exempting cheese, not exempting cheese, or establishing an alternative sodium level would have on diets; (3) the minimum levels of sodium that can be achieved in the production of an acceptable cheese product; (4) the technology available to reduce sodium levels in cheese products; and (5) the extent to which salt (sodium chloride) is required in the cheese-making process.

Comments received in response to the ANPRM also indicated that frankfurters and luncheon meat may have difficulty meeting the second-tier sodium level of the “healthy” definition. However, those products fall outside FDA’s jurisdiction, as they are regulated by USDA; therefore, they are not addressed in this proposal.

Another issue raised by the petitioner was the role of salt as a preservative in refrigerated foods, particularly meat and poultry products, because the petitioner contended that refrigeration alone cannot be relied upon to ensure food safety. However, a comment stated that the difference between the first-tier (480 mg) and the second-tier (360 mg) sodium levels is insignificant with respect to food safety. The comment noted that sodium does not protect against microbiological contamination in processed meats and that no one factor is responsible for product safety.

Again, since meat and poultry fall outside FDA’s jurisdiction, they will not be addressed in this rulemaking. The agency requests comments on whether sodium levels of 360 to 480 mg are protective and play a role in food safety for foods that FDA regulates; whether changing from the first- to the second-tier sodium level would negatively impact food safety; and what other preservation methods could be used to ensure food safety in conjunction with lower sodium levels.

Based on the data summarized, it appears that: (1) A reasonable number of “healthy” individual food products were available in the marketplace from 1993 through 1999; (2) in many food categories there has been an increase in the number of “healthy” products and

brands; and (3) many “healthy” individual foods, such as those with reference amounts at the lower end of the scale or those that typically contain limited amounts of sodium, would remain unaffected by the proposed change to the second-tier sodium level for individual foods. Therefore, with the possible exception of cheeses, the overall impact of permitting the second-tier sodium level to take effect for individual foods appears to be limited to minor reductions in the number of “healthy” products in some food categories.

Accordingly, the agency tentatively concludes that the second-tier sodium level is the appropriate sodium requirement for the “healthy” definition for individual foods. The agency believes the second-tier sodium level provides a meaningful definition of “healthy” that will enable consumers to construct a diet that is consistent with current dietary guidelines but is not so narrowly defined as to disqualify many foods that are recommended to be in the diet (59 FR 24232 at 24240).

Therefore, the agency is proposing not to amend the second-tier “healthy” sodium level of 360 mg for individual foods in current § 101.65(d)(2)(ii)(C)(1) and (d)(2)(ii)(C)(2), and (d)(3)(ii)(C)(1) and (d)(3)(ii)(C)(2). These paragraphs are being revised in format, however, as discussed in section III. F of this document. The second-tier sodium level for individual foods is to take effect at the end of the stay period, January 1, 2006 (67 FR 30795).

The agency is requesting comments and information on the potential impact of the second-tier sodium level on specific individual food categories. In particular, FDA is seeking information on the range of sodium content in food categories and the proportion of products that contain sodium at or below the first- and second-tier levels of current § 101.65.

2. Dietary Supplements

Dietary supplements, like other individual foods, must meet all of the requirements in § 101.65(d)(2) to make “healthy” claims. FDA has evaluated data for dietary supplements and tentatively concludes that permitting the second-tier sodium level to go into effect is unlikely to reduce the availability of “healthy” dietary supplements. The agency assessed the prevalence of dietary supplement products that contain salt or sodium and are labeled as “healthy.” The agency used a database developed by Research Triangle Institute (RTI) (Ref. 8), which includes detailed information on approximately 3,000 dietary supplement