

argue that the first-tier sodium level strikes that balance better than the second-tier level for meals and main dishes, but that the second-tier level strikes the balance better for individual foods. Other sodium levels may perform well in this type of analysis, but FDA has no way of differentiating health effects or manufacturing costs due to marginal differences in the allowable sodium content of “healthy” food products.

Therefore, the options we consider for this analysis are option 1 (allow second-tier levels to take effect) and option 2 (eliminate second-tier levels), split into separate categories for individual foods (2a) and meals and main dishes (2b). The proposed rule would adopt 2b, but not 2a.

1. Implement the current rule without modification, which would make the second-tier sodium levels effective on January 1, 2006.
- 2a. Amend the current rule, adopting as permanent the first-tier sodium level for all or specific “healthy” individual foods.
- 2b. Amend the current rule, adopting as permanent the first-tier sodium level for “healthy” meals and main dishes.
- 2c. Amend the current rule, adopting as permanent the first-tier sodium levels for “healthy” meals and main dishes and for all or specific “healthy” individual foods.

The “baseline” in this case is the current rule or option 1, so the benefits of the other options are the reformulation, rebranding, and relabeling costs avoided by retaining the first-tier sodium content requirements for individual foods or meals and main dishes. The cost of the other options is the negative health impact due to a net increase in sodium intake under options 2a, 2b, and 2c.

Option 2a: Retain the First-Tier Sodium Level for Individual “Healthy” Foods. FDA considers the current rule’s second-tier sodium level for “healthy” appropriate for individual foods. Although this analysis does not quantify in detail the net benefit associated with lower sodium levels in food, the costs associated with option 2a in all likelihood outweigh the benefits. The agency does not have the information necessary to calculate the effects on the market of the 870 foods that use a “healthy” claim, but FDA invites comments regarding how to quantify the qualitative effects summarized here.

Benefits of Option 2a. The benefits are the reformulation, rebranding, and relabeling costs avoided by manufacturers if they do not have to modify their products to meet the

second-tier sodium level for individual foods. In the market analysis, FDA identified 870 individual food products among 69 brands that make a “healthy” claim (Ref. 2). The FLAPS survey also identified several additional individual foods that make a “healthy” claim but are not from a “healthy” brand (Ref. 4). However, according to the comments on the ANPRM and subsequent analysis by FDA, only 3 of the over 80 food product categories would have material trouble meeting the second-tier “healthy” sodium level: Soups, cheeses, and meats (primarily frankfurters and ham). Of the three food product categories that FDA tentatively concludes are impacted by this option, sodium levels for “healthy” meats are regulated by USDA and therefore are not part of this analysis. Discussions on cheese and soup categories follow.

Other individual foods in other categories may have costs associated with meeting the second-tier sodium level, but FDA has no information concerning costs for those other individual foods. FDA invites comments on the costs that may be incurred by other “healthy” individual foods, including dietary supplements, in meeting the second-tier sodium level.

Cheese. Reformulating cheeses to meet the second-tier sodium level would be difficult. However, FDA believes that, as of May 2001, every “healthy” cheese product had already been taken off the market. FDA identified 32 “healthy” cheeses, under one brand, on the market in 1999 according to the marketplace data analysis (Ref. 2). In an informal telephone inquiry, FDA confirmed that by May 2001, there were no longer “healthy” cheeses produced under this brand (Ref. 5).

Having no products to analyze prevents FDA from performing a detailed analysis of the potential impact of the second-tier sodium level on cheese. “Healthy” cheeses could have been taken off the market for several reasons. First, an aspect of the product unrelated to sodium content (e.g. lower fat requirements) could have been responsible for low product demand. If so, option 2a would not lead to any societal benefits through influencing the market for cheese. Second, firms may not be able to create an acceptable “healthy” cheese product even under the first-tier sodium level for individual foods. This means that there would be no cost or benefit difference between the first and second tiers of sodium content. Third, if “healthy” cheeses were taken off the market in anticipation of being unable to comply with the second-tier sodium level, adopting option 2a would

probably encourage producers to re-introduce “healthy” cheese products.

In this case, FDA believes it likely that sodium content was not the primary factor in the decision to take “healthy” cheeses off the market. Many light mozzarella cheeses currently have a sodium content lower than second-tier sodium levels—between 167 and 357 mg per 50 g serving in our examples from Washington, DC, area grocery stores (Ref. 5)—and the “healthy” version of this cheese was among the most popular sellers among all “healthy” cheeses but was still pulled from the market (Ref. 2).

Soups. Costs associated with the current rule, and therefore benefits of avoiding these costs under option 2a, would be small for soups. “Healthy” soups had about a 7 percent market share by sales in 1999, but a major producer of “healthy” soups supports the second-tier sodium level; this is persuasive evidence that the private benefits to producers of preserving “healthy” as a high-quality health signal can be as valuable as the private cost of reformulation. This producer states in its comments to the ANPRM that, for most major varieties of its brand of “healthy” soup, it was able to achieve taste parity under the second-tier sodium level. However, another major soup producer does not support the second-tier level.

Costs of Option 2a. The principal costs of this option are all associated with the deterioration of “healthy” as a signal of a truly healthy individual food.

Based on the comments to the ANPRM, over 90 percent of “healthy” individual foods could meet the second-tier sodium limit without material adverse changes in taste or texture. Cheeses and soups represent a small percentage of all “healthy” individual foods. Retaining the first-tier sodium level for all individual foods would diminish the effectiveness of the “healthy” low sodium signal substantially, compared to the current rule. Alternatively, if FDA retained the first-tier “healthy” sodium level only for soups and cheeses, FDA believes this inconsistency would also diminish the usefulness of the term “healthy” as a low sodium signal.

In addition, the current and proposed rule’s second-tier level for individual foods is more consistent with the “healthy” definition for meals and main dishes. As explained in detail in section III of this document, the first-tier sodium level for combinations of “healthy” individual foods allows significantly more sodium than when those same foods are combined into meals and main dishes. “Healthy” meal