

and main dish products must contain at least two noncondiment food groups, and still can only contain 600 mg sodium per meal or main dish under the first-tier sodium level. In contrast, two “healthy” individual foods combined in exactly the same way could contain 720 mg sodium under the stayed second-tier level, and up to 960 mg sodium under option 2a, or 40 percent of the RDI. The current and proposed rule’s second-tier level for individual foods is fairly consistent with the meal and main dish first-tier sodium level, but the first-tier difference of up to 360 mg sodium between a meal and two individual foods is substantial and could have a health effect if consumers are using “healthy” specifically as a low sodium signal. FDA believes this inconsistency in the labeling claim “healthy” could lead to higher sodium intake, if the first-tier sodium level were to remain in effect for individual foods.

FDA believes that the major cost of option 2a is the increased health risk caused by higher sodium intake due to retaining the higher first-tier sodium level for individual foods. FDA further believes that the costs of this option outweigh the benefits of adopting as permanent the first-tier sodium limit for all or particular individual foods.

Option 2b: Retain the First-Tier Sodium Level for Meals and Main Dishes (the Proposed Rule).

Costs of Option 2b. The cost of this option, as in option 2a for individual foods, is the increased health risk due to higher sodium intake. However, FDA finds that adopting option 2b will not significantly affect the average amount of sodium consumed in an overall diet. The net increase in sodium intake under the proposed rule is insubstantial even under the most favorable assumptions of the effects of the current rule. Under some plausible scenarios, the average amount of sodium consumed could remain the same or actually increase if the current rule were implemented without amendment.

In the original analysis of the regulation defining the “healthy” claim, FDA referred to the many benefits of improved nutrition labeling, including decreased rates of cancer, coronary heart disease, obesity, hypertension, and allergic reactions to food. FDA also considered “healthy” claims an important contributor to the \$4.4 billion to \$26.5 billion benefit of improved food labels over the 20 years following the rule (59 FR 24232 at 24247 and 24248).

Several comments on the 1997 ANPRM expressed concern that “healthy” claims at the first-tier sodium level may undermine consumer attempts to improve their diets and health, as these meals are not truly healthy. An inaccurate “healthy” claim is not a useful signal that a product is indeed healthy.

In order to get a rough estimate of the difference in sodium intake between the current and proposed rule, we took a sample of 106 frozen meals and main dishes from a Washington, DC area grocery store (Ref. 5). The agency believes this sample is reasonably representative of the U.S. prepared dinner market, although it may not encompass all meal and main dish choices available nationwide. We also tested these results with a second Web-based sample (Ref. 5).

According to the Washington, DC grocery store sample, the current market for meals and main dishes can be characterized as having three segments. The first is the bargain segment, with two or three producers that offer basic meals, usually priced from \$1 to \$1.50 lower than the average product on the market. The second segment, or “normal” market, also has two or three major producers, with prices ranging from slightly lower to the same as the health-positioned goods in the third segment. Products in the second segment appear to compete mainly on taste or price rather than health attributes, although such products sometimes make health-related or dietary claims (e.g., “low-fat”). The third segment is the “claims” segment, which includes the “healthy” branded products, low-fat products, and more expensive specialty dishes such as organic goods. Many of these products prominently display fat and calorie information on the front of the package; these brands clearly use nutritional content as a marketing tool.

According to our analysis (Ref. 5), the “healthy” branded goods have the lowest average sodium content among the “claims” brands and the lowest average sodium content on the market. On average, they have 42 mg less sodium per meal than their next lowest competitor. Both the “healthy” branded goods and their main competitor that does not make “healthy” claims have average sodium levels under the first-tier limit of 600 mg for meals and main dishes.

We explore several possible consumer and producer responses to option 2b—retaining the first-tier sodium level for meals and main dishes—as compared to option 1—allowing the second-tier sodium level to go into effect—in the following scenarios. If FDA adopted option 1, firms would respond to the imposition of the second-tier sodium level for meals and main dishes in a strategic way. Among the “healthy” brands, producers would have the option of either reformulating their products to meet the second-tier level, or relabeling their products without the “healthy” claim or the “healthy” brand name. The concern here is the consumer response to these actions. Reformulated products may be less palatable or more expensive, leading to a loss of market share. Rebranded (or relabeled) products would no longer carry the “healthy” claim and therefore would not be subject to a sodium limit. Indeed, several independent comments to the ANPRM expressed concern that lowering the sodium requirement to the second-tier level could encourage a consumer to switch to higher sodium alternatives.

The scenarios are summarized in table 1 of this document. The first number in each cell is the average amount of sodium in mg and the second number in parentheses is the market share for each brand. The average sodium content amounts of 551 mg, 593 mg, 722 mg, and 856 mg per meal are the result of analysis explained in a technical memo (Ref. 5). The “healthy” brand has slightly over 9 percent of the total frozen dinner meal market when measured by sales volume, and the non-“healthy” brand 1 in the “claims” segment of the market has 10.5 percent. Nonfrozen meals and main dishes, including chili, are also important in the overall market, but 99 percent of the sales of the “healthy” brand and 100 percent of the sales of “claims” brand 2 are in the frozen meal category. The “other” brands in table 1 of this document represent the normal and bargain market segments previously described. We assume that the three “claims” brands in this analysis are a reasonable approximation to the “claims” market segment as previously described in this document. Each of their shares in the total market is divided by the sum of the shares of the three brands in the total market, which makes their market shares in the “claims” segment of the market (.45 + .52 + .03) equal to 1.