

be reformulated up to 480 mg. Based on comments to the ANPRM, we assume that 37.5 percent of all “healthy” meals and main dishes (one-half of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would be reformulated down to 480 mg of sodium without a loss of taste. An additional 19 percent of all healthy meals and main dishes (one-fourth of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would be reformulated even though the reformulation would lead to some loss of taste. The remaining 19 percent of all healthy meals and main dishes (one-fourth of the 75 percent of “healthy” meals and main dishes currently above 480 mg) would either have “healthy” removed from the label or cease being produced.

The total response of producers to the second-tier level of 480 mg would therefore be:

- Producers increase the sodium level to 480 mg for the 25 percent of “healthy” meals and main dishes that are currently below 480 mg of sodium.
- Producers reduce the sodium level to 480 mg for 56 percent of “healthy” meals and main dishes (37.5 percent with no loss of taste, 19 percent with some loss of taste).
- Producers either drop “healthy” from the label or cease producing 19 percent of all “healthy” meals and main dishes.

In this scenario, consumers respond to the loss of taste and disappearance of products by switching choices within the “claims” segment of the market, which includes “healthy” and similar meals and main dishes. They switch with equal probability to any one of the three brands in the “claims” segment, which means that one-third will switch to another “healthy” product and two-thirds will switch to non-“healthy” products. The market share loss of the “healthy” brand is therefore 25 percent of its market, or two-thirds of the 37.5 percent of the market that experiences loss of taste, or disappearance of products. This is 11.3 percent of the total “claims” market. The average sodium intake implied by the market activity in this scenario under option 1 is 566 mg per meal.

*Scenario 6b: Combined Total Response to Option 2b.* We assume that producers will reformulate most, but not all, of the “healthy” products to the first-tier limit. We believe producers of “healthy” products will choose to position themselves as a slightly lower sodium alternative in this market, as they are currently positioned, but reformulate to increase sodium for taste reasons. Because of improved taste,

these producers increase their market share by 10 percent under this scenario, so the average sodium intake under the proposed amendment would be 588 mg per meal.

The difference between scenarios 6a and 6b is the best estimate of the “sodium cost” of the proposed rule, which is only 22 mg per meal.

FDA’s technical memo (Ref. 5) repeats the basic parts of this analysis for a second sample of products pulled from the Web sites of a producer of “healthy” products and a “claims” segment producer, which we performed as a stress test of the first sample conclusions. The result from this somewhat different sample of meal products is quite close to the 22 mg “sodium cost” calculated in scenario 6 of table 1 of this document.

According to our analysis, the sodium increase under option 2b, the proposed rule, would be insubstantial. Almost all studies linking sodium’s influence on hypertension, coronary heart disease, and stroke consider the effect of a change in sodium consumption two orders of magnitude larger than these changes. A 100 mmol (2,300 mg) difference per day is typical in both clinical and epidemiological studies; these studies do not address the relative dose-response relationship of the small sodium intake differences found in the scenarios. Even if the effect were linear (i.e., even if the health risk associated with the mg change per day in sodium due to this proposed rule were a simple percentage of the 2,300 mg risk), the total statistical lives saved by implementing the second-tier sodium level for meals and main dishes would be less than 1 under the total effects calculation in table 1 of this document and in the results of the second sample (Ref. 5). However, FDA does not make this linear assumption. FDA believes that the health effects from this low level of sodium increase are negligible.

*Benefits of Option 2b.* The benefits of avoiding reformulation and relabeling costs under this option are substantial. As discussed in section III. C of this document, FDA identified 148 meal and main dish products labeled “healthy” among 10 brands.

Producers would have to expend resources to reformulate their meals to meet the second-tier sodium level. Lost market share due to product reformulation would not be a net loss, but rather a transfer from one company to another. Reformulation costs themselves are the lower limit of the cost to society of the current rule. If producers could reformulate perfectly, without altering any property other than sodium content, then reformulation

would be the total cost of the rule. But if they could not replicate the desirable characteristics of their product, consumers would also suffer the utility loss of a market with fewer meal choices. This is a concern, since some dietitians recommend “healthy” claim products for their lower sodium content.

In the product samples used for the scenario analyses regarding the cost of the second-tier sodium level on meals and main dishes, a significant percentage (around 75 percent in the store-based sample and 50 percent in the Web site sample) of the major “healthy” producer’s products are above the second-tier sodium levels. If this is representative of the market as a whole, then approximately 74 to 111 products would need to reduce their sodium to meet the second-tier level. In estimating the total effects of the second-tier sodium level on meals and main dishes, we assumed 56 percent reformulation, or 83 of the 148 products on the market (see scenario 6a, in table 1 of this document).

Preliminary testing costs incurred in the first stage of reformulation—according to comments on the ANPRM received from a frozen meal “healthy” brand producer that has begun investigating possible reformulation—are well over \$1 million, but we do not have detailed reformulation cost estimates for meals and main dishes. The following reformulation cost estimations are based on a detailed example of tortilla chip reformulation, but the steps are typical of food reformulation in general. FDA requests information on any reformulation processes for the meal and main dish industry that are different from those described here.

The reformulation process typically starts in a laboratory, where researchers develop a new lower sodium formula for their meals. Then the company investigates availability and price of new ingredients (herbs, for example) and new equipment. If the reformulated meal passes these obstacles, it moves to the test kitchen, where researchers produce the product in small batches. If approved at this level, the meal graduates to a pilot plant. Cooking the product in large runs at the pilot plant may prove unsuccessful and require a manufacturer to restart the reformulation process, incurring additional expense. However, if pilot plant tests go well, full scale plant trials commence.

For reformulation of a meal, FDA assumes 5,000 hours of professional time at \$30 per hour, \$190,000 for development and pilot plant operating expenses, and \$100,000 for market