

suggesting that the agency should amend the “healthy” definition were asked to address what the amended regulation should require to ensure that the term “healthy” could appear on a significant number of foods, without being “so broadly defined as to lose its value in highlighting foods that are useful in constructing a diet that is consistent with dietary guidelines” (62 FR 67771 at 67772). FDA asked those who believed the second-tier sodium requirements were appropriate and should not be changed to provide data demonstrating that the second-tier “healthy” definition was not so restrictive as to effectively preclude the use of the term.

In the ANPRM, FDA requested data or evidence on what would happen to the use of the term “healthy” in the marketplace if the second-tier sodium levels were to take effect. In addition, the agency asked how many “healthy” products would be eliminated if the second-tier sodium levels were to take effect and whether there would be other impacts on the number of consumer choices. The agency also asked for data regarding the technological feasibility of reducing the sodium content of individual foods, including raw, single-ingredient seafood and game meats, to 360 mg per reference amount and of reducing the sodium content of meals and main dishes to 480 mg sodium per serving size.

FDA also requested information and views on consumer acceptance of foods at the second-tier sodium levels. The agency further requested information about the availability or lack of availability of acceptable sodium substitutes, the difficulties in manufacturing different lines of food products with lowered sodium levels, and the impact of these lower sodium levels on the shelf-life stability and safety of the food. FDA also requested comments on other approaches to reducing the amount of sodium in foods that bear the term “healthy” (62 FR 67771 at 67773 and 67774).

If comments responding to the ANPRM revealed agreement that there were technological hurdles that could not be overcome for all foods or certain types of food, the agency stated that it would be interested in exploring different options for maximizing the public health gains expected from reducing dietary sodium levels. The agency identified four options. First, the agency could make no changes in the stayed rule, and the second-tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii) would become effective at the end of the stay period. This was identified as the default option if industry failed to

provide evidence, data, or arguments that supported amending the rule.

Second, as requested by the petitioner, FDA could propose to amend the definition of “healthy” to make the first-tier sodium levels the qualifying levels for all food products, and to delete in their entirety the second-tier sodium levels. Third, the agency could continue the stay based on data and information submitted in response to the ANPRM suggesting technological advancements could be made but would require more time. Fourth, the agency could reconsider the second-tier sodium levels and create new levels based on other factors such as percentile reductions based on market basket norms (62 FR 67771 at 67774).

In response to requests for an extension to coincide with the end of the comment period for the U.S. Department of Agriculture’s (USDA’s) interim final rule on the use of “healthy” on the label or labeling of meat and poultry products (63 FR 7279, February 13, 1998), FDA extended the closing date of the comment period for the ANPRM, from March 16, 1998, to May 19, 1998 (63 FR 13154, March 18, 1998).

In the **Federal Register** of March 16, 1999 (64 FR 12886), FDA published a final rule extending the partial stay of the second-tier sodium requirements in § 101.65 until January 1, 2003. The agency noted that it took this action to provide time for: (1) FDA to reevaluate the supporting and opposing information received in response to the ConAgra petition, (2) the agency to conduct any necessary rulemaking on the sodium limits for the term “healthy,” and (3) companies to respond to any changes that may result from agency rulemaking. On May 8, 2002 (67 FR 30795), FDA issued another final rule to extend the partial stay of the second-tier sodium requirements in § 101.65 until January 1, 2006.

While the partial stay was pending, USDA and the Department of Health and Human Services jointly published the “Dietary Guidelines for Americans 2000” (dietary guidelines) (Ref. 1). This report provides recommendations for nutrition and dietary guidelines for the general public and suggests a diet with a moderate sodium intake, not exceeding 2,400 mg per day. The health concerns relating to high salt intake are high blood pressure and loss of calcium from bones, which may lead to risk of osteoporosis and bone fractures (Ref. 1).

II. Summary of Comments From the ANPRM

FDA received 22 responses, each containing one or more comments, to the December 30, 1997, ANPRM.

Most of the comments stated that the requirements for the use of the term “healthy” should be amended and presented evidence to persuade the agency to change the sodium levels. The comments provided information that a large number of meal and main dish products currently labeled as “healthy” would not be able to meet the “healthy” definition should the second-tier sodium levels take effect. The comments also stated that technological advances have not yet yielded an acceptable salt substitute.

Several comments discussed the possibility of the agency engaging in rulemaking to set new sodium levels. For instance, a few comments suggested using a sodium level based on a percentile reduction from the market-basket norm (e.g., 25 percent less sodium than otherwise comparable products that are currently on the market). The levels could be established for each food category or for those particular food items having difficulty meeting the second-tier sodium levels. One comment objected to “relaxing” the standards and suggested even tighter regulation in the interest of public health (200 mg for individual foods and 400 mg for meal products).

A few comments stated that the second-tier sodium levels were reasonable and should no longer be delayed. Evidence presented in these comments consisted of: (1) Information suggesting that manufacturers could conform to the second-tier sodium levels without presenting food safety concerns, and (2) summary lists of products that would remain in the marketplace if the second-tier sodium levels took effect.

The remaining comments did not directly address the issue of whether FDA should amend the sodium levels, but, rather, provided general information or opinions regarding sodium levels. For example, one such comment stated that there are health risks associated with a low-sodium diet.

FDA used information provided in the comments, along with information the agency gathered through an independent data analysis, to determine its proposed action.

III. Proposed Action

A. Introduction

The agency established a definition for the term “healthy” as an implied nutrient content claim (59 FR 24232).