

Further, the first-tier sodium level for “healthy” meal and main dish products provides a lower sodium intake than the amount that would be consumed if a meal or main dish product consisted of “healthy” individual foods at the second-tier sodium level. The agency believes that the proposed sodium requirements represent levels that are achievable by manufacturers but sufficiently restrictive to provide consumers with a meaningful definition of the term “healthy” that will assist them in constructing a diet consistent with dietary guidelines. Thus, FDA tentatively concludes that the second-tier sodium level is appropriate for individual foods, and the first-tier sodium level is appropriate for “healthy” meal and main dish products.

E. Clarification

To clarify the scope of implied nutrient content claims under § 101.65(d), FDA is modifying § 101.65(d)(1) to specify that a claim that suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, is an implied nutrient content claim if it is made in connection with either an explicit or implied claim or statement about a nutrient. This change makes the regulatory text consistent with the preamble discussions in both the proposed and final rules (58 FR 2944 at 2945, January 6, 1993; 59 FR 24232 at 24235, May 10, 1994), where FDA made clear that claims made in association with an implied claim or statement about a nutrient would be covered by the regulation. Thus, the regulation now states that a claim that suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, is an implied nutrient content claim if it is made in connection with an explicit or implicit claim or statement about a nutrient.

F. Plain Language

By January 1, 1999, Federal agencies were to use plain language in all proposed and final rulemaking documents published in the **Federal Register** (Ref. 10). FDA is therefore proposing to revise the format in § 101.65(d) for all nutrient requirements for the term “healthy.” The codified language is currently in a text-based format. FDA is proposing a summary table format. This new format should aid the reader in comprehending and following these regulations.

Finally, FDA is proposing several minor changes in the wording of § 101.65(d) to make the regulation more concise and easier to understand. These

changes are not intended to affect the meaning of the regulation.

IV. Environmental Impact

The agency tentatively concludes under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic impacts of the proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, public safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). This proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million, adjusted for inflation. The current inflation-adjusted statutory threshold is \$115 million.

1. The Need for Regulation

To bear the term “healthy,” products must not exceed established levels for fat, saturated fat, cholesterol, and sodium. The existing regulation states that meals and main dishes, as defined in § 101.13(l) and (m) respectively, must have sodium levels no higher than 600

mg per serving size (usually the entire meal) in the first-tier compliance period, and sodium levels no higher than 480 mg per serving size in the second-tier compliance period, which was originally scheduled to begin on January 1, 1998. The regulation also states that “healthy” foods other than meals and main dishes must have sodium levels no higher than 480 mg per reference amount in the first-tier compliance period, and sodium levels no higher than the second-tier 360 mg per serving size thereafter. The agency initially stayed the second-tier sodium levels until January 1, 2000 (62 FR 15390, April 1, 1997). FDA has since extended the stay twice: First until January 1, 2003 (64 FR 12886), and more recently until January 1, 2006 (67 FR 30795, May 8, 2002).

In December 1996, ConAgra petitioned FDA to eliminate the second-tier, lower sodium levels. The petitioner claimed that these levels were too difficult to meet, and therefore would force the removal from the market of many products that were still healthy and contained less sodium than their direct competitors.

This proposal modifies the definition of the term “healthy” in only one respect: It makes the first-tier sodium level of 600 mg permanent for meals and main dishes. “Healthy” individual foods still would have to comply with the second-tier limit of 360 mg per serving once that limit goes into effect.

2. Regulatory Options

FDA identified several options in the ANPRM: (1) Make no change to the current rule, i.e. allow the second-tier sodium levels to go into effect; (2) amend the definition of “healthy” as requested in the petition, i.e. eliminate the second-tier sodium levels; (3) continue the stay to give producers time to develop technological alternatives to sodium; or (4) consider different second-tier sodium limits. Analyzing probable technological change (option 3) is beyond the scope of this analysis; innovation is very difficult to predict. FDA views any technological change as mitigating the eventual cost of this rule, but requests comments as to how to quantify this effect.

Also, analyzing alternative second-tier sodium limits in terms of net benefits (option 4) is not feasible in this analysis. The optimum sodium level for individual foods, meals, and main dishes balances the health benefits of limiting sodium intake with the cost to industry and of making food product preparation more complicated and the cost to consumers of limiting product choice. In the analysis that follows, we