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Revisions made at the Suggestion of OMB
or in Response to Comments from OMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

REVISIONS
DURING
OMB REVIEW
1-21-03

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N-384H and 96P-0500]

RIN 0910-~~AA19~~ AC49

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Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term “Healthy”

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation for sodium levels for foods that use the nutrient content claim “healthy.” The agency is proposing that a previously established, but not yet implemented, more restrictive, second-tier sodium level would be permitted to take effect as a criterion that individual foods must meet to qualify to bear the term “healthy.” The agency is proposing to retain the current first-tier sodium level for meal and main dish products because implementing the second-tier sodium level could result in the substantial elimination of meal and main dish products bearing the claim “healthy” from the marketplace. After evaluating data from various sources, the agency believes that the proposed sodium levels will help consumers achieve a total diet that is consistent with current dietary recommendations, as the proposed levels will give consumers a reasonable number of “healthy” products from which to choose. The agency has also revised the regulatory text for the definition of

food could contain no more than 480 milligrams (mg) of sodium (first-tier sodium level): (1) Per reference amount customarily consumed per eating occasion (reference amount); (2) per serving size listed on the product label (serving size); and (3) per 50 grams (g) for products with small reference amounts (i.e., less than or equal to 30 g or less than or equal to 2 tablespoons). After January 1, 1998 (§ 101.65(d)(2)(ii)(C)), an individual food bearing the term “healthy,” or a related term, could contain no more than 360 mg of sodium (second-tier sodium level) per reference amount, per serving size, and per 50 g for products with small reference amounts. The agency derived this 360 mg sodium level by applying a 25 percent reduction to the original sodium disclosure level of 480 mg for individual foods (59 FR 24232 at 24240).¹

To qualify to bear “healthy” or a related term, meal and main dish products could contain no more than 600 mg of sodium (first-tier sodium level) per serving size before January 1, 1998 (§ 101.65(d)(4)(ii)(A)), and no more than 480 mg of sodium (second-tier sodium level) per serving size after January 1, 1998 (§ 101.65(d)(4)(ii)(B)). The agency selected the 480 mg level because it was low enough to assist consumers in meeting dietary goals, while simultaneously giving consumers who eat such foods the flexibility to consume other foods whose sodium content is not restricted; because there were many individual foods and meal-type products on the market that contained less than 600 mg sodium; and because comments suggesting other levels did not provide supporting data (59 FR 24232 at 24240). ← INSERT (A)

¹ Under § 101.13(h)(1) (21 CFR 101.13(h)(1)), individual foods containing more than 480 mg sodium per reference amount, per labeled serving size, or per 50 g (if the reference amount is 30 g or less or 2 tablespoons or less) must bear a label statement referring consumers to information about the amount of sodium in the food. Such nutrient disclosures are required when a food contains more than certain amounts of total fat, saturated fat, sodium, and cholesterol and that food bears a nutrient content claim. *id.*, see section 403(r)(2)(B) of the act. The agency developed disclosure levels based on dietary guidelines and taking into account the significance of the food in the total daily diet, based on daily reference values for total fat, saturated fat, cholesterol, and sodium (58 FR 2302 at 2307, January 6, 1993).

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Higher levels of sodium were rejected in the earlier rulemaking (59 FR 24232 at 24239) because the agency determined higher levels would not be useful to consumers wanting to use foods labeled "healthy" to limit their sodium intake to achieve current dietary recommendations.

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sold under that brand name (e.g., raisin bran versus corn flakes; 12-ounces (oz) package versus 16-oz package) (Ref. 2).

B. Individual Foods

1. Conventional Foods

In the marketplace data analysis of “healthy” individual foods, the agency estimated the total number of “healthy” products and brands available in 1993, in 1999, and any time in the timeframe from 1993 to 1999. The agency also estimated the number of “healthy” individual foods for specific food

categories. When compiling the marketplace data analysis, the agency ^{INSERT (D)} considered all conventional foods that did not meet the meal or main dish definition in § 101.13(l) and (m) (including soups, salads (e.g., precut in a bag, prepared refrigerated salads), and single-ingredient seafood and game meats) to be individual foods. FDA considered dietary supplements separately using a different database. Dietary supplements are discussed in section III. B. 2 of this document.

FDA estimated that in 1999 the marketplace had 872 “healthy” individual food products available to the consumer, compared to 842 such products available in 1993 (Ref. 2). There was also an increase in the number of “healthy” brands for individual foods in the marketplace from 1993 to 1999. In 1993, only 50 brands carried a “healthy” product, while 69 brands were available in 1999.

Considering that the 1993 figures are representative of the marketplace prior to the 1994 final rule defining “healthy,” the increase in “healthy” products shows that, in addition to manufacturers being able to comply with the definition established in 1994, they have also been able to develop additional “healthy” products. Manufacturers have increased the number of

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FDA does not have any data to determine either the number of "healthy" products or the pace of increase in the availability of "healthy" products prior to 1993.

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 OMB
~~not~~ a significant regulatory action ^{under} ~~as defined by~~ 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

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 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.

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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 and 2b and 2c.

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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.

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Adding this to the reformulation costs of the 83 products yields a total cost estimate of \$29,908,000 for years one and two, and a residual of the lost premium of \$11,648,000 for what would have been the rest of the normal life cycle of the lost “healthy” brand. Clearly, these costs are very large for a rule which would lead to little or no health benefit for the population, and avoiding these costs represents a large benefit of option 2b, the proposed rule.

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3. Net Benefits of the Proposed Rule

This analysis attempts to take limited data to illustrate in some detail what would actually take place in the market under the proposed rule. First, the costs to the “healthy” signal’s meaning and consistency outweigh the benefits of retaining the first-tier sodium level for individual foods. However, the meal and main dish analysis shows that while the benefits of retaining the first-tier sodium level (the costs foregone) are substantial for companies that would need to reformulate to comply with the second-tier sodium level or rebrand and relabel themselves out of the “healthy” market, the health costs associated with retaining the first-tier sodium level are both unquantifiable and most likely quite insubstantial or nonexistent. Therefore, the net benefits of the proposed rule, which would allow the second-tier sodium level to go into effect for individual foods but would adopt as permanent the first-tier sodium level for meals and main dishes, are positive.

B. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic effect of the rule on small entities. FDA finds

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Option 2c: Retain the First-Tier Sodium Levels for "Healthy" Meals and Main Dishes and Individual "healthy" Foods. The benefits and costs of option 2c are very close to the sum of the benefits and costs associated with options 2a and 2b. However, as stated in the discussion of option 2a above, retaining the first tier sodium levels for "healthy" individual foods would significantly decrease the consistency between sodium levels in "healthy" meals and main dishes and the sodium levels in meals put together by combining "healthy" individual foods. The less consistent the sodium levels in "healthy" meals and individual foods, the less consistent, and therefore less useful, is the low sodium signal conveyed by the "healthy" label.

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Costs of Option 2c. The cost of this proposed amendment, as with option 2a for individual foods, and option 2b for meals and main dishes, is the increased risk due to higher sodium intake and the diminishing effectiveness of the "healthy" low sodium signal. Since option 2c is essentially combining options 2a and 2b, the costs associated with a higher sodium intake are roughly the sum of the costs associated with options 2a and 2b.

As discussed above in detail, the average increased sodium intake occurring under option 2b is insubstantial (roughly 22mg per meal) and the health effects from this low level of sodium increase are negligible. As stated above, even under the conservative assumption of a linear dose response, the statistical lives saved by decreasing allowable sodium in "healthy" meals and main dishes to tier-2 levels would be less than 1. Furthermore, the effectiveness of the "healthy" low sodium signal would not be diminished since tier-1 levels of sodium for meals and main dishes allow for even less sodium than would appear in a meal composed of tier-2 individual "healthy" ingredients.

However, the potential increase in sodium intake, as discussed in detail under option 2a, due to relaxing the current level of sodium allowable in individual "healthy" foods, as well as the costs associated with the deterioration of the "healthy" signal, is significant.

Therefore, FDA believes the costs of option 2c, due to the reduced effectiveness of the "healthy" low sodium signal and the health risks due to increased sodium intake are significant, but only negligibly higher than those costs described for option 2a.

Benefits of Option 2c. The benefits of avoiding reformulation, rebranding, and relabeling costs under this

roughly
option are the sum of the benefits associated with options 2a and 2b. — KMS

FDA estimates, as discussed in the benefits section of option 2a, that the benefits of avoiding reformulation and relabeling costs associated by retaining the first-tier sodium levels for individual "healthy" foods are small.

As discussed in the benefits section of option 2b, the benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for "healthy" meals and main dishes are substantial. FDA estimates the total cost of reformulation and relabeling avoided in option 2b is \$29,908,000 for years one and two, and \$11,648,000 per year thereafter.

Therefore, FDA believes the benefits of option 2c, due to the avoided reformulation and relabeling costs associated with implementing the tier-2 sodium levels for both "healthy" meal and main dishes and "healthy" individual foods, are substantial but only slightly higher than those benefits described for option 2b.

Net Benefits of Option 2c. The net benefits of option 2c, retaining the first-tier level of sodium for both "healthy" meals and main dishes and individual "healthy" foods, are the sum of the net benefits of options 2a and 2b. — KMS

The net benefits of option 2a, retaining the first-tier level of sodium for individual "healthy" foods are negative. The costs due to the health risk associated with increased sodium intake and the lost consistency and meaning of the "healthy" low sodium signal outweigh the benefits due to avoided reformulation, rebranding, and relabeling costs.

The net benefits of option 2b, retaining the first-tier level of sodium for "healthy" meals and main dishes are positive. The benefits in avoided reformulation, rebranding and relabeling costs substantially outweigh the negligible costs due to a very small potential increase in average daily sodium intake.

Since the net benefits of retaining the first-tier sodium level for "healthy" meals and main dishes are so substantial, FDA believes the net benefits of 2c, the sum of the net benefits associated with 2a and 2b, are roughly positive, but lower than the net benefits of the proposed rule, which would adopt as permanent the first-tier sodium limits for meals and main dishes only. — KMS