

Rules and Regulations

Federal Register

Vol. 63, No. 30

Friday, February 13, 1998

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DEPARTMENT OF AGRICULTURE

9 CFR Parts 317 and 381

[Docket No. 97-035F]

RIN 0583-AC47

Food Labeling: Nutrient Content Claims, Definition of Term; Healthy

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: In response to a petition, the Food Safety and Inspection Service (FSIS) is extending until January 1, 2000, the effective date of the requirement that individual meat and poultry products labeled as "healthy," or any other derivative of the term "health," contain no more than 360 mg sodium and meal-type products contain no more than 480 mg sodium. The petitioner raised issues regarding the technological feasibility of developing consumer-acceptable products with reduced sodium content and lack of scientific data about a link between sodium levels and health and safety factors. FSIS determined that the petitioner's concerns have merit and, as a result, is extending the effective date for the second tier, lower level sodium provisions.

DATES: *Effective date:* This rule is effective February 13, 1998. Written comments on extension of the effective date should be received by March 16, 1998. Written comments about instituting additional rulemaking should be received by May 19, 1998.

ADDRESSES: Submit one original and two copies of written comments to the FSIS Docket Clerk, Docket #97-035F, Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700. All comments submitted on this rule will be available for public inspection in the Docket Clerk's Office

between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. William J. Hudnall, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation; telephone (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

In the May 10, 1994, **Federal Register** (59 FR 24220), FSIS published a final rule to establish a definition of the term "healthy," or any other derivative of the term "health" and similar terms, on meat and poultry product labeling. The Agency believes it is important to give consumers accurate, informative labeling on meat and poultry products that conform with such labeling on other foods. The final rule provides a definition for the implied nutrient content claim "healthy" for individual and meal-type products. Under 9 CFR 317.363(b)(3) and 381.463(b)(3), for a food to qualify to use the term "healthy," or a derivative of that term, on its label or in its labeling, the product must not contain more than 360 mg of sodium, except it shall not contain more than 480 mg of sodium during the first 24 months of implementation (through November 10, 1997) per reference amount customarily consumed (RACC) and per labeled serving size. Under 9 CFR 317.363(b)(3)(i) and 381.463(b)(3)(i), a meal-type product, to qualify to bear this term, shall not contain more than 480 mg of sodium, except that it shall not contain more than 600 mg. of sodium during the first 24 months of implementation, per labeled serving size.

On December 7, 1996, FSIS received a petition from ConAgra, Inc., requesting that 9 CFR 317.363(b)(3) and 381.463(b)(3) be amended to "eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second tier levels of 360 mg sodium requirements for individual foods and 480 mg sodium for meal-type products." As an alternative, the petitioner requested that the effective date of November 10, 1997, be delayed until food technology can develop acceptable products with reduced sodium content, and until there is better understanding of the relationship between sodium and hypertension.

The petitioner cited as grounds for its request: (1) a lack of scientific basis supporting the Daily Reference Value for sodium (9 CFR 317.309(c)(9) and 381.409(c)(9)) and the allowable maximum levels of sodium in sections 317.363(b)(3) and 381.463(b)(3); (2) a lack of consumer acceptance of products containing low sodium levels; (3) a lack of acceptable sodium substitutes and the difficulties in manufacturing whole lines of products at these low sodium levels; and (4) USDA's failure to provide adequate notice and an opportunity for public comment on the "second tier" sodium levels in the healthy definition, to follow congressional intent and the directives of the Nutrition Labeling and Education Act of 1990, and to consider all the science available, particularly studies which demonstrate possible harm to the general population by low sodium diets. FSIS believes that some of these assertions have raised questions that warrant further consideration.

Regarding the efforts of industry to lower the sodium level in foods, the petitioner stated that the technology does not yet exist to manufacture certain low fat meat and poultry products at the lower, second tier "healthy" definition levels of sodium and still provide foods that will be acceptable to consumers. The petitioner submitted the results of a consumer survey that examines consumer acceptance of several products with different sodium levels. Although the survey found reductions in consumer acceptance at levels of 480 mg sodium compared with higher (600 mg) sodium levels, there was a statistically significant drop in acceptance at levels of 360 mg sodium per serving.

The petitioner described several technological concerns with lowering sodium levels in foods. These concerns related to the functional role of salt, such as the impact on the microbial stability of perishable products, changes in product texture and in water-binding capabilities, and effects on flavor characteristics of other ingredients and on total electrolyte levels that, according to the petitioner, play a critical role in product safety.

The Agency does not find merit in the petitioner's questions regarding the lack of scientific basis for the usefulness of lowered sodium levels in the diet of the general population. There is significant agreement that lower dietary sodium

levels reduce the risk of hypertension. (Note references at end of document.) The overwhelming majority of experts and of authoritative bodies still favors making recommendations for the general public to moderate sodium intake. This consensus is reflected in the Dietary Guidelines for Americans.

FSIS also finds the petitioner's claim that the Agency failed to provide adequate notice and an opportunity for public comment on the second tier sodium levels in the "healthy" definition to be without merit. The sodium requirements for individual USDA-regulated foods and meal-type products that were adopted in the "healthy" final rule were promulgated in response to full notice-and-comment rulemaking procedures. In the proposal, the Agency specifically asked for comments in evaluating whether the definition of "healthy" that was being proposed was appropriate. FSIS also acknowledged its proposed definition of the term "healthy" differed from the definition that was proposed by the Food and Drug Administration (FDA) with regard to sodium levels, and asked for comments on whether it was necessary that the two Agencies provide uniform criteria for use of this term or whether different definitions may be appropriate. FSIS fully considered all the comments it received, and then issued final sodium level regulations in accordance with proper notice-and-comment rulemaking provisions of the Administrative Procedure Act.

However, the Agency finds that the issues relative to technological and safety concerns of reduced sodium foods raise important new questions that merit further consideration. FSIS recognizes that the food industry has made a significant effort over the last few years to lower both the fat and sodium levels in meat food and poultry products while maintaining taste and texture attributes that are acceptable to consumers. The Agency continues to believe, however, that the scientific evidence suggests further reductions in fat and sodium intakes will result in meaningful public health gains.

FSIS has defined the term "healthy" to help consumers identify meat and poultry products that will help them meet guidelines for a healthy diet. Consumers appreciate the significance of this term, and many make purchasing decisions based on its presence on a food label. Therefore, manufacturers have an incentive to produce foods that qualify to bear this term. If the petitioner is correct that the technology does not yet exist that will permit manufacturers to produce certain types of low fat meat and poultry, products

that will contain the second tier, lower levels of sodium, and still be acceptable to consumers, the possibility exists that "healthy" may disappear from the market for such foods. Therefore, the Agency finds that it needs to explore whether it has created an unattainable sodium standard for some meat and poultry products. If it is determined that the standard is unattainable, further determination must be made about the health implications, if any.

FSIS is considering whether to institute rulemaking to resolve the issues raised by the petitioner and to reevaluate the sodium provisions of its nutrient content claims regulations pertaining to the use of the term "healthy." In this document, the Agency is asking for data regarding the technological feasibility of reducing the sodium content of individual foods to 360 mg per RACC and of meal-type dishes to 480 mg sodium per labeled serving and for additional information or views on consumer acceptance of meat and poultry foods with such sodium levels.

With regard to technological feasibility, the Agency is asking for information about the availability or lack of availability of acceptable sodium substitutes, the difficulties in manufacturing different lines of meat and poultry products with lowered sodium levels, and the impact of these sodium levels on the shelf-life stability and the safety of the food. Are there certain types of meat and poultry products for which it is not possible to reach the second tier levels of sodium? If so, what are these foods? Should FSIS make special exemptions for them, or should FSIS exclude them from bearing the term "healthy?" The Agency also is asking for comments on other approaches to reduce the amount of sodium in meat and poultry products labeled "healthy." It is important that consumers seeking to eat a health-promoting diet have food choices available that enable them to reduce the amount of sodium in their diet.

The Agency believes it is in the public interest to extend the effective date for the lower standards for sodium in the definition of "healthy" in 9 CFR 317.363(b)(3) and 381.463(b)(3) while the Agency attempts to resolve the issues raised by the petition. Therefore, FSIS is announcing an extension in the effective date of the second tier, lower sodium level provisions until January 1, 2000.

FDA also was persuaded by the petitioner that it is in the public interest to stay its effective date for the lower standards for sodium in its definition of "healthy." Therefore in the April 1,

1997, **Federal Register** (62 FR 15390), FDA issued a stay in the effective date until January 1, 2000, for the second tier sodium levels to allow itself time to reevaluate the standard, the data contained in the petition, and any additional data that it may receive; to conduct any subsequent notice-and-comment rulemaking that it finds is necessary; and to allow ample time for implementation of the rule or of any changes in the rule that may result from the Agency's reevaluation.

If it appears from the comments that agreement exists that there are technological hurdles that cannot be overcome at this time for all, or certain types of, meat and poultry products, the Agency is interested in exploring options for maximizing the public health gains that would come from reducing dietary sodium levels. Therefore, FSIS has identified two options that it could consider.

As an option, FSIS could propose to amend the definition of "healthy" in 9 CFR 317.363(b)(3) and 381.463(b)(3), as requested in the petition, and could make the current sodium levels for individual foods and meal-type products the qualifying levels. FSIS may propose this option if the evidence submitted in response to this rule demonstrates that it is technologically impossible to find salt substitutes for use in any type of meat and poultry product that would satisfy the requirements for texture, safety, and consumer acceptance. There must be evidence that failure of some foods to meet the definition for "healthy" would significantly reduce consumers' choices in meeting guidelines for a healthy diet.

As a second option, the Agency could reconsider the sodium levels that it has established as the second tier of the "healthy" definition. For example, a possibility might be that individual meat food and poultry products would have to contain 360 mg sodium or less per RACC or at least 25 percent less sodium per RACC than the norm, as long as the final sodium level does not exceed 480 mg per RACC. For meal-type products, the Agency might consider the use of a percent reduction from the disclosure level.

If the definition is set at a reasonable achievable level of a 25 percent reduction from the disclosure level, more meat and poultry products are likely to be available. Further, market competition may encourage some manufacturers to exceed this minimal reduction. On the other hand, a primary consideration is whether a 25 percent reduction from the disclosure level or market basket norm is of adequate

dietary significance to warrant the use of the term "healthy."

Based on the above information, the Agency requests comments on whether it should institute rulemaking to reevaluate the sodium provisions of the nutrient claims regulations pertaining to the use of the term "healthy" and on the other issues raised in the petition.

FSIS is dispensing with the requirements of notice and opportunity for comment for this final rule because the Agency finds these procedures to be impracticable. In light of the information provided by the petition, FSIS must have additional time to reevaluate the standard for "healthy" with regard to sodium levels and to explore whether it has created an unattainable sodium standard and other technological issues. The Agency is finalizing this rule immediately because the original effective date for the second tier sodium level requirements has expired. However, FSIS is providing the public with an opportunity to comment on its decision to finalize immediately.

Executive Order 12866 and the Regulatory Flexibility Act

This final rule has been determined to be non-significant and was not reviewed by OMB under Executive Order 12866.

The Administrator has made an initial determination that this interim final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This interim final rule will impose no new requirements on small entities.

FSIS believes that net social benefits are associated with the adoption of this rule because the value of incremental benefits is likely to exceed the incremental costs. The incremental benefits include the potential reductions in the cases of hypertension associated with reduced consumption of sodium. The reductions in hypertension cases would tend to reduce the number of visits to doctors and hospitals associated with these heart diseases. It also would reduce cases of mortality associated with these diseases. The reductions in the costs associated with these mortality and morbidity cases constitute an incremental benefit to society. Society also is likely to benefit from increased productivity brought about by improved health and welfare of the workers consuming low sodium diets.

If the reduction in sodium levels reduces the preservation characteristics of the products, the industry might incur additional costs to preserve the products by other means such as by innovating new chemical preservatives. This incremental cost, however, could

be offset by the reduced costs of sodium in the products. Hence, the costs associated with this rule are not likely to increase.

Unfortunately, we do not have data on the costs and benefits referred to above. Conceptually, however, it appears that the benefits are likely to exceed considerably the costs and result in a net benefit to society.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Requirements

Paperwork requirements for this rule have been approved under OMB Control Number 0583-0092.

References

1. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health," U.S. Government Printing Office, Washington, DC, pp. 139-143, 157-161, and 167-174, 1988.

2. Food and Nutrition Bureau (FNB)/National Academy of Sciences, "Diet and Health," National Academy Press, Washington, DC, pp 353-356, 549-553, and 556-561, 1989.

3. Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, "The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," *Archives of Internal Medicine*, 153: 154-183, 1993.

4. Nutrition Committee, American Heart Association, "Dietary Guidelines for Healthy American Adults—A Statement for Health Professionals from the Nutrition Committee, American Heart Association." *Circulation*, 94:1795-1800, 1996.

5. LSRO, "Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relations for Sodium and Hypertension," Bethesda, MD, December 1991.

6. FNB, National Research Council, "Recommended Dietary Allowances," 10th ed., National Academy Press, Washington, DC, pp 247-261, 1989.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is amending parts 317 and 381 of the Federal meat and poultry products inspection regulations as set forth below:

PART 317—LABELING, MARKING DEVICES AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

Subpart B—Nutrition Labeling

§ 317.363 [Amended]

2. Section 317.363 is amended by removing the phrase "during the first 24 months of implementation" in paragraph (b)(3) introductory text and (b)(3)(i) and replacing it with "effective through January 1, 2000."

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

Subpart Y—Nutrition Labeling

§ 381.463 [Amended]

4. Section 381.463 is amended by removing the phrase "during the first 24 months of implementation" in paragraph (b)(3) introductory text and (b)(3)(i) and replacing it with "effective through January 1, 2000."

Done at Washington, DC, on: February 4, 1998.

Thomas J. Billy,
Administrator.

[FR Doc. 98-3718 Filed 2-12-98; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97-AGL-57]

Establishment of Class E Airspace; St. Paul, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at St. Paul, MN. An airspace review for St. Paul, Downtown Holman Field, MN, indicated the need for surface area controlled airspace during periods when the control tower is closed. The surface area provides a safer operating environment for business/corporate turbo jet and turbo prop aircraft which operate into and out of the airport when the control tower is