

of that term on its label, or in its labeling, must not contain more than 360 mg of sodium: (a) per reference amount customarily consumed (RACC); (b) per labeled serving size; and (c) per 50 grams (g) for products with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less. Further, under 9 CFR 317.363(b)(3)(i) and 381.463(b)(3)(i), after November 10, 1997, a meal-type product qualifying to use the aforementioned term or any other derivative of the term on its label or in its labeling must not contain more than 480 mg of sodium per labeled serving size.

During the initial 24 months of the requirement's implementation date, which is defined as the time period prior to November 10, 1997, the maximum sodium level for individual meat and poultry products would be allowed to reach 480 mg, and the maximum sodium level for meal-type products would be allowed to reach 600 mg. This time period and its correlating maximum levels are referred to as the "first-tier sodium level." After November 10, 1997, the maximum sodium level for individual meat and poultry products would be decreased to 360 mg, and the maximum sodium level for meal-type products would be decreased to 480 mg. This time period and its correlating maximum levels are referred to as the "second-tier sodium level."

Within the same **Federal Register** publication, the Food and Drug Administration (FDA) published a final rule (59 FR 24232) to define the term "healthy" under section 403(r) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)).² FDA's rule established the same sodium levels associated with the use of the "healthy" claim that FSIS' rule established for two separate timeframes. However, the timeframes in FDA's rule differed from those established by FSIS' rule.

On December 17, 1996, ConAgra, Inc., petitioned FSIS to "eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second-tier levels of 360 mg sodium requirement for individual foods and 480 mg sodium for meal-type products."³ In response to the petition,

FSIS published an interim final rule on February 13, 1998 (63 FR 7279), which amended §§ 317.363(b)(3) and 381.463(b)(3) by extending the effective date for the second-tier sodium levels (360 mg for individual meat and poultry products and 480 mg for meal-type products) associated with the term "healthy" until January 1, 2000.⁴ The Agency extended the effective date for the following reasons: (1) To allow time for FSIS to reevaluate the standard, including the data contained in ConAgra's petition and any additional data that the Agency received; (2) to conduct any necessary rulemaking; and finally (3) to allow time for industry to respond to the rule or to any change in the rule that may have resulted from the Agency's reevaluation.

FDA also received a petition from ConAgra, Inc., requesting that the second-tier sodium levels associated with use of the term "healthy" be removed from the regulations. In response to this petition, FDA announced a stay of the provisions relating to the lower sodium standards until January 1, 2000 (62 FR 15390).⁵

In its interim final rule, FSIS asked the public for data and comments in regard to the second-tier sodium levels in the "healthy" definition and other approaches to reduce the amount of sodium in meat and poultry products labeled "healthy." FSIS received 20 responses to the February 13, 1998, interim final rule, which presented strong and opposing views on whether the Agency should let the second-tier sodium levels take effect, and provided a significant amount of data relating to the use of the term "healthy." Based on the information available, the Agency concluded that, in some cases, the second-tier sodium levels may be overly restrictive, thereby eliminating a term that may potentially assist consumers in maintaining a healthy diet. Accordingly, FSIS published a subsequent interim final rule on December 28, 1999 (64 FR 72490), further extending the second-tier sodium levels' effective date until

January 1, 2003.⁶ Similarly, FDA published a final rule (64 FR 12886), which extended the stay on their provisions in regard to the lower sodium levels through January 1, 2003, as well.⁷

FSIS received 8 responses to its December 28, 1999, interim final rule. Six responses conveyed support for extending the effective date of the second-tier sodium level until adequate medical and technological research can be conducted to demonstrate that lowering the maximum amount of sodium used to produce these types of products will contribute to or enhance a "healthy" diet. The commenters stated that a "healthy" diet can not be solely defined or maintained by consuming lower amounts of sodium. Instead, a "healthy" diet must rely on maximizing and minimizing a consumer's intake of all nutrients, including sodium, based on the individuality of the consumer. In addition, the commenters stated that lowering the sodium level would affect the products' palatability, which would negatively impact the demand for such products. Further, consumers would be forced to add salt to these products to enhance their taste prior to consumption, which negates the premise of lowering sodium intake as a means of lowering the health risks associated with consuming high levels of sodium. One commenter asserted that establishing a maximum level of sodium contained in meat and poultry products labeled as "healthy" does not correlate to the definition of "healthy" with respect to positive health benefits. Another commenter stated that the lowest achievable sodium level should be used as the maximum limit when producing individual or meal-type meat and poultry products, and that FSIS should proceed with the intended effective date for the second-tier sodium level requirements.

As of this date, FSIS and FDA are continuing their efforts: (1) To reevaluate appropriate sodium levels associated with the use of the term "healthy"; and (2) to fully consider all options that preserve the public health

Notice, Directives, and **Federal Register** Publications section.

⁴ Interim Final Rule, Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 63 FR 7279-7281, February 13, 1998. This document may be viewed in the FSIS Docket Room Monday through Friday from 8:30 a.m. until 4:30 p.m., or accessed via the World Wide Web at <http://www.fsis.usda.gov/FOIA/popular.htm> under the Notices, Directives, and **Federal Register** Publications section.

⁵ Final Rule; partial stay, Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 62 FR 15390-15391, April 1, 1997. This document may be accessed via the World Wide Web at <http://www.access.gpo.gov>.

⁶ Interim Final Rule, Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 64 FR 72490-72491, December 28, 1999. This document may be viewed in the FSIS Docket Room Monday through Friday from 8:30 a.m. until 4:30 p.m., or accessed via the World Wide Web at <http://www.fsis.usda.gov/FOIA/popular.htm> under the Notices, Directives, and **Federal Register** Publications section.

⁷ Final Rule; extension of partial stay, Food Labeling: Nutrient Content Claims, Definition of Term: Healthy; Extension of Partial Stay, 64 FR 12886, March 16, 1999. This document may be accessed via the World Wide Web at <http://www.access.gpo.gov>.

² Final Rule, Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 FR 24232-24249, May 10, 1994. This document may be accessed via the World Wide Web at <http://www.access.gpo.gov>.

³ FSIS Petition #96-08, ConAgra, Inc.; received December 17, 1996. This document may be viewed in the FSIS Docket Room Monday through Friday from 8:30 a.m. until 4:30 p.m., or accessed via the World Wide Web at <http://www.fsis.usda.gov/FOIA/popular.htm> as a related document under the