Rules and Regulations

Federal Register
Vol. 71, No. 7
Wednesday, January 11, 2006

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 05–033IF; FDMS Docket Number FSIS–2005–0038]

RIN 0583–AD19

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that its regulations will continue to provide that individual meat and poultry products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 480 milligrams (mg) of sodium; and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. FSIS is deferring indefinitely, until further notice, implementation of the requirements that individual meat and poultry products bearing the claim ''healthy'' (or any other derivative of the term ''health'') contain no more than 360 milligrams (mg) of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') contain no more than 480 mg of sodium.

DATES: *Effective date:* January 11, 2006. Comments must be received on or before February 10, 2006.

ADDRESSES: FSIS invites interested persons to submit comments on this interim final rule. Comments may be submitted by any of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select the FDMS Docket Number to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.

Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

Electronic mail: *fsis.regulationscomments@fsis.usda.gov*.

All submissions received must include the Agency name and docket number 05–033IF.

All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be posted to the *regulations.gov* Web site. The background information and comments also will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, 300 12th Street, SW., Room 602 Cotton Annex Building, Washington, DC 20250–3700, (202) 205–0279.

SUPPLEMENTARY INFORMATION:

Background

On May 10, 1994, FSIS published a final rule that established a definition for the term ''healthy'' and that permitted the use of the term ''healthy'' or any other derivative of the term ''health,'' such as ''healthful'' or ''healthier'' on meat and poultry product labeling (59 FR 24220). During the first 24 months of the rule's implementation date (November 10, 1995, through November 10, 1997), under §§ 317.363(b)(3) and 381.463(b)(3), an individual meat or poultry product that used the term ''healthy'' or any other derivative of the term ''health'' on its labeling, could not contain more than 480 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. Furthermore, according to the final rule, as set forth in §§ 317.363(b)(3)(i) and 381.463(b)(3)(i), from November 10, 1995, through November 10, 1997, a meal-type product that used the term ''healthy'' or any other derivative of the term ''health'' on its labeling could not contain more than 600 mg of sodium per labeled serving size. These levels are referred to as the ''first-tier sodium levels.''

After the first 24 months of the rule's implementation (i.e., after November 10, 1997), an individual meat or poultry product that used the term ''healthy'' or any other derivative of the term ''health'' on its labeling could 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. Also after November 1997, a meal-type product that used the term ''healthy'' or any other derivative of the term ''health'' on its labeling could not contain more than 480 mg of sodium per labeled serving size. These lower, more restrictive sodium levels that were to go into effect after November 10, 1997, are referred to as the ''second-tier sodium levels.''

In the same **Federal Register** publication as FSIS' final rule, the Food and Drug Administration (FDA) published a final rule (59 FR 24232) that defined the term ''healthy'' under the Federal, Food, Drug and Cosmetic Act. FDA's rule required the same sodium levels for use of the ''healthy'' claim be met as did FSIS' rule, but the timeframes established for meeting the required sodium levels in FDA's rule differed from those established in 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 required levels of 360 mg sodium for individual foods and 480 mg sodium for meal-type products. (FSIS Petition 96–08.) In response to the petition, FSIS published an interim final rule on February 13, 1998, that amended §§ 317.363(b)(3) and 381.463(b)(3) by extending the effective date for the second-tier sodium levels until January 1, 2000 (63 FR 7279).

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 effective date of the provisions that established lower sodium standards be met, i.e., the second-tier sodium levels, until January 1, 2000 (62 FR 15390).

In its interim final rule, FSIS asked the public for data and comments in regard to the second-tier sodium levels established in the ''healthy'' definition and other approaches that could be implemented 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. They also provided a significant amount of data relating to the use of the term ''healthy.'' Based on the information available, the Agency tentatively concluded that, in some cases, a required reduction of sodium to the second-tier levels might be overly restrictive, thereby eliminating a term that could assist consumers in making healthful food choices and 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. Similarly, FDA published a final rule (64 FR 12886) that extended its stay, through January 1, 2003, for the lower sodium levels for foods that it had established.

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 levels until adequate medical and technological research could be conducted to demonstrate that lowering the maximum amount of sodium used to produce meat and poultry products would contribute to or enhance a ''healthy'' diet. 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 allowed 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.

On January 6, 2003, FSIS again published an interim final rule that amended §§ 317.363(b)(3) and 381.463(b)(3) by extending the effective date of the second-tier sodium levels until January 1, 2006 (68 FR 460). Similarly, on May 8, 2002, FDA further extended its partial stay, until January 1, 2006 (67 FR 30795), for the lower sodium levels for foods that it had established. The agencies took these actions to continue 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 intent behind establishing maximum sodium content levels for foods, while providing manufacturers with the opportunity to use the term on food labeling consistently with dietary guidelines. FSIS did not receive any comments in response to its January 6, 2003, interim final rule extending the effective date of the lower sodium limits.

2004 ConAgra Foods, Inc., Petition

On November 30, 2004, ConAgra Foods, Inc., petitioned FSIS concerning the second-tier sodium levels in the definition of ''healthy'' (FSIS Petition 05–07). The company stated that implementation of the second-tier sodium levels could cause the disappearance of whole categories of ''healthy'' food products from the market. The company explained that taste, food safety, and manufacturing issues preclude hotdogs, processed meats, and soups from being produced to meet consumers' expectations at a sodium level of 360 mg. According to the petition, at this sodium level, hot dogs fall apart, and processed meats have an unacceptable texture and reduced microbial protection. In addition, the company stated that market data and taste tests show that consumers will not eat these products when they contain no more than 360 mg of sodium. The company also stated that there are no viable salt substitutes currently on the market.

According to the company, consumers overall buy relatively few ''healthy'' products even at the present sodium levels utilized in the manufacture of products, and lowering the sodium levels of a product line that already has relatively low sodium levels, by 120 mg, will have no positive effect on public health. The company opined that the first-tier sodium levels in the ''healthy'' definition appear to have succeeded in lowering the overall sodium in foods since the rule's implementation. However, the company predicted that implementing the second-tier sodium levels could have the unintended consequence of forcing some products out of the marketplace. This result would leave higher sodium substitutes in the marketplace and, therefore, create an overall increase in sodium intake.

FDA Rule

On September 29, 2005, FDA amended its regulations concerning the maximum sodium levels permitted for foods that bear the implied nutrient content claim ''healthy.'' The Agency retained the less restrictive, first-tier sodium level requirements for all food categories, including individual foods (480 mg) and meals and main dishes (600 mg), and dropped the second-tier (more restrictive) sodium level requirements for all food categories. Based on comments received about technological barriers to reducing sodium in processed foods and poor sales of products that meet the second-tier sodium level, FDA determined that requiring the more restrictive sodium levels would likely inhibit the development of new ''healthy'' food products and risk substantially eliminating existing ''healthy'' products from the marketplace. After reviewing the comments and evaluating the data from various sources, FDA became convinced that retaining the first-tier sodium level requirements for all food products bearing the term ''healthy'' would encourage the manufacture of a greater number of products that were consistent with dietary guidelines for a variety of nutrients (70 FR 56828).

Control of Listeria Moncytogenes in Ready-to-Eat Products

On June 6, 2003, FSIS published an interim final rule that amended its regulations to require that official establishments that produce post-lethality exposed ready-to-eat (RTE) meat and poultry products meet the specific requirements of one of three alternatives for addressing *L. monocytogenes* (68 FR 34208). In Alternative 1, an establishment controls *L. monocytogenes* by using a post-lethality treatment of the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. In Alternative 2, an

establishment may choose to address *L. monocytogenes* by using a post-lethality treatment OR an antimicrobial agent or process that suppresses or limits the growth of the pathogen. In Alternative 3, an establishment may control *L. monocytogenes* in the post-lethality processing environment through sanitation procedures only.

Many of the antimicrobial agents used to control *L. monocytogenes* under Alternatives 1 and 2 are sodium containing agents such as sodium lactate, sodium diacetate, and sodium citrate. These agents usually affect sodium levels in foods. In the 2004 ConAgra Foods, Inc. petition, ConAgra explained that companies have consistently used sodium lactate or sodium lactate and diacetate blends to control *L. monocytogenes* in processed meats. The petition explains that these ingredients can be incorporated in product formulation to completely suppress the growth of *L. monocytogenes*. According to the company, potassium lactate may also be used to inhibit *L. monocytogenes*. This antimicrobial compromises the flavor of products, however, while the sodium containing antimicrobials minimize any adverse effects on products' tastes or other organoleptic properties.

Conclusion

In light of the interim final rule concerning *L. monocytogenes* controls and ConAgra Foods' 2004 petition to FSIS, FSIS has determined that it needs additional time to evaluate what levels of sodium in meat and poultry products are appropriately associated with the use of the term ''healthy'' on these products'' labeling and to fully consider all options that preserve the public health intent of establishing sodium content limitations while providing manufacturers with the opportunity to use the term in food labeling consistently with dietary guidelines. Moreover, FSIS needs, when appropriate, to have its labeling regulations be consistent with those promulgated by FDA. As is explained above, FDA amended its regulations to drop the second-tier sodium level requirements for all categories of ''healthy'' foods. At this time, FSIS has concluded that it would be contrary to the public interest to require manufacturers to comply with the second-tier sodium levels within the ''healthy'' definition by the codified effective date of January 1, 2006. Therefore, FSIS is amending the regulations to provide that the first-tier, less restrictive, sodium levels are effective indefinitely, until further notice.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This interim final rule is not intended to have retroactive effect.

If this interim final rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Executive Order 12866 and the Regulatory Flexibility Act

This interim final rule has been determined to be non-significant and was not reviewed by the Office of Management and Budget 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 needs time to complete its evaluation of the effects of further reducing the levels of the sodium content of meat and poultry products labeled as ''healthy'' to determine whether the costs of such an action exceed its benefits. There are data that support the belief that if the sodium content of foods labeled as ''healthy'' is required to be lowered it could result in fewer ''healthy'' foods being consumed or in consumers adding table salt to improve the palatability of the ''healthy'' products. In addition, data suggest that lack of available substitutes for sodium would impair the industry's ability to continue manufacturing ''healthy'' foods as currently defined, especially with the increased usage of antimicrobial agents that contain sodium to control *L. monocytogenes* in RTE meat and poultry products as a result of FSIS' June 6, 2003, interim final rule. Moreover, FSIS is taking this action so that its labeling regulations remain consistent with those promulgated by FDA. As is explained above, FDA amended its regulations to drop the second-tier sodium level requirements for all categories of ''healthy'' foods.

Waiver of Proposed Rulemaking

In accordance with the Administrative Procedures Act (5 U.S.C. 553), it is the practice of the Administrator to offer interested parties the opportunity to comment on proposed regulations. However, the extended effective date in this interim final rule does not establish any new rules. In addition, this interim final rule should be published in the **Federal Register** as soon as possible following January 1, 2006, because that is the current effective date for the second-tier sodium levels in the ''healthy'' definition regulations. Therefore, the Administrator has determined that publication of a proposed rule is impracticable and contrary to the public interest under 5 U.S.C. 553(b)(B). For the same reasons, the Administrator is waiving the 30-day delayed effective date under 5 U.S.C. 553(d).

Paperwork Requirements

There is no paperwork associated with this action.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Interim_&_Final_Rules_Index/index.asp*. The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or

Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection, Nutrition.

9 CFR Part 381

Food labeling, Nutrition, 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 follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

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

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

§ 317.363 [Amended]

■ 2. Section 317.363 is amended by:

■ A. Removing the phrases ''shall not contain more than 360 mg of sodium, except that it'' and ''effective through January 1, 2006,'' in paragraph (b)(3) introductory text;

■ B. Removing the phrases ''shall not contain more than 480 mg of sodium, except that it'' and ''effective through January 1, 2006,'' in paragraph (b)(3)(i); and

■ C. Adding a footnote 1 after ''serving size'' in paragraph (b)(3)(i) to read ''This regulation previously provided that, after January 1, 2006, individual meat products bearing the claim ''healthy'' (or any derivative of the term ''health'') must contain no more than 360 mg of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim ''healthy'' (or any derivative of the term ''health'') has been deferred indefinitely due to technological barriers and consumer preferences.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 3. The authority 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.

§ 381.463 [Amended]

■ 4. Section 381.463 is amended by:

■ A. Removing the phrases ''shall not contain more than 360 mg of sodium, except that it'' and ''effective through January 1, 2006,'' in paragraph (b)(3) introductory text;

■ B. Removing the phrases ''shall not contain more than 480 mg of sodium, except that it'' and ''effective through January 1, 2006,'' in paragraph (b)(3)(i); and

■ C. Adding a footnote 1 after ''serving size'' in paragraph (b)(3)(i) to read ''This regulation previously provided that, after January 1, 2006, individual poultry products bearing the claim ''healthy'' (or any derivative of the term ''health'') must contain no more than 360 mg of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim ''healthy'' (or any derivative of the term ''health'') has been deferred indefinitely due to technological barriers and consumer preferences.''

Done at Washington, DC, on: January 9, 2006.

Barbara J. Masters,

Administrator.

[FR Doc. 06–268 Filed 1–10–06; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30474; Amdt. No. 3149]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 11, 2006. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 11, 2006.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Ave, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169; or

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*