



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2019-0008]

Expansion of Use of the Term "Healthy"

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will allow establishments to use the implied nutrient content claim "healthy" on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D. FSIS is making this announcement to maintain consistent requirements for food labels by allowing the same uses of the claim "healthy" for meat and poultry products as are currently allowed for food products under the Food and Drug Administration's (FDA's) jurisdiction.

DATES: This notice is applicable **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

Hand- or Courier-Delivered Items: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2019-0008. Written comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 9-146, 1400 Independence Avenue SW., Washington, DC 20250-3700; Telephone (301) 504-0879; Fax (202) 245-4792.

SUPPLEMENTARY INFORMATION:

Background

FSIS is the public health regulatory agency in the USDA that is responsible for ensuring that the nation's commercial supply of meat and poultry products is safe, wholesome, and accurately labeled and packaged. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601-695, at 607) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451-470, at 457), the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce. The FMIA and PPIA also prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading (21 U.S.C. 601(n) and 607(d); 21 U.S.C. 453(h) and 457(c)).

FSIS Regulations for "Healthy" Claims

FSIS regulations (9 CFR 317.363(b) and 381.463(b) define the parameters for the use of the implied nutrient content claim "healthy" or any other derivative of the term "health" and similar terms on meat and poultry product labeling. The definitions establish specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, and sodium; and requirements for nutrients to encourage in the diet, including vitamin A, vitamin C, calcium, iron, protein, and fiber.

On May 10, 1994, FSIS published a final rule defining the term "healthy" that included new standards for sodium (59 FR 24220). FSIS created initial "first-tier" sodium standards, and "second-tier" sodium standards that would become more rigorous after a 24-month time period. After extending the first-tier sodium standards in the **Federal Register** (63 FR 7279, 64 FR 72490, and 68 FR 460), FSIS decided, in 2006, to indefinitely defer to the first-tier sodium standards (71 FR 1683). Consequently, FSIS continues to apply the original (first-tier) levels of sodium established in the 1994 regulation when approving labels for "healthy."

Recent Changes to Regulations and Policy

In December 2015, USDA and the U.S. Department of Health and Human Services (HHS) published the *2015-2020 Dietary*

Guidelines for Americans.¹ The Dietary Guidelines were designed for professionals to help all individuals consume a healthy and nutritionally-adequate diet. Specific recommendations in the Dietary Guidelines have evolved over time, as nutrition science has advanced. For example, scientific understanding and nutrition guidance has shifted from recommending diets low in total fat to recommending keeping overall fat intake within the age-appropriate acceptable macronutrient distribution ranges (AMDR), and instead prioritizing replacing saturated fats with polyunsaturated and monounsaturated fats and keeping trans fat intake as low as possible.

On May 27, 2016, FDA issued two final rules updating the Nutrition Facts label and serving size information for packaged foods(81 FR 33742 and 81 FR 34000). The above-mentioned *2015-2020 Dietary Guidelines for Americans* served as the scientific basis for these two FDA final rules that included changes in the individual nutrients that must be declared on the Nutrition Facts label and changes to the DV of other individual nutrients. The changes reflected the most recent nutrition and public health research and recent dietary recommendations from expert groups. These rules also improved the presentation of nutrition information on the Nutrition Facts label to help consumers make

¹ https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf

more informed choices and maintain healthy dietary practices. Consistent with FDA's final rules, FSIS has proposed to change its nutrition labeling regulations (82 FR 6732). In November 2016, FSIS published a **Federal Register** notice allowing FSIS products to voluntarily adopt the FDA Nutrition Facts label format (81 FR 80631). The notice explained that at least one label sketch with the FDA nutrition format must be submitted to FSIS before that format could be generically approved for other products.

On September 28, 2016, FDA announced in the **Federal Register** that it was requesting comments on the use of the term "healthy" in the labeling of human food products (81 FR 66562). According to this **Federal Register** notice, FDA published the notice in accordance with the FDA Foods and Veterinary Medicine Program's 2016-2025 Strategic Plan and in response to a citizen petition requesting that FDA update the nutrient content claim regulations to be consistent with current Federal dietary guidance. Specifically, FDA's notice stated that the petitioner requested that the Agency amend the regulation defining "healthy" as it relates to total fat intake and to emphasize whole food and dietary patterns rather than specific nutrients.

Additionally, in the same **Federal Register** publication, FDA announced the availability of a guidance document for industry entitled "Use of the Term 'Healthy' in the Labeling of

Human Food Products: Guidance for Industry" (81 FR 66527). According to FDA, the science supporting public health recommendations for the intake of various nutrients had evolved, as evidenced in the *2015-2020 Dietary Guidelines*. FDA also announced the Agency's intention to temporarily exercise enforcement discretion with respect to some of the criteria for bearing the implied nutrient content claim "healthy" until 21 CFR 101.65(d)(2) is amended through rulemaking.

In the **Federal Register** notice, FDA explained that it intended to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim "healthy" meet the low-fat requirement provided that: (1) the amounts of mono- and polyunsaturated fats are declared on the label; and (2) the amounts of mono- and polyunsaturated fats declared constitute most of the fat content.

FDA also stated, in the notice, that it intends to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim "healthy" contain at least ten percent of the DV per RACC of vitamin A, vitamin C, calcium, iron, protein, or fiber, if the food instead contains at least ten percent of the DV per RACC of potassium or vitamin D. FDA's guidance document is available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf>.

FSIS's Policy

To maintain consistent requirements for food labels, FSIS has used its enforcement discretion to allow the same uses of the claim "healthy" for meat and poultry products as are allowed for food products under FDA jurisdiction under FDA's 2016 guidance. There are few labels that qualify for the "healthy" claim under the allowances in this notice that wouldn't qualify otherwise. According to FSIS's Label Submission and Approval System (LSAS)² data, the types of products utilizing FDA's guidance for the claim "healthy" are mostly products that meet the definition of meal-type in 317.313(1)/381.413(1). Egg product labels are not affected by this policy because FSIS inspected egg products are required by regulation to use the FDA nutrition requirements in 21 CFR part 101 in compliance with 9 CFR 590.411(e) - as such, egg product labeling follows the FDA nutrition panel and the FDA enforcement discretion even though FSIS's Labeling and Program Delivery Staff (LPDS) reviews and approves FSIS inspected egg product label applications. Because FSIS has received multiple questions from industry about our policy, FSIS is announcing in this **Federal Register** notice that it will continue to recognize FDA's 2016 guidance to alleviate consumer confusion and promote uniformity in the marketplace.

² FSIS's Label Submission and Approval System (LSAS) is a web-based software application that integrates and implements an electronic label application process for establishments to submit label applications to FSIS.

Specifically, FSIS has allowed and will continue to allow the implied nutrient content claim "healthy" on foods that have a fat profile of predominantly mono and polyunsaturated fats (i.e. sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food), but do not meet the regulatory definition of "low fat," as specified in 9 CFR 317.363(b)(1)/381.463(b)(1) or that contain at least ten percent of the DV per RACC of potassium or vitamin D as one of the options in 9 CFR 317.363(b)(4) and 381.463(b)(4), provided the remaining criteria for healthy in 9 CFR 317.363 and 381.463 have been met.

FSIS's LPDS has reviewed many proposed labels referencing FDA's "healthy" notice, and most have contained errors and needed correction. If a company wishes to use FDA's "healthy" claim, they will first need to submit at least one label sketch to LPDS for approval.

A corporation's parent-company only needs to submit one label application for a product produced in multiple establishments that are owned by the corporation. Subsequent similar labels for other products that use FDA's "healthy" claim can be generically approved. Submitting one label and receiving approval helps ensure that the rest of the labels are in compliance with FDA and FSIS regulations. Labels using the modified "healthy" claim must be submitted to LPDS in the new FDA nutrition panel format.

FSIS will continue to allow the use of implied nutrient content claim "healthy" on foods that have a fat profile of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food), but do not meet the regulatory definition of "low fat," as specified in 9 CFR 317.363(b)(1) and 381.463(b)(1) or that contain at least ten percent of the DV per RACC of potassium or vitamin D as one of the options in 9 CFR 317.363(b)(4) and 381.463(b)(4), provided the remaining criteria for healthy in 9 CFR 317.363 and 381.463 have been met until FSIS's "healthy" regulations (9 CFR 317.363(b) and 381.463(b)) are amended through rulemaking. FSIS will continue to coordinate with FDA on any changes to these regulations.

Additional Public Notification:

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our

constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through 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 automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

USDA Nondiscrimination Statement:

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination, any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination:

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at:

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC.

Paul Kiecker,

Administrator.

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