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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 381, and 412

[Docket No. FSIS-2016-0021]

Food Safety and Inspection Service labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Guidance.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of the Agency's compliance guideline on documentation needed to support animal-raising claims on product labels that must be submitted for Agency approval before they can be used on product labels. The updated guideline reflects FSIS's current position and procedures for reviewing animal-raising claims and includes explanations of animal-raising claims that FSIS may approve and the types of supporting documentation that the Agency requires to be submitted to support these claims.

DATES: Submit Comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: A downloadable version of the compliance guideline is available to view and print at

<http://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES> once copies of the guideline have been published.

FSIS invites interested persons to submit comments on this guidance. Comments may be submitted by one 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. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-0021. 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 to comment received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

For Further Information Contact: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

A federally inspected meat or poultry establishment is required to use labels that are in compliance with the Federal Meat Inspection Act (FMIA; 21 U.S.C. § 601 et seq., 607), the Poultry Products Inspection Act (PPIA; 21 U.S.C. § 451 et seq., 457), and the implementing regulations. Requirements include all mandatory labeling requirements as prescribed in Title 9 of the Code of Federal Regulations section 317.2 and 381 Subpart N.

All labels with special claims, including animal-raising claims, need to be submitted to FSIS prior to being used on the product under 9 CFR 412.1(c)(3). As with all labels with special claims, labels with animal-raising claims must be submitted to the Labeling and Program Delivery Staff, Office of Policy and Program Development in FSIS with specific documentation to support all such claims that appear on that label. Examples of animal-raising claims include, but are not

limited to: "Raised Without Antibiotics," "Organic," "Grass-Fed," "Free-Range," and "Raised without the use of hormones."

For most animal-raising claims, the documentation typically needed to support these claims includes:

1. A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the claim;

2. A signed and dated document describing how the animals are raised (e.g., vegetarian-fed, raised without antibiotics, grass-fed), to support that the specific claim made is truthful and not misleading;

3. A written description of the product-tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;

4. A written description for the identification, control, and segregation of non-conforming animals or products; and

5. If a third party certifies a claim, a current copy of the certificate.

FSIS previously issued a compliance guideline on animal-raising claims in 2002. The changes included in this version of the guideline include definitions for frequently used animal-

raising claims, the detailed supporting documentation required for each specific claim that appears on the label, additional information regarding the claim *grass fed*, information required for duplicating raising claims from purchased product, and examples of labels bearing claims.

This guideline represents FSIS's current position and procedures for approving animal-raising claims, and although FSIS is requesting comments on this guideline and may update it in response to comments, FSIS encourages establishments that wish to submit request for approvals of animal raising claims on product labels to begin using this guideline.

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 also will make copies of this publication available 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 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 email 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.

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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 on: September 29, 2016

Alfred V. Almanza,
Acting Administrator.

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