

# Notices

Federal Register

Vol. 73, No. 198

Friday, October 10, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS-2008-0026]

#### Product Labeling: Use of the Animal Raising Claims in the Labeling of Meat and Poultry Products

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is issuing this notice to initiate a public process to review its policies regarding the approval of animal raising claims in the labeling of meat and poultry products. FSIS evaluates animal raising claims by considering information on animal production practices submitted by companies as part of their label approval requests. The Agency approves these claims if the animal production information submitted with the label application supports the claims being made and the claim is truthful and not misleading.

The Agency's recent experience with labeling claims related to the raising of poultry have led FSIS to initiate a review of its evaluation and approval process for labels of meat and poultry products that contain animal raising claims. The Agency is publishing this notice to solicit public input and to announce that FSIS and the Agricultural Marketing Service will jointly hold a public meeting to discuss these issues.

**DATES:** The public meeting will be held on October 14, 2008. Comments on this notice and the issues discussed at the public meeting must be received by November 14, 2008.

**ADDRESSES:** The public meeting will be held from 8:30 a.m. to 12:30 p.m. at the L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024, (202) 484-1000.

FSIS will finalize an agenda on or before the meeting date and will post it on the FSIS Internet Web page [http://www.fsis.usda.gov/News?Meetings\\_&Events/](http://www.fsis.usda.gov/News?Meetings_&Events/).

The official transcript of the meeting will be available for viewing by the public in the FSIS docket room and on the FSIS Web site [http://www.fsis.usda.gov/News?Meetings\\_&Events/](http://www.fsis.usda.gov/News?Meetings_&Events/) when it becomes available.

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

Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, FSIS Docket Room, 1400 Independence Avenue, SW., Room 2534, Washington, DC 20250.

All submissions received must include the Agency name and docket number FSIS-2008-0026. Documents referred to in this notice, and all comments submitted in response to this notice, 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, except Federal holidays. Comments also will be posted on the Agency's Web site at [http://www.fsis.usda.gov/regulations\\_&policies/2008\\_Notices\\_Index/index.asp](http://www.fsis.usda.gov/regulations_&policies/2008_Notices_Index/index.asp).

Individuals who do not wish FSIS to post their personal contact information—mailing address, e-mail address, telephone number—on the Internet may leave this information off of their comments.

**FOR FURTHER INFORMATION CONTACT:** For technical information: Charles Gioglio, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, USDA, FSIS, 1400 Independence Avenue, SW., Washington, DC 20250, (202) 205-3625, e-mail: [Charles.Gioglio@fsis.usda.gov](mailto:Charles.Gioglio@fsis.usda.gov).

Pre-registration for this meeting is recommended. To pre-register, please contact Sheila Johnson by telephone at (202) 690-6498 or by e-mail at [Sheila.Johnson@fsis.usda.gov](mailto:Sheila.Johnson@fsis.usda.gov). Persons requiring a sign language interpreter or

special accommodations should contact Sheila Johnson as soon as possible.

#### 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, poultry, and egg products is safe, wholesome, and accurately labeled and packaged. FSIS develops and implements regulations and policies to ensure that meat, poultry, and egg product labeling is truthful and not misleading. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, 607) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, 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.

Section 203(c) of the Agricultural Marketing Act (AMA) of 1946, as amended (7 U.S.C. 1622), directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices." The Agricultural Marketing Service (AMS) has played a lead role in achieving the objectives of the AMA in part through the development of voluntary standards for agricultural products.

As part of its prior approval process for label claims, FSIS has been asked to evaluate and approve label claims that highlight certain aspects of the way animals used as the source for meat and poultry products are raised. Examples of animal raising claims that the Agency has approved include "raised without antibiotics," "not fed animal by-products," "free range," "vegetarian fed diet," and "raised without added hormones." FSIS typically evaluates such claims by reviewing testimonials, affidavits, animal production protocols, and other relevant documentation provided by animal producers.

When FSIS evaluates a meat or poultry product label that includes an animal raising claim, it reviews the animal production protocol submitted in support of the label claim to ensure that it describes practices that are accurately reflected in the claim being made. Supporting documentation may

be submitted directly by the establishment seeking approval of the label or by producers, growers, or others on the establishment's behalf. If a company submits information that demonstrates that an animal production claim is truthful and not misleading, FSIS allows products derived from animals raised according to the protocol to bear the raising claim on their labels.

In addition to producer testimonials and affidavits, establishments or animal producers may also submit certifications from a certifying organization or entity to support animal raising claims. FSIS accepts these certifications if the Agency has evaluated the certifying entity's animal raising standards and determined that they are truthful and not misleading and accurately reflect the claim being made. FSIS also allows the label of a meat or poultry product to bear a certified claim if the claim clearly identifies the certifying entity, e.g., "certified free range by \* \* \* (name of certifying entity)," and the Agency determines, based on its review of the entity's standards, that the standards truthfully define the claim. FSIS makes this determination in consultation with AMS and other agencies with relevant expertise.

#### Issues Associated With Animal Raising Claims

It has become clear, however, that the use of animal raising claims in the labeling of meat and poultry products presents issues that can be difficult for FSIS to address through its pre-market label approval process.

As discussed above, FSIS assesses animal raising claims by evaluating supporting documentation that companies submit as part of their label approval requests. However, because FSIS does not regulate food animal production, the Agency may not always have all the relevant information necessary to the proper evaluation of the animal raising practices described in a producer's animal production protocol.

In addition, while FSIS' approval of an animal raising claim depends on submissions that describe how the source animals were raised, animal producers and certifying entities may have different views on the specific animal production practices that qualify a product to bare a given animal raising claim on its label. Thus, the same animal raising claim may reflect different animal raising practices, depending on how an animal producer or certifying entity defines the basis for the claim.

For example, FSIS approves "free range" raising claims on the labels of poultry products if the producer

demonstrates that the birds were allowed continuous, free access to the outside for over 51% of their lives through a normal growing cycle. Under this standard, some producers or certifying organizations may support a "free range" labeling claim if the source birds for the poultry products were allowed access to a yard outside, regardless of whether the birds actually use the yard. On the other hand, other producers or certifying entities may establish stricter standards for themselves and request that FSIS approve a "free range" claim only if the source birds actually use the yard.

As with animal producers and certifying entities, consumers often have a wide variety of views regarding the meaning of specific animal raising claims.

#### Policy Review and Public Meeting

FSIS has decided to initiate a review of its policies for evaluating and approving animal raising claims on labels. FSIS will carry out this policy review in cooperation with AMS.

To facilitate this review, FSIS is publishing this **Federal Register** notice to solicit public input on ways to improve the Agency's label approval policies and practices with respect to raising claims and to continue to ensure that approved labels are truthful and not misleading.

In addition, FSIS and AMS will hold a public meeting on October 14, 2008, to discuss the development, evaluation, and proposed process for animal raising claims. FSIS is collaborating with AMS on these issues because AMS has taken a lead in establishing voluntary standards and in developing programs, such as Quality System Verification Programs (QSVPs) to verify or certify marketing claims that relate to animal raising practices.

#### Certification by Certifying Entities, Request for Comments

The use of animal raising claims in the labeling of meat and poultry products is an important issue for members of the industry that want to use these claims to differentiate their meat or poultry products from other similar products in the marketplace. It is also an important issue for consumers that prefer to purchase products derived from animals raised under certain conditions.

FSIS wants to ensure that its policies for evaluation and approval of animal raising claims will create a level playing field for companies that want to use such claims in marketing their products and that will allow consumers to use

animal raising claims information to assist in their purchase decisions.

One approach under consideration is to rely on outside certifying entities. A certifying entity would evaluate a company's animal production protocol to determine whether those practices meet the certifying entities standards for certifying the claim. The certifying entity would define and publish its standards. FSIS would review the certifying entities standards to determine whether they would in any way render the claim false or misleading. For example, poultry "raised without antibiotics" claims certified by a certifying entity whose standards covered only on the period post-hatch, and allowed the administration of antibiotics *in ovo* would be considered misleading by the Agency and not approved for label use.

The certifying entity would also conduct audits to verify that the animals used as the source for meat and poultry products bearing the raising claims were raised according to those standards. Companies interested in using animal raising claims in the labeling of their meat or poultry products would submit documentation of the certification as part of their label approval requests.

If FSIS were to adopt this approach, companies could use the services of a private certifying entity or request that USDA's AMS establish a voluntary audit-based program on specific animal raising claims. For example, AMS's Livestock and Seed (LS) Program offers verification services through QSVPs to substantiate claims that cannot be determined by direct examination of livestock, their carcasses, or component parts, thus allowing the product to be labeled as "Verified by USDA" (<http://www.ams.usda.gov/ARCAudits>). One specific QSVP is the USDA Process Verified Program, which allows a supplier to make marketing claims about feed practices or other raising practices, and then label and market their product as "USDA Process Verified".

FSIS and AMS are interested in comments on the use of certification provided by certifying entities to verify animal raising claims and other possible approaches for approving the use of such claims in the labeling of meat and poultry products. The agencies plan to discuss this and the other issues related to animal raising claims at the October 14, 2008, public meeting.

The agencies are interested in public input on the following questions concerning the use of certifying entities in evaluating and approving animal raising claims in the labeling of meat and poultry products.

1. Should FSIS continue to approve label claims based on animal raising standards developed by private certifying entities and by companies themselves if FSIS has reviewed the standards and determines that they would not render a claim false or misleading?

2. Should FSIS establish any performance criteria or standards for private certifying entities? Should the Agency require that private certifying entities be reviewed and approved by AMS?

3. Should FSIS establish minimum standards that companies would have to achieve to qualify to use certain animal raising claims?

4. For those animal raising claims for which AMS has adopted standards, should FSIS adopt the AMS standards as the minimum standards?

5. Would the approach outlined in this document create any inequities or create any problems for companies interested in using animal raising claims on the labels of their meat or poultry products?

6. What other approaches should FSIS consider for evaluating and approving animal raising claims?

#### 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 notice, FSIS will announce it on-line through the FSIS Web page located at [http://www.fsis.usda.gov/regulations\\_&\\_policies/2008\\_Notices\\_Index/index.asp](http://www.fsis.usda.gov/regulations_&_policies/2008_Notices_Index/index.asp).

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, 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 automatic and customized access to selected food safety news and

information. This service is available at [http://www.fsis.usda.gov/news\\_and\\_events/email\\_subscription/](http://www.fsis.usda.gov/news_and_events/email_subscription/).

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.

Done at Washington, DC, on: October 7, 2008.

**Alfred V. Almanza,**  
Administrator.

[FR Doc. E8-24191 Filed 10-7-08; 4:15 pm]

**BILLING CODE 3410-DM-P**

## DEPARTMENT OF AGRICULTURE

### Food Safety Inspection Service

[Docket No. FSIS 2008-0035]

#### Sampling and Testing Procedures for *Escherichia coli* O157:H7 in Beef Manufacturing Trimmings

**AGENCY:** Food Safety and Inspection Service (FSIS), USDA.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is announcing that it will hold a public meeting on October 14 and 15, 2008, to discuss sampling and testing procedures used by FSIS and industry for *Escherichia coli* (*E. coli*) O157:H7 in beef manufacturing trimmings and draft guidance to industry concerning this pathogen. Copies of the guidance materials are available on the FSIS Web site.

**DATES:** The public meeting will be held on October 14 and 15, 2008.

**ADDRESSES:** The public meeting will be held from 1 p.m. to 4:30 p.m. on October 14 and from 8:30 a.m. to 4 p.m. on October 15 at: L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024, (202) 484-1000. FSIS invites interested persons to submit comments on the issues addressed at the public meeting. FSIS will finalize an agenda on or before the meeting date and will post it on the FSIS Web page [http://www.fsis.usda.gov/News?Meetings\\_&\\_Events/](http://www.fsis.usda.gov/News?Meetings_&_Events/). The official transcript of the meeting will be available for viewing by the public in the FSIS Docket Room and on the FSIS Web site [http://www.fsis.usda.gov/News?Meetings\\_&\\_Events/](http://www.fsis.usda.gov/News?Meetings_&_Events/) when it becomes available.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, FSIS Docket Room, 1400 Independence Avenue, SW., Room 2534, Washington, DC 20250.

All submissions received must include the Agency name and docket number FSIS-2008-0035. Documents referred to in this notice, and all comments submitted in response to this notice 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, except Federal holidays. Comments also will be posted on the Agency's Web site at [http://www.fsis.usda.gov/regulations\\_&\\_policies/2008\\_Notices\\_Index/index.asp](http://www.fsis.usda.gov/regulations_&_policies/2008_Notices_Index/index.asp).

Individuals who do not wish FSIS to post their personal contact information—mailing address, e-mail address, telephone number—on the Internet may leave this information off of their comments.

**FOR FURTHER INFORMATION CONTACT:** Pre-registration for this meeting is recommended. To pre-register, go to the FSIS Web site at [http://www.fsis.usda.gov/News\\_&\\_Events/Reg\\_Ecoli\\_101408/index.asp](http://www.fsis.usda.gov/News_&_Events/Reg_Ecoli_101408/index.asp).

For additional information, please contact Keith Payne by telephone at (202) 690-6522 or by e-mail at [keith.payne@fsis.usda.gov](mailto:keith.payne@fsis.usda.gov). Persons requiring a sign language interpreter or special accommodations should contact Keith Payne as soon as possible.

#### SUPPLEMENTARY INFORMATION:

##### Background

The presence of *E. coli* O157:H7 in raw beef products continues to be a concern to FSIS. Based on *E. coli* O157:H7 test results from FSIS, other Federal and State entities, and industry, *E. coli* O157:H7 continues to contaminate finished product. Controls in food safety systems, including sanitary dressing procedures, do not consistently prevent, eliminate, or reduce *E. coli* O157:H7 to an undetectable level. Therefore, testing may be a means to ensure that contaminated product does not enter commerce. The meeting will focus on sampling and testing of beef manufacturing trimmings for *E. coli* O157:H7.

##### Issues To Be Discussed at the Public Meeting

FSIS will discuss the issues associated with the uniformity and