

**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service****9 CFR Parts 317 and 381**

[Docket No. FSIS-2008-0027]

RIN 0583-AD38

**Mandatory Country of Origin Labeling of Muscle Cuts of Beef (Including Veal), Lamb, Chicken, Goat, and Pork; Ground Beef, Ground Lamb, Ground Chicken, Ground Goat, and Ground Pork**

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Affirmation of interim final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is affirming, without change, its interim final rule requiring a country of origin statement on the label of any meat or poultry product that is a covered commodity, as defined by the Agricultural Marketing Service (AMS), and that is to be sold by a retailer, also as defined by AMS, in accordance with the regulations set out in AMS' final rule, "Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts." FSIS is also affirming, without change, the provisions of the interim final rule that amended its regulations to provide that it will consider the addition of compliant country of origin statements to the labels of covered meat or poultry products to be generically approved. FSIS is thus conforming its regulations to the AMS final rule. FSIS is not amending its regulations or labeling policies for meat or poultry products that are non-covered commodities.

**DATES:** This final rule is effective on March 20, 2009.

**FOR FURTHER INFORMATION CONTACT:** Rosalyn Murphy-Jenkins, Acting Director, Labeling and Program Delivery Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0279.

**SUPPLEMENTARY INFORMATION:****FSIS' Interim Final Rule**

On August 28, 2008 (73 FR 50701), FSIS published an interim final rule conforming its regulations to the AMS interim final country of origin labeling (COOL) rule, published August 1, 2008 (73 FR 45106). As FSIS explained in its interim final rule, the Farm Security and Rural Investment Act of 2002 (Section 10816 of Public Law 107-171) and the Food, Conservation and Energy Act of

2008 (Section 11002 of Public Law 110-246) amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*) to require that retailers notify their customers of the country of origin of covered commodities. Under the law, covered commodities include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; as well as other non-meat covered commodities.

The law defines "retailer" as having the meaning given that term in section 1(b) of the Perishable Agricultural Commodities Act of 1930 (PACA) (7 U.S.C. 499 *et seq.*). In addition, the law states that any person engaged in the business of supplying a covered commodity to a retailer shall provide information to the retailer about the country of origin of the covered commodity.

The law exempts covered commodities from mandatory COOL if they are ingredients in processed foods. The law also prescribes specific criteria that must be met for a covered commodity to bear a "United States country of origin" declaration. Furthermore, the law requires that country of origin labeling for ground beef, ground lamb, ground pork, ground goat, and ground chicken include a list of all the countries of origin contained therein or reasonably contained therein.

The Agricultural, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2006 (Pub. L. 109-97) delayed the applicability of mandatory COOL for all covered commodities except wild and farm-raised fish and shell fish until September 30, 2008. Therefore, FSIS' interim final COOL regulations were effective September 30, 2008. The requirements of the interim final rule did not apply to meat or poultry product covered commodities produced or packaged before September 30, 2008. FSIS' interim final rule remains in effect until this final rule becomes effective.

**AMS Final Rule**

AMS's final COOL regulations were published on January 15, 2009 (74 FR 2658). The preamble to AMS final COOL regulations summarizes the contents of the final rule and highlights changes from the interim final rule.

AMS made two changes to the definitions of meat product covered commodities in 7 CFR part 65, subpart A. AMS changed the definition of "ground beef" in the final rule in response to comments. The revised definition excludes "beef patties," as defined in 9 CFR 319.15(c), from the definition of "covered commodity."

Under AMS' final rule, the term "ground beef" includes products defined in 9 CFR 319.15(a), *i.e.*, chopped fresh or frozen beef, with or without seasoning and without the addition of beef fat as such, containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders. The term "ground beef" also includes products defined by the term "hamburger" in 9 CFR 319.15(b) (7 CFR 65.155).

In response to comments, AMS also changed the definition of "lamb" in the final rule to include mutton. Under AMS' final rule, the term "lamb" means meat produced from sheep (7 CFR 65.190).

AMS' country of origin regulations in 7 CFR 65.300 include requirements for labeling covered commodities of United States origin (7 CFR 65.300(d)). AMS' interim final rule contained a provision allowing U.S. origin covered commodities to be further processed or handled in a foreign country and to retain their U.S. origin. In response to comments, AMS deleted this provision. To the extent that it is allowed under existing Department of Homeland Security Customs and Border Protection (CBP) or FSIS regulations, U.S. origin covered commodities may still be eligible to bear a U.S. origin declaration if they are processed in another country such that a substantial transformation (as determined by CBP) does not occur. Below, FSIS has included a discussion of the effect of the COOL regulations on U.S. meat and poultry products exported for processing.

The effective date of AMS's January 15, 2009, final regulation is March 16, 2009. In its final rule, AMS explained that it had provided a six month education and outreach period following the effective date of its interim final rule to allow the regulated industries to adapt to the changes in its COOL regulations. AMS provided in its final rule that this period of education and outreach would continue through March 2009.

**FSIS Final Rule**

This final rule will conform its final rule to AMS' final rule. In this final rule, FSIS made no changes to its interim final rule in response to comments. Therefore, consistent with FSIS' interim final rule, FSIS is amending 9 CFR 317.8(b) and 381.129 to require that a country of origin statement on the label of a meat or poultry product that is a "covered commodity," as defined in 7 CFR part 65, subpart A, that is to be sold by a "retailer," as defined in 7 CFR 65.240, comply with the country of origin notification and markings

requirements in 7 CFR 65.300 and 65.400.

Also, consistent with its interim final rule, FSIS is amending its generic approval labeling regulations (9 CFR 317.5 and 381.133) to specify that the addition of country of origin statements on the labels of meat or poultry product covered commodities that are to be sold by retailers and that comply with COOL requirements will be considered to be generically approved. FSIS is providing that such country of origin statements will be generically approved to facilitate implementation of COOL. Under the Federal meat and poultry products inspection regulations, country of origin statements on non-covered meat or poultry products generally are not generically approved labeling. FSIS generally considers country of origin statements on non-covered commodities to be special claims that require sketch approval from FSIS (9 CFR 317.4 and 381.132).

The Federal meat and poultry product inspection regulations require country of origin statements on the immediate containers of imported products (9 CFR 327.14 and 381.205). These regulations require that the country of origin statement be immediately under the name or descriptive designation of the product. AMS' final regulations do not affect these requirements.

This action is authorized under the Federal Meat Inspection Act and the Poultry Products Inspection Act and is consistent with the Agricultural Marketing Act of 1946.

The AMS final rule was effective March 16, 2009. Because it is important that AMS and FSIS have consistent regulations, the Administrator has determined under 5 U.S.C. 533 that it is in the public interest to make this final rule effective on the date of publication. Making this rule effective on the date of publication is in the public interest because it will minimize confusion among industry and consumers. For this reason, FSIS's final rule will be effective on the date of publication.

#### Responses to Comments

FSIS received 33 comments in response to the interim final rule. Several commenters supported FSIS conforming its regulations to AMS' regulations and supported FSIS providing for generic approval of country of origin statements that comply with AMS' regulations.

Many of the comments raised issues concerning the requirements and effects of AMS' interim final COOL regulations, including recordkeeping requirements, acceptable abbreviations, costs and benefits, international effects, and

health effects. These comments were directed to the AMS interim final regulations, did not specifically address FSIS' interim final rule, and are considered to be outside the scope of this rulemaking. Furthermore, AMS has addressed the issues these comments raised in the preamble to its final rule. Therefore, FSIS has not responded to these comments in the discussion below.

*Comments:* Many of the comments recommended that COOL be required on all products, including processed food products.

*Response:* The COOL statute specifically defines the commodities covered by the mandatory COOL program. The COOL statute specifically exempts covered commodities from mandatory COOL if they are an ingredient in a processed food item. These comments are outside the scope of this FSIS rulemaking.

*Comments:* One company recommended more guidance on what is considered a "processed food item." Specifically, the commenter questioned whether FSIS generic approval for COOL will be available when the product is marinated, enhanced or injected with tenderizers such as papain, bromelain, or ficin or with ingredients such as lemon juice concentrates, chicken broth, dried beef stock, natural flavor and spices.

*Response:* AMS' final rule defines a "processed food item" as a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one other covered commodity or other substantive food component (e.g., chocolate, breading, tomato sauce). The "processed food item" definition also provides that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item (7 CFR 65.220). Furthermore, in the preamble to its final rule, AMS stated that enhancement with enzymatic tenderizers, such as ficin and bromelain, do not by themselves change the character of the covered commodity. Therefore, the use of the ingredients listed in the comment would not, by themselves, result in a covered commodity becoming a processed food item. Based on AMS' regulations, if an establishment used such ingredients in a covered commodity and did not process the product in a way that resulted in a change in the character of the product, the product would continue to be a covered commodity. In

this situation, the required compliant country of origin statements on the product label could be generically approved.

*Comments:* One commenter questioned whether FSIS or another Federal agency would use a COOL noncompliance as a basis to recall product.

*Response:* AMS provided a six month education and outreach period following the effective date of its interim final COOL regulations. As FSIS explained in a notice to inspection program personnel, FSIS will follow AMS enforcement policy during this same period. After this period has elapsed, if noncompliance with COOL regulations is disclosed on meat or poultry product labeling, FSIS will consult with AMS and consider appropriate enforcement action. If FSIS enforcement action is necessary, FSIS will consider rescinding label approval (9 CFR 500.8), requesting a recall, or taking such other enforcement action as is appropriate in light of the facts involved in the particular situation.

*Comments:* One industry association recommended that FSIS work with AMS to convey information concerning COOL requirements. The commenter also recommended that FSIS provide additional guidance on COOL as it relates to FSIS' labeling requirements.

*Response:* FSIS will continue to consult closely with AMS concerning COOL requirements. FSIS is working with AMS to develop additional COOL guidance for meat and poultry establishments.

*Comments:* One commenter questioned whether establishments can use up existing label stocks or are required to have new labels printed immediately to be compliant with the COOL rule.

*Response:* AMS' and FSIS' final rules do not require that covered commodities be individually labeled with COOL information. Retailers can use placards and other signage to convey origin information.

*Comments:* One commenter questioned how beef trim co-mingled from different countries is to be labeled when it leaves the establishment.

*Response:* As is noted above, the establishment is not required to label the product. Rather, in this situation, the establishment is required to make available to the purchasers of the trim information about the countries of origin of the beef trim (7 CFR 65.500(b)).

#### COOL for U.S. Products Exported for Processing

In addition to the comments discussed above, an industry association

has questioned how United States origin meat or poultry products that are exported to a foreign country for processing prior to re-importation back to the United States should be labeled under the final COOL regulations. To the extent that existing CBP or FSIS regulations allow for products that have been minimally processed in a foreign country to reenter the United States as "Product of the U.S.," nothing in the AMS final rule precludes this practice.

It should be noted, however, that FSIS meat and poultry product inspection regulations require country of origin statements on the immediate containers of imported products (9 CFR 327.14 and 381.205). Therefore, if a U.S. country of origin meat or poultry product is transported to be minimally processed (e.g., marinated) in Canada prior to re-importation back to the United States, the immediate containers of the finished product would have to be labeled with the statement, "product of Canada." Notwithstanding this requirement, FSIS regulations allow such product to be repackaged for sale at retail. If such product is repackaged for sale at retail, the retailer could provide labeling indicating that the product is of U.S. origin if the product otherwise meets the criteria in 7 CFR 65.260.

#### Executive Order 12988

This final rule has been reviewed under the Executive Order 12988, Civil Justice Reform. Under this final rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

#### Executive Order 12866 and the Regulatory Flexibility Act

This final rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB). All costs and benefits associated with this rule are accounted for in AMS' final rule economic analysis.

#### Effect on Small Entities

AMS' final rule includes a final regulatory flexibility analysis. AMS believes that its regulations will have a significant economic impact on a substantial number of small entities. FSIS' conforming regulations will not have any additional impact on small entities.

#### Paperwork Reduction Act

AMS' final rule includes an estimate of the annual recordkeeping burden associated with COOL requirements. FSIS' final rule has been reviewed under the Paperwork Reduction Act and imposes no additional paperwork or recordkeeping requirements.

#### Government Paperwork Elimination Act (GPEA)

FSIS is committed to compliance with the GPEA, which requires Government agencies, in general, to provide the public the option of communicating electronically with the government to the maximum extent possible. The Agency will ensure that all forms used by the establishments are made available electronically.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce it online through the FSIS Web page located at [http://www.fsis.usda.gov/Regulations\\_&Policies/2009\\_Interim\\_&Final\\_Rules\\_Index/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/2009_Interim_&Final_Rules_Index/index.asp). FSIS will also 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 constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and 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 accounts.

#### List of Subjects

##### 9 CFR Part 317

Food labeling, Meat inspection.

##### 9 CFR Part 381

Food labeling, Poultry and poultry products.

■ For the reasons discussed in the preamble, FSIS adopts the interim rule published August 28, 2008 (73 FR 50701) as final without change.

Done in Washington, DC, on March 17, 2009.

Alfred V. Almanza,  
Administrator.

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## DEPARTMENT OF ENERGY

### 10 CFR Part 820

#### RIN 1990-AA30

#### Procedural Rules for DOE Nuclear Activities

**AGENCY:** Office of Health, Safety and Security, Department of Energy.

**ACTION:** Final rule.

**SUMMARY:** The Department of Energy (DOE) is today publishing a final rule to amend its Procedural Rules for DOE Nuclear Activities at Part 820 to be consistent with section 610 of the Energy Policy Act of 2005, Public Law 109-58 (EPAct of 2005), signed into law by President Bush on August 8, 2005. Section 610 amends provisions in section 234A. of the Atomic Energy Act of 1954 (AEA) concerning civil penalty assessments against certain DOE contractors, subcontractors and suppliers. Specifically, this final rule revises DOE regulations at section 820.20 to be consistent with the changes under section 610 of the EPAct of 2005.

**DATES:** *Effective Date:* This rulemaking is effective on April 20, 2009.

**FOR FURTHER INFORMATION CONTACT:** John S. Boulden III, Acting Director (HS-40), Office of Enforcement, Office of Health, Safety and Security, U.S. Department of Energy, 19901 Germantown Road, Germantown, Maryland 20874, (301) 903-2178; or Sophia Angelini, Attorney Advisor (GC-52), Office of the General Counsel, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585, (202) 586-6975.

#### SUPPLEMENTARY INFORMATION:

- I. Background
- II. DOE's Response to Comments
- III. Procedural Requirements
  - A. Review Under Executive Order 12866