

**DEPARTMENT OF AGRICULTURE****Agricultural Marketing Service****7 CFR Part 65**

[Docket No. AMS-LS-07-0081]

RIN 0581-AC26

**Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts****AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Interim final rule with request for comments.

**SUMMARY:** The Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), the 2002 Supplemental Appropriations Act (2002 Appropriations), and the Food, Conservation and Energy Act of 2008 (2008 Farm Bill) amended the Agricultural Marketing Act of 1946 (Act) to require retailers to notify their customers of the country of origin of covered commodities. 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; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts. The implementation of mandatory country of origin labeling (COOL) for all covered commodities, except wild and farm-raised fish and shellfish, was delayed until September 30, 2008.

The 2008 Farm Bill contains a number of provisions that amended the COOL provisions in the Act. These changes include the addition of chicken, goat, macadamia nuts, pecans, and ginseng as covered commodities, the addition of provisions for labeling products of multiple origin, as well as a number of other changes that are discussed more fully in the Supplementary Information portion of this rule. However, the implementation date of September 30, 2008, was not changed by the 2008 Farm Bill. Therefore, in order to meet the September 30, 2008, implementation date and to provide the newly affected industries the opportunity to provide comments prior to issuing a final rule, the Department is issuing this interim final rule. This interim final rule contains definitions, the requirements for consumer notification and product marking, and the recordkeeping responsibilities of both retailers and suppliers for covered commodities. The

provisions in this interim final rule do not affect the regulatory requirements for fish and shellfish that were published in the October 5, 2004, **Federal Register**.

**DATES:** This interim final rule is effective September 30, 2008. Comments must be submitted on or before September 30, 2008 to be assured of consideration. The requirements of this rule do not apply to covered commodities produced or packaged before September 30, 2008.

**ADDRESSES:** Comments should be submitted through the Internet at <http://www.regulations.gov>. Send written comments to: Country of Origin Labeling Program, Room 2607-S; Agricultural Marketing Service (AMS), USDA; STOP 0254; 1400 Independence Avenue, SW., Washington, DC 20250-0254, or by facsimile to 202/354-4693. All comments received will be posted on the Web site at: <http://www.regulations.gov>. Comments sent to the above location that specifically pertain to the information collection and recordkeeping requirements of this action should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Erin Morris, Associate Deputy Administrator, Poultry Programs, AMS, USDA, by telephone on 202/720-5131, or via e-mail at: [erin.morris@usda.gov](mailto:erin.morris@usda.gov).

**SUPPLEMENTARY INFORMATION:** The information that follows has been divided into three sections. The first section provides background information including questions and answers about this interim final rule, a summary of the history of this rulemaking, and a general overview of the law, including the changes contained in the 2008 Farm Bill. The second section provides a discussion of the rule's requirements, including a summary of changes from the October 30, 2003, proposed rule as well as a summary of the comments received in response to the relevant prior requests for comments associated with this rulemaking and the Agency's responses to these comments. The prior requests for comments include: The proposed rule published in the October 30, 2003, **Federal Register** (68 FR 61944); the interim final rule for fish and shellfish published in the October 5, 2004, **Federal Register** (69 FR 59708); the reopening of the comment period (for costs and benefits) for the interim final rule that was published in the

November 27, 2006, **Federal Register** (71 FR 68431); the reopening of the comment period for all aspects of the interim final rule that was published in the June 20, 2007, **Federal Register** (72 FR 33851); and the reopening of the comment period for the proposed rule for all covered commodities that was published in the June 20, 2007, **Federal Register** (72 FR 33917). The last section provides for the required impact analyses including the Regulatory Flexibility Act, the Paperwork Reduction Act, Civil Rights Analysis, and the relevant Executive Orders.

**I. Background***Questions and Answers Concerning This Interim Final Rule*

What are the general requirements of Country of Origin Labeling?

The 2002 and 2008 Farm Bills amended the Act to require retailers to notify their customers of the country of origin of beef (including veal), lamb, pork, chicken, goat, wild and farm-raised fish and shellfish, perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts. The implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish was delayed until September 30, 2008. The law defines the terms "retailer" and "perishable agricultural commodity" as having the meanings given those terms in section 1(b) of the Perishable Agricultural Commodities Act of 1930 (PACA) (7 U.S.C. 499 *et seq.*). Under PACA, a retailer is any person engaged in the business of selling any perishable agricultural commodity at retail. Retailers are required to be licensed when the invoice cost of all purchases of perishable agricultural commodities exceeds \$230,000 during a calendar year. The term perishable agricultural commodity means fresh and frozen fruits and vegetables.

Food service establishments are specifically exempted as are covered commodities that are ingredients in a processed food item. In addition, the law specifically outlines the criteria a covered commodity must meet to bear a "United States country of origin" designation.

How do I find out if my product is considered a covered commodity or if it is labeled accurately under the COOL law?

This regulation contains the requirements for labeling covered commodities and for determining whether a product is subject to this rule. However, additional questions regarding

whether a product is considered a covered commodity or is labeled accurately under this regulation may be e-mailed to [cool@usda.gov](mailto:cool@usda.gov).

Given that the law exempts covered commodities from mandatory COOL if they are an ingredient in a processed food item, what is the definition of a processed food item and what types of products are considered processed food items?

A processed food item is 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), except 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. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding). Examples of items excluded include: Meatloaf, meatballs, fabricated steak, breaded veal cutlets, corned beef, sausage, breaded chicken tenders, and teriyaki flavored pork loin; a salad mix that contains lettuce and a dressing packet, a salad mix that contains lettuce and carrots, a fruit cup that contains melons, bananas, and strawberries; a bag of mixed vegetables that contains peas and carrots; and roasted peanuts.

What requirements must be met for a retailer to label a covered commodity as being of United States origin?

The law prescribes specific criteria that must be met for a covered commodity to bear a "United States country of origin" declaration. The specific requirements for covered commodities are as follows: Perishable agricultural commodities, pecans, ginseng, peanuts, and macadamia nuts—covered commodities must be produced in the United States; beef, lamb, pork, chicken, and goat—covered commodities must be derived exclusively from animals (1) born, raised, and slaughtered in the United States (including animals born and raised in Alaska and Hawaii and transported for a period of time not more than 60 days through Canada to the United States and slaughtered in the United States); or (2) present in the

United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States.

How should I label a retail product that contains a single type of covered commodity (such as a bag of frozen strawberries) prepared from raw material sources having different origins?

In this interim final rule, a single type of covered commodity (e.g., frozen peas), presented for retail sale in a consumer package, that has been prepared from raw material sources having different origins is referred to as a commingled covered commodity. Further, a commingled covered commodity does not include ground meat products. If the retail product contains two different types of covered commodities (e.g., peas and carrots), it is considered a processed food item and is not subject to mandatory COOL.

In the case of perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts, for imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with imported and/or United States origin commodities, the declaration shall indicate the countries of origin for all covered commodities in accordance with Customs and Border Protection (CBP) marking regulations (19 CFR part 134).

What are the requirements for labeling ground meat products, which often contain raw material sources from multiple countries?

The 2008 Farm Bill specifies that the notice of country of origin for ground beef, ground lamb, ground pork, ground goat, and ground chicken shall include a list of all of the countries of origin contained therein or reasonably contained therein. This interim final provides that when a raw material from a specific origin is not in a processor's inventory for more than 60 days, the country shall no longer be included as a possible country of origin.

Why can't the Department of Agriculture (USDA) track only imported products and consider all other products to be of "United States Origin"?

The COOL provision of the Farm Bill applies to all covered commodities. Moreover, the law specifically identifies the criteria that products of United States origin must meet. The law further states that "Any person engaged in the business of supplying a covered commodity to a retailer shall provide

information to the retailer indicating the country of origin of the covered commodity." And, the law does not provide authority to control the movement of product. In fact, the use of a mandatory identification system that would be required to track controlled product through the entire chain of commerce is specifically prohibited.

When will the requirements of this regulation take effect?

The effective date of this regulation is September 30, 2008, because the statute provides for a September 30, 2008, implementation date. However, because some of the affected industries (goat, chicken, pecans, ginseng, and macadamia nuts) did not have prior opportunities to comment on this rulemaking and because the 2008 Farm Bill made changes to several of the labeling provisions for meat covered commodities, it is reasonable to allow time for covered commodities that are already in the chain of commerce and for which no origin information is known or been provided to clear the system. Therefore, the requirements of this rule do not apply to covered commodities produced or packaged before September 30, 2008. In addition, during the six month period following the effective date of the regulation, AMS will conduct an industry education and outreach program concerning the provisions and requirements of this rule. AMS has determined that this allocation of enforcement resources will ensure that the rule is effectively and rationally implemented. This AMS plan of outreach and education should significantly aid the industry in achieving compliance with the requirements of this rule.

How will the requirements of this regulation be enforced?

USDA has entered into agreements with States having existing enforcement infrastructure to assist in compliance reviews for fish and shellfish covered commodities. These agreements will be expanded to encompass all covered commodities. USDA determines the number of reviews to be conducted and has developed comprehensive procedures for the compliance reviews. Only USDA is able to initiate enforcement actions against a person found to be in violation of the law. The COOL statute does not provide for a private right of action. USDA may also conduct investigations of complaints made by any person alleging violations of these regulations when the Secretary determines that reasonable grounds for such investigation exist.

What are the recordkeeping requirements of this regulation?

Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of beef, lamb, chicken, goat, and pork is the slaughter facility, must possess or have legal access to records that are necessary to substantiate that claim. In the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the origin claim, provided it is made by someone having first-hand knowledge of the origin of the animal(s) and identifies the animal(s) unique to the transaction.

USDA continues to look for ways to minimize the burden associated with this rule. Therefore, under this interim final rule, slaughter facilities that slaughter animals that are part of a National Animal Identification System (NAIS) compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag and/or the presence of any accompanying animal markings (i.e., "Can", "M"), as applicable, on which to base their origin claims. This provision also applies to such animals officially identified as a group lot.

For retailers, records and other documentary evidence relied upon at the point of sale by the retailer to establish a covered commodity's country(ies) of origin must be maintained for one year from the date the origin declaration is made at retail and, upon request, provided to any duly authorized representatives of USDA within 5 business days of the request.

For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish a product's origin. Pre-labeled products are those covered commodities that are labeled for country of origin by the firm or entity responsible for making the initial claim or by a further processor or repacker (i.e., firms that receive bulk products and package the products as covered commodities in a form suitable for the retailer). The country of origin information of pre-labeled covered commodities must be legibly printed on

the shipping container, immediate container, or consumer ready package. In addition to indicating country of origin information, pre-labeled products must contain sufficient supplier information to allow USDA to trace-back the product to the supplier initiating the claim. Records that identify the covered commodity, the supplier, and for products that are not pre-labeled, the country of origin information must be maintained for a period of 1 year from the date the origin declaration is made at retail. Retailer and supplier records may be maintained in any location.

How does this regulation impact existing State country of origin labeling programs?

To the extent that State country of origin labeling programs encompass commodities that are not governed by this regulation, the States may continue to operate them. For those State country of origin labeling programs that encompass commodities that are governed by this regulation, these programs are preempted. However, this preemption does not apply to State marketing programs for commodities such as Washington apples, Idaho potatoes, etc.

While the COOL statute does not contain an express preemption provision, it is clear from the language in the statute that Congress intended preemption of State law. The law assigns enforcement responsibilities to the Secretary and encourages the Secretary to enter into partnerships with States with enforcement infrastructure to assist in the administration of the program. The law provides for a 30-day period in which retailers and suppliers may take the necessary corrective action after receiving notice of a nonconformance. The Secretary can impose a civil penalty only if the retailer or supplier has not made a good faith effort to comply, and only after the Secretary provides notice and an opportunity for a hearing. Allowing private rights of actions would frustrate the purpose of this comprehensive enforcement system in which Congress struck a delicate balance of imposing a requirement, but ensuring that the agency had wide latitude in enforcement discretion. Thus, it is clear that State laws and other actions were intended to be preempted.

#### *Prior Documents in This Proceeding*

This interim final rule is issued pursuant to the 2002 Farm Bill, the 2002 Appropriations, and the 2008 Farm Bill, which amended the Act to require retailers to notify their customers of the

origin of covered commodities. In addition, the FY 2004 Consolidated Appropriations Act (Pub. L. 108-199) delayed the implementation of mandatory country of origin labeling (COOL) for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006. The Agriculture, 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 shellfish until September 30, 2008.

On October 11, 2002, AMS published Guidelines for the Interim Voluntary Country of Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts (67 FR 63367) providing interested parties with 180 days to comment on the utility of the voluntary guidelines.

On November 21, 2002, AMS published a notice requesting emergency approval of a new information collection (67 FR 70205) providing interested parties with a 60-day period to comment on AMS' burden estimates associated with the recordkeeping requirements as required by the Paperwork Reduction Act of 1995 (PRA). On January 22, 2003, AMS published a notice extending this comment period (68 FR 3006) an additional 30 days.

On October 30, 2003, AMS published the proposed rule for the mandatory COOL program (68 FR 61944) with a 60-day comment period. On December 22, 2003, AMS published a notice extending the comment period (68 FR 71039) an additional 60 days. On June 20, 2007, AMS reopened the comment period for the proposed rule for all covered commodities (72 FR 33917).

On October 5, 2004, AMS published the interim final rule for fish and shellfish (69 FR 59708) with a 90-day comment period. On December 28, 2004, AMS published a notice extending the comment period (69 FR 77609) an additional 60 days. On November 27, 2006, the comment period was reopened on the costs and benefits aspects of the interim final rule (71 FR 68431). On June 20, 2007, the comment period was reopened for all aspects of the interim final rule (72 FR 33851).

#### *Overview of the Law*

Section 10816 of Public Law 107-171 (7 U.S.C. 1638-1638d) and Section 11002 of Public Law 110-234 amended the Act (7 U.S.C. 1621 *et seq.*) to require retailers to inform consumers of the

country of origin of covered commodities.

The intent of this law is to provide consumers with additional information on which to base their purchasing decisions. COOL is a retail labeling program and as such does not provide a basis for addressing food safety. Food products, both imported and domestic, must meet the food safety standards of the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS).

Under the 2002 Farm Bill, the term "covered commodity" was defined as muscle cuts of beef (including veal), lamb, pork; ground beef, ground lamb, ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities; and peanuts. The 2008 Farm Bill added muscle cuts and ground chicken and goat; pecans; ginseng; and macadamia nuts as covered commodities. The law excludes items from needing to bear a country of origin declaration when a covered commodity is an "ingredient in a processed food item." The law defines the terms "retailer" and "perishable agricultural commodity" as having the meanings given those terms in PACA.

The law specifically outlines the criteria a covered commodity must meet in order to bear a "United States country of origin" declaration. In the case of perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts, the covered commodity must be exclusively produced in the United States. In addition, under the 2008 Farm Bill, for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng produced in the United States, designation of the State, region, or locality of the United States where such commodity was produced shall be sufficient to identify the country of origin.

In the case of beef, lamb, pork, chicken, and goat, covered commodities, the law states that they may bear a U.S. origin declaration only if they are derived exclusively from animals born, raised, and slaughtered in the United States (including animals born and raised in Alaska and Hawaii and transported for a period of time not more than 60 days through Canada to the United States and slaughtered in the United States). In addition, under the 2008 Farm Bill, animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States, are also eligible to bear a United States origin declaration.

The 2008 Farm Bill provided further direction on country of origin labeling

for meat covered commodities. These changes include additional provisions concerning labeling meat covered commodities that have multiple countries of origin and specify that a retailer of a covered commodity derived from an animal that is imported into the United States for immediate slaughter shall designate the origin of such covered commodity as the country from which the animal was imported and the United States. In addition, the 2008 Farm Bill specifies that meat covered commodities derived from an animal that was not born, raised, or slaughtered in the United States shall designate a country other than the United States as the country of origin.

The 2008 Farm Bill also specifies how ground meat products shall be labeled. The notice of country of origin for ground beef, ground pork, ground lamb, ground chicken, or ground goat shall include a list of all countries of origin contained therein or a list of all reasonably possible countries of origin contained therein.

To convey the country of origin information, the law states that retailers may use a label, stamp, mark, placard, or other clear and visible sign on the covered commodity or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers. Food service establishments, such as restaurants, cafeterias, food stands, and other similar facilities are exempt from these labeling requirements.

The law makes reference to the definition of "retailer" in section 1(b) of PACA as the meaning of "retailer" for the application of the labeling requirements under the COOL law. Under PACA and thus this interim final rule, a retailer is any person engaged in the business of selling any perishable agricultural commodity at retail. Retailers are required to be licensed when the invoice cost of all purchases of perishable agricultural commodities exceeds \$230,000 during a calendar year. Therefore, retail establishments, such as butcher shops, which do not generally sell fruits and vegetables, do not meet the PACA definition of a retailer and therefore are not subject to this rule.

The law requires any person engaged in the business of supplying a covered commodity to a retailer to provide the retailer with the product's country of origin information. In addition, the law states the Secretary of Agriculture may conduct an audit of any person that prepares, stores, handles, or distributes a covered commodity for retail sale to verify compliance with the law and this regulation. Any person subject to such

an audit shall provide the Secretary with verification of the country of origin of covered commodities. The 2008 Farm Bill states that records maintained in the course of the normal conduct of the business of such person, including animal health papers, import or customs documents, or producer affidavits, may serve as such verification. The law prohibits the Secretary from using a mandatory identification system to verify the country of origin of a covered commodity. Under the 2008 Farm Bill, the Secretary is prohibited from requiring the maintenance of additional records other than those maintained in the normal conduct of business. The law provides examples of existing certification programs that may be used to certify the country of origin of a covered commodity.

The 2008 Farm Bill also modified the enforcement provisions for both retailers and suppliers. Under the 2002 Farm Bill, civil penalties up to \$10,000 per violation were specified for retailers and suppliers. Under the 2008 Farm Bill, civil penalties have been reduced to up to \$1,000 for each violation. In addition, the 2008 Farm Bill specifies that the Secretary must provide retailers and suppliers with a 30-day period during which the retailer or supplier can take the necessary steps to comply with the law after receiving notice from the Secretary. Under the 2002 Farm Bill, only retailers were provided with this 30-day period. In addition, the 2008 Farm Bill states that the Secretary may fine a retailer or supplier, after providing notice and an opportunity for a hearing, only if the retailer or supplier has not made a good faith effort to comply with the law and continues to willfully violate the law. The law also encourages the Secretary to enter into partnerships with States with enforcement infrastructure to the extent possible to assist in the program's administration.

## II. Summary of Changes From the Proposed Rule

As previously mentioned, the 2008 Farm Bill made a number of changes to the COOL provisions contained in the Act. These changes have been incorporated into this interim final rule as appropriate. In addition, the Agency has made other modifications for clarity and to reduce the burden on regulated parties where practicable as the added costs of implementing this rule will likely be passed on to consumers. Many of these changes were incorporated in the interim final rule for fish and shellfish that was published in the October 5, 2004, **Federal Register** (69 FR 89708). Thus, readers may find it

helpful to review the interim final rule for fish and shellfish for further discussions of some of the changes that were made from the proposed rule such as those changes made to the definition of a processed food item and to the recordkeeping provisions.

Further, enforcement of the interim final rule for fish and shellfish will be consistent with the statute as amended by the 2008 Farm Bill. Comments are specifically requested concerning the revisions to recordkeeping provisions made herein. Any comments received pursuant to this rulemaking, to the extent relevant, will be reviewed in connection with the continuing regulatory action on the mandatory COOL program for fish and shellfish. A summary of the changes made in this interim final rule is discussed below.

#### *Definitions*

The 2008 Farm Bill added muscle cuts and ground chicken and goat; pecans; macadamia nuts; and ginseng as covered commodities. Therefore, a definition for born in reference to chicken as well as definitions for chicken, ginseng, goat, ground chicken, and ground goat have been added for clarity. In addition, the definition of "covered commodity" has also been modified accordingly to include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.

The definitions of "canned" and "produced in any other country other than the United States" have been deleted as they have been determined to be unnecessary.

A definition for "commingled covered commodities" and "imported for immediate slaughter" have been added for clarity.

The following definitions have been deleted as the requirements for labeling wild and farm-raised fish and shellfish covered commodities were promulgated in a separate action: "farm-raised fish", "hatched", "processed (for fish and shellfish)", "U.S. flagged vessel", "vessel flag", "waters of the United States", and "wild fish and shellfish". In addition, other definitions such as "covered commodity", "production step", "raised", and "United States country of origin" have been modified to remove references to fish and shellfish.

The definition of "ground beef" has been modified to provide clarity and to expand the scope of ground beef items covered by this rule. Under this interim final rule, the term "ground beef" has the meaning given that term in 9 CFR

319.15(a), i.e., chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, and containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders, and also includes products defined by the terms "hamburger" in 9 CFR 319.15(b) and "beef patties" in 9 CFR 319.15(c). A full explanation of this change is discussed in the Comments and Responses section.

The definition of "processed food item" has been modified to provide additional clarity as to the types of retail items that are considered processed food items and are therefore exempt from labeling under this interim final rule. Based on the comments received on the proposed rule in which numerous commenters suggested that the scope of what is considered a covered commodity should be narrowed and because the Department was concerned about the burden of this rule on affected entities as the added costs of implementing this rule will likely be passed on to consumers, AMS is adopting the definition of a processed food item in this interim final rule that was promulgated in the interim final rule for fish and shellfish. Thus, under this interim final rule, items that are cooked, cured, smoked, and restructured would all be considered processed food items. Under the proposed rule, items that were cooked would have been required to be labeled. A full explanation of this change is discussed in the Comments and Responses section.

The definition of "raised" has also been modified to provide clarity. The term "raised" is defined in this interim final rule for the purpose of providing clarity with respect to the specific production steps specified in the law, born, raised, and slaughtered, and how the origin of covered commodities shall be labeled. This definition does not impact any other labeling claims subject to approval by FSIS.

Pursuant to the 2008 Farm Bill, the definition of "United States country of origin" has also been modified. Under this interim final rule, beef, pork, lamb, chicken, and goat derived from animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States, shall be considered of United States origin. The 2002 Farm Bill and thus the October 30, 2003, proposed rule, did not contain such a provision. This provision will help address the issue of the lack of origin information on some animals currently residing in the United States.

#### *Country of Origin Notification for Muscle Cuts and Ground Meat*

The October 30, 2003, proposed rule contained provisions for labeling covered commodities when the product entered the United States during the production process. In general, animals that were born and/or raised in country X and slaughtered in the United States were to be labeled as being imported from country X and identifying the production steps that occurred in the United States. The 2008 Farm Bill contains provisions on labeling covered commodities of multiple countries of origin. Under this interim final rule, if an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y, where Country X and Country Y represent the actual or possible countries of foreign origin.

If an animal was imported into the United States for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal shall be designated as Product of Country X and the United States.

In both cases above, the origin declaration may include more specific information related to production steps provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

#### *Labeling Ground Meat Covered Commodities*

The proposed rule contained provisions for labeling commingled products—including ground beef. However, the 2008 Farm Bill specifies how ground meat items shall be labeled.

Under this interim final rule, the declaration for ground beef, ground pork, ground lamb, ground goat, and ground chicken covered commodities shall list all countries of origin contained therein or that may be reasonably contained therein. Further, this interim final rule provides that when a raw material from a specific origin is not in a processor's inventory for more than 60 days, the country shall no longer be included as a possible country of origin. Under the proposed rule, the label for these products was required to include an alphabetical listing of the countries of origin for all raw materials contained therein.

### *Labeling Comingled Covered Commodities*

For covered commodities other than meat items, this interim final rule, to a great extent, includes the labeling provisions for comingled covered commodities that were developed in the interim final rule for fish and shellfish based on comments received on the proposed rule. Most of the commenters requested greater flexibility in labeling these types of products. Other commenters expressed concern as to whether listing the countries in alphabetical order is acceptable under FDA and CBP regulations. For a more complete discussion of the rationale for this change, readers are invited to review the interim final rule for fish and shellfish (69 FR 59708), which is posted on the AMS Web site at <http://www.ams.usda.gov/AMSV1.0/>. Further, changes are made in this regulation to make clear that in those instances in which CBP marking regulations apply pursuant to 19 CFR part 134, this regulation does not impose any additional marking requirements. Accordingly, under this interim final rule, for imported covered commodities that are comingled with covered commodities (of the same type) sourced from a different origin the declaration shall indicate the countries of origin in accordance with existing CBP marking regulations (19 CFR part 134).

### *Markings*

With regard to markings, in addition to the change made by the 2008 Farm Bill with respect to State, region, and locality labels, which is further discussed below, the Agency has made several changes to provide for increased flexibility in labeling. In general, these changes mirror the changes that were made to the marking provisions contained in the interim final rule for fish and shellfish as a result of comments received on the proposed rule. Many commenters requested the use of check boxes to convey origin information. Other commenters requested that bulk commodities should be allowed to be comingled in bins as long as the signage indicates the countries of origin of the contents of the bin. Numerous other commenters recommended that State and regional designations should be accepted in lieu of country of origin. For a more complete discussion of the relevant comments, readers are invited to review the interim final rule for fish and shellfish.

Accordingly, under this interim final rule, the declaration of the country of origin of a product may be in the form

of a check box provided it is in conformance with other Federal labeling laws. Also, under this final rule, a bulk container (e.g., display case, shipper, bin, carton, and barrel), used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed. Under the proposed rule, the use of check boxes was not expressly allowed and covered commodities from more than one origin that were offered for sale in a bulk container were required to be individually labeled.

Under the proposed rule, State or regional label designations were not permitted in lieu of country of origin. However, the 2008 Farm Bill, and thus this interim final rule, expressly authorize the use of State, regional, or locality label designations in lieu of country of origin for perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts.

### *Recordkeeping*

The 2008 Farm Bill made changes to the recordkeeping provisions of the Act. Specifically, the 2008 Farm Bill states that records maintained in the course of the normal conduct of the business of such person, including animal health papers, import or customs documents, or producer affidavits, may serve as such verification. Under the 2008 Farm Bill, the Secretary is prohibited from requiring the maintenance of additional records other than those maintained in the normal conduct of business. In addition to the changes made as a result of the 2008 Farm Bill, other changes have been made to reduce the recordkeeping burden. In general, these changes, to a great extent, include the changes that were made to the recordkeeping provisions contained in the interim final rule for fish and shellfish as a result of comments received on the proposed rule. The majority of the commenters recommended shorter retention times for both retailer and supplier records. Other commenters expressed concern that the preamble for the proposed rule provided no explanation of the records that would be necessary to establish the chain of custody of a product. For a more complete discussion of the relevant comments, readers are invited to review the interim final rule for fish and shellfish. These changes include the removal of the store-level recordkeeping requirement, a reduction in the length of time that records must be maintained, the removal of the requirement for a unique identifier, and revisions to the recordkeeping requirements for pre-labeled products.

With respect to establishing the chain of custody of a product, in response to comments received, the Agency has deleted this language from the rule. Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction. Under the proposed rule, records would have been required to be kept for 2 years.

For retailers, this rule requires records and other documentary evidence relied upon at the point of sale by the retailer to establish a covered commodity's country(ies) of origin must be maintained for one year from the date the origin declaration is made at retail and, upon request, provided to any duly authorized representatives of USDA within 5 business days of the request. Under the proposed rule, retailers were required to have maintained these records at the retail store for 7 days following the sale of the product. For pre-labeled products, the rule provides that the label itself is sufficient evidence on which the retailer may rely to establish a product's origin. The proposed rule would not have provided for this method of substantiation. The rule now requires that records identify the covered commodity, the supplier, and for products that are not pre-labeled, the country of origin information. This information must be maintained for a period of 1 year from the date the origin designations are made at retail. Under the proposed rule, these records would have been required to be maintained for 2 years.

Accordingly, under this interim final rule, upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be kept in any location.

USDA continues to look for ways to minimize the burden associated with this rule. Therefore, under this interim final rule, in addition to relying on producer affidavits to initiate an origin claim, slaughter facilities that slaughter animals that are part of a National Animal Identification System (NAIS) compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag and/or the presence of any accompanying animal

markings (i.e., “Can”, “M”), as applicable, on which to base their origin claims. This provision also applies to such animals officially identified as a group lot.

#### *Responsibilities of Retailers and Suppliers*

With regard to the “safe harbor” language contained in the proposed rule, which allows retailers and suppliers to rely on the information provided unless they could have been reasonably expected to have knowledge otherwise, based on comments received, this “safe harbor” language has been removed from this interim final rule. The commenters contend that because the statute states that retailers are not subject to fines unless the Secretary determines they have willfully violated the statute, the standard of willfulness is a higher bar to liability than the standard of negligence that is encompassed in the reasonable reliance standard utilized in the “liability shield.” A complete discussion is contained in the Comments and Responses section of this interim final rule.

#### Highlights of This Interim Final Rule Covered Commodities

The term “covered commodity” includes: Muscle cuts of beef, lamb, pork, chicken, and goat; ground beef, ground lamb, ground pork, ground chicken, and ground goat; perishable agricultural commodities (fresh and frozen fruits and vegetables); peanuts; pecans; ginseng; and macadamia nuts.

#### Exemption for Food Service Establishments

Under this interim final rule, food service establishments are exempt from COOL labeling requirements. Food service establishments are restaurants, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, or other similar facilities operated as an enterprise engaged in the business of selling food to the public. Similar food service facilities include salad bars, delicatessens, meal preparation stations in which the retailer sets out ingredients for different meals and consumers assemble the ingredients into meals to take home, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer’s premises.

#### Exclusion for Ingredient in a Processed Food Item

Items are excluded from labeling under this regulation when a covered commodity is an ingredient in a

processed food item. Under this interim final rule, a “processed food item” is defined 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, breadding, tomato sauce), except 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. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (cold or hot), and restructuring (e.g., emulsifying and extruding). Examples of items excluded from country of origin labeling include teriyaki flavored pork loin, meatloaf, roasted peanuts, breaded chicken tenders, fruit medley, mixed vegetables, and a salad mix that contains lettuce and carrots and/or salad dressing.

#### Labeling Covered Commodities of United States Origin

The law prescribes specific criteria that must be met for a covered commodity to bear a “United States country of origin” declaration. Therefore, covered commodities may be labeled as having a United States origin if the following specific requirements are met:

(a) Beef, pork, lamb, chicken, and goat—covered commodities must be derived from animals exclusively born, raised, and slaughtered in the United States; from animals born and raised in Alaska or Hawaii and transported for a period of time not more than 60 days through Canada to the United States and slaughtered in the United States; or from animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States.

(b) Perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts—covered commodities must be from products exclusively produced in the United States.

#### Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin (That Includes the United States)

Under this interim final rule, if an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate

slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y, where Country X and Country Y represent the actual or possible countries of foreign origin.

If an animal was imported into the United States for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal shall be designated as Product of Country X and the United States.

In both cases above, the origin declaration may include more specific information related to production steps provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

#### Labeling Imported Covered Commodities

Under this interim final rule, an imported covered commodity for which origin has already been established as defined by this law (e.g., born, raised, slaughtered or grown) and for which no production steps have occurred in the United States shall retain its origin as declared to U.S. Customs and Border Protection (CBP) at the time the product enters the United States, through retail sale.

Covered commodities imported in consumer-ready packages are currently required to bear a country of origin declaration on each individual package under the Tariff Act of 1930 (Tariff Act). This interim final rule does not change these requirements.

#### Labeling Commingled Covered Commodities

In this interim final rule, a commingled covered commodity is defined as a single type of covered commodity (e.g., frozen peas), presented for retail sale in a consumer package, that has been prepared from raw material sources having different origins. Further, a commingled covered commodity does not include ground meat products. If the retail product contains two different types of covered commodities (e.g., peas and carrots), it is considered a processed food item and is not subject to mandatory COOL.

In the case of perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts, for imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with imported and/or United States origin commodities, the declaration shall indicate the countries

of origin for all covered commodities in accordance with CBP marking regulations (19 CFR part 134). For example, a bag of frozen peas that were sourced from France and India is currently required under CBP regulations to be marked with that origin information on the package.

#### Defining Country of Origin for Ground Meat Products

The law states that the origin declaration for ground beef, ground pork, ground lamb, ground goat, and ground chicken covered commodities shall list the countries of origin contained therein or shall list the reasonably possible countries of origin. Therefore, under this interim final rule, when a raw material from a specific origin is not in a processor's inventory for more than 60 days, the country shall no longer be included as a possible country of origin. This does not mean that labels must change every 60 days. Labels containing the applicable countries (e.g., Country X, Y, Z) may extend beyond a given 60-day period depending on how long raw materials from those countries are actually in inventory. In the event of a supplier audit by USDA, records kept in the normal course of business should provide the information necessary to verify the origin claim.

#### Remotely Purchased Products

For sales of a covered commodity in which the customer purchases a covered commodity prior to having an opportunity to observe the final package (e.g., Internet sales, home delivery sales, etc.) the retailer may provide the country of origin notification either on the sales vehicle or at the time the product is delivered to the consumer.

#### Markings

Under this interim final rule, the country of origin declaration may be provided to consumers by means of a label, placard, sign, stamp, band, twist tie, pin tag, or other clear and visible sign on the covered commodity or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers. In general, abbreviations are not acceptable. Only those abbreviations approved for use under CBP rules, regulations, and policies, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland", "Luxemb" for Luxembourg, and "U.S." for the "United States" are acceptable. The declaration of the country of origin of a product may be in the form of a statement such as "Product of USA," "Produce of the USA", or "Grown in

Mexico"; may only contain the name of the country such as "USA" or "Mexico"; or may be in the form of a check box provided it is in conformance with CBP marking regulations and other Federal labeling laws (i.e., FDA, FSIS). For example, CBP marking regulations (19 CFR part 134) specifically require the use of the words "product of" in certain circumstances. The adjectival form of the name of a country may be used as proper notification of the country of origin of imported commodities provided the adjectival form of the name does not appear with other words so as to refer to a kind or species of product. Symbols or flags alone may not be used to denote country of origin. The labeling requirements under this rule do not supersede any existing Federal legal requirements, unless otherwise specified, and any country of origin designation must not obscure or intervene with other labeling information required by existing regulatory requirements.

For domestic and imported perishable agricultural commodities, macadamia nuts, peanuts, pecans, and ginseng, State, regional, or locality label designations are acceptable in lieu of country of origin labeling.

In order to provide the industry with as much flexibility as possible, this rule does not contain specific requirements as to the exact placement or size of the country of origin declaration. However, such declarations must be legible and conspicuous, and allow consumers to find the country(ies) of origin easily and read it without strain when making their purchases, and provided that existing Federal labeling requirements must be followed. For example, the country of origin declaration may be located on the information panel of a package of frozen produce as consumers are familiar with such location for displaying nutritional and other required information. Likewise, in the case of store overwrap and other similar type products, which is the type of packaging used for fresh meat and poultry products, the information panel would also be an acceptable location for the origin declaration as this is a location that is currently utilized for providing other Federally-mandated labeling information (i.e., safe handling instructions, nutrition facts, and ingredients statement). However, to the extent practicable, the Agency encourages retailers and suppliers to place this information on the front of these types of packages, also known as the principal display panel, so it will be readily apparent to consumers.

#### Recordkeeping Requirements and Responsibilities

The law states that the Secretary may conduct an audit of any person that prepares, stores, handles, or distributes a covered commodity for retail sale to verify compliance. As such, records maintained in the normal course of business that verify origin declarations are necessary in order to provide retailers with credible information on which to base origin declarations.

Under this interim final rule, any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly (i.e., growers, distributors, handlers, packers, and processors, etc.), must make available information to the subsequent purchaser about the country(ies) of origin of the covered commodity. This information may be provided either on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale provided it identifies the product and its country(ies) of origin.

Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction.

In addition, the supplier of a covered commodity that is responsible for initiating a country of origin declaration, which in the case of beef, lamb, pork, chicken, and goat is the slaughter facility, must possess or have legal access to records that are necessary to substantiate that claim. In the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the origin claim, provided it is made by someone having first-hand knowledge of the origin of the animal(s) and identifies the animal(s) unique to the transaction.

USDA continues to look for ways to minimize the burden associated with this rulemaking. Therefore, slaughter facilities that slaughter animals that are part of a National Animal Identification System (NAIS) compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag and/or the presence of any accompanying animal markings (i.e., "Can", "M"), as applicable, on which to base their origin claims. This would also include such

animals officially identified as a group lot.

For an imported covered commodity, the importer of record as determined by CBP, must ensure that records: Provide clear product tracking from the United States port of entry to the immediate subsequent recipient and accurately reflect the country(ies) of origin of the item as identified in relevant CBP entry documents and information systems; and maintain such records for a period of 1 year from the date of the transaction.

Under this interim final rule, retailers also have recordkeeping responsibilities. Records and other documentary evidence relied upon at the point of sale by the retailer to establish a covered commodity's country(ies) of origin must be maintained for one year from the date the origin declaration is made at retail. Upon request, these records must be provided to any duly authorized representatives of USDA within 5 business days of the request and may be maintained in any location. For pre-labeled products (i.e., labeled by the manufacturer/first handler) the label itself is sufficient evidence on which the retailer may rely to establish the product's origin. Pre-labeled products are those covered commodities that are labeled for country of origin by the firm or entity responsible for making the initial claim or by a further processor or repacker (i.e., firms that receive bulk products and package the products as covered commodities in a form suitable for the retailer). The country of origin information of pre-labeled covered commodities must be legibly printed on the shipping container, immediate container, or consumer ready package. In addition to indicating country of origin information, pre-labeled products must contain sufficient supplier information to allow USDA to trace-back the product to the supplier initiating the claim. Records that identify the covered commodity, the supplier, and for products that are not pre-labeled, the country of origin information must be maintained for a period of 1 year from the date the origin declaration is made at retail.

#### Enforcement

The law encourages the Secretary to enter into partnerships with States to the extent practicable to assist in the administration of this program. As such, USDA has entered into partnerships with States that have enforcement infrastructure to conduct retail compliance reviews.

Routine compliance reviews may be conducted at retail establishments and

associated administrative offices, and at supplier establishments subject to these regulations. USDA will coordinate the scheduling and determine the procedures for compliance reviews. Only USDA will be able to initiate enforcement actions against a person found to be in violation of the law. USDA may also conduct investigations of complaints made by any person alleging violations of these regulations when the Secretary determines that reasonable grounds for such investigation exist.

Retailers and suppliers, upon being notified of the commencement of a compliance review, must make all records or other documentary evidence material to this review available to USDA representatives within 5 business days of receiving a request and provide any necessary facilities for such inspections.

The law contains enforcement provisions for both retailers and suppliers that include civil penalties of up to \$1,000 for each violation. For retailers and persons engaged in the business of supplying a covered commodity to a retailer (suppliers), the law states that if the Secretary determines that a retailer or supplier is in violation of the Act, the Secretary must notify the retailer or supplier of the determination and provide the retailer or supplier with a 30-day period during which the retailer or supplier may take necessary steps to comply. If upon completion of the 30-day period the Secretary determines the retailer or supplier has (1) not made a good faith effort to comply and (2) continues to willfully violate the Act, after providing notice and an opportunity for a hearing, the retailer or supplier may be fined not more than \$1,000 for each violation.

In addition to the enforcement provisions contained in the Act, statements regarding a product's origin must also comply with other existing Federal statutes. For example, the Federal Food, Drug, and Cosmetic Act prohibits labeling that is false or misleading. In addition, for perishable agricultural commodities, mislabeling country of origin is also in violation of PACA misbranding provisions. Thus, inaccurate country of origin labeling of covered commodities may lead to additional penalties under these statutes as well.

With regard to the voluntary use of NAIS compliant tags on which to base origin claims, 9 CFR 71.22 prohibits the removal of official identification devices except at the time of slaughter.

#### Comments and Responses

On October 30, 2003, AMS published the proposed rule for the mandatory COOL program (68 FR 61944) with a 60-day comment period. On December 22, 2003, AMS published a notice extending the comment period (68 FR 71039) an additional 60 days. AMS received over 5,600 timely comments from consumers, retailers, foreign governments, producers, wholesalers, manufacturers, distributors, members of Congress, trade associations and other interested parties. The majority of the comments received were from consumers expressing support for the requirement to label the method of production of fish and shellfish as either wild and/or farm-raised. Numerous other comments related to the definition of a processed food item, the recordkeeping requirements for both retailers and suppliers, and the enforcement of the program. In addition, over 100 late comments were received that generally reflected the substance of the timely comments received. To the extent that these comments applied to fish and shellfish covered commodities, these comments have already been addressed in the interim final rule for fish and shellfish (69 FR 59708).

On June 20, 2007, AMS reopened the comment period for the proposed rule for all covered commodities (72 FR 33917). AMS received over 721 comments from consumers, retailers, foreign governments, producers, wholesalers, manufacturers, distributors, members of Congress, trade associations and other interested parties. The majority of the comments received were from consumers expressing support for mandatory COOL for the remaining covered commodities. Numerous comments were received that provided insights and suggestions relating to the definitions for "processed food item," "blended products," "retailer," and "ground beef." Several foreign governments expressed concern that the law itself may not be consistent with the World Trade Organization or North American Free Trade Agreement obligations of the United States. Other commenters pointed out that COOL provides no food safety benefit to consumers. Some commenters expressed concerns that poultry and food service establishments are exempt from COOL regulations. Several commenters discussed the challenges and possible solutions for labeling country of origin when products have entered the United States during the production process. Many commenters requested an implementation period to allow clearing from channels of

commerce those preexisting animals and commodities for which accurate labeling would be difficult.

Any comments received on the October 30, 2003, proposed rule that were not addressed previously in the interim final rule for fish and shellfish, as well as any new comments received in response to the June 20, 2007, comment reopening, will be addressed in this rule.

On October 5, 2004, AMS published the interim final rule for fish and shellfish (69 FR 59708) with a 90-day comment period. On December 28, 2004, AMS published a notice extending the comment period (69 FR 77609) an additional 60 days. On November 27, 2006, the comment period was reopened on the cost and benefit aspects of the interim final rule (71 FR 68431). AMS received over 192 comments from consumers, retailers, foreign governments, producers, wholesalers, manufacturers, distributors, members of Congress, trade associations and other interested parties. The majority of the comments received were from consumers expressing support for the requirement to label fish and shellfish with the country of origin and method of production as either wild and/or farm-raised, and to extend mandatory COOL to the remaining covered commodities. Most of the comments did not address the specific question of the rule's costs and benefits. A limited number of the comments did relate to the costs and benefits of the documentation and recordkeeping requirements of the law. Some commenters noted no increased sales or demand for seafood as a result of COOL. Several commenters provided evidence regarding the costs of compliance with the interim final rule covering fish and shellfish. Other commenters cited academic and Government Accountability Office studies to argue that USDA overestimated the costs to implement systems to meet COOL requirements, and that the true costs to industry will be much lower than those projected by the economic impact analysis contained in the interim final rule for fish and shellfish. To the extent that these comments apply to the overall costs and benefits of mandatory COOL for the remaining covered commodities, they will be addressed herein.

When the proposed rule was published on October 30, 2003, the regulatory provisions were all proposed to be contained in a new part 60 of Title 7 of the Code of Federal Regulations. Under this interim final rule, the regulatory provisions for the covered commodities other than fish and

shellfish will appear at 7 CFR part 65. For the ease of the reader, the discussion of the comments will refer to the initial regulatory numbering scheme. The numbering scheme for the regulatory provisions in this interim final rule is different and therefore may not align with the proposed rule.

#### Definitions

##### Born

*Summary of Comments:* One commenter recommended that a new definition be added that would define the term "born" in the case of:

(a) Beef, pork, and lamb: The country in which cattle, hogs, and sheep were birthed on or after September 30, 2004.

(b) Cattle, hogs, and sheep: All cattle, hogs, and sheep birthed prior to September 30, 2004, and residing within the United States on September 30, 2004, shall be deemed to be born in the United States, except those identified as foreign (through various means).

*Agency Response:* The implementation date for covered commodities other than fish and shellfish was delayed until September 30, 2008. The 2008 Farm Bill amended section 282(a)(2) of the Act such that beef, lamb, pork, chicken, and goat can be designated as having a United States origin if derived from an animal that was present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States. Accordingly, the issue raised in the comment has been addressed by the 2008 Farm Bill amendment, and this rule reflects that statutory change.

##### Covered Commodity

*Summary of Comments:* Numerous commenters suggested that the definition of covered commodity should be amended to include poultry.

*Agency Response:* The 2008 Farm Bill amended section 281(2)(A) of the Act to include chicken as a covered commodity as well as goat, pecans, ginseng, and macadamia nuts. Therefore, the term "covered commodity" has been defined in this interim final rule as "muscle cuts of beef, lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; perishable agricultural commodities; peanuts; pecans; ginseng; and macadamia nuts." Accordingly, the commenters' concerns regarding adding poultry as a covered commodity have been addressed by the 2008 Farm Bill.

##### Food Service Establishment

*Summary of Comments:* Several commenters stated their opposition to

the labeling exemption for food service establishments and pointed out that this provision will result in a substantial amount of product being unlabeled for country of origin. One commenter encouraged USDA to retain the food service establishment definition and to add meal preparation services as another example.

*Agency Response:* Section 282(b) of the Act provides for an exemption for food service establishments. Therefore, this interim final rule retains the provision for an exemption for food service establishments. In addition, language describing meal preparation stations as another example of a food service establishment has been added to the preamble. Accordingly, these recommendations have been adopted in part.

##### Ground Beef

*Summary of Comments:* Several commenters suggested that the definition of ground beef be modified so that all beef products that are ground would be covered regardless of the amount of beef fat, and regardless of whether it contains added water, phosphates, binders, or extenders.

*Agency Response:* In the October 30, 2003, proposed rule, the Agency defined the term "ground beef" as having the meaning given the term in 9 CFR 319.15(a), i.e., chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, and containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders. The Agency has considered the comments received and agrees that the definition of ground beef contained within the proposed rule was too narrow as it would have excluded products such as hamburger and potentially beef patties. Consumers likely would have been confused as to why certain ground beef products were labeled with country of origin while others were not. Accordingly, AMS has revised the definition of ground beef such that "ground beef" has the meaning given that term in 9 CFR 319.15(a), i.e., chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, and containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders, and also includes products defined by the terms "hamburger" in 9 CFR 319.15(b) and "beef patties" in 9 CFR 319.15(c). This revised definition will result in the inclusion of hamburger and beef patties by allowing for the addition of beef fat and water. However, ground beef, hamburger, and beef

patties that contain seasonings and/or other ingredients such as binders or extenders would meet the definition of a processed food item and would therefore not be covered under this rule.

#### Processed Food Item

*Summary of Comments:* AMS received numerous comments on the definition of a processed food item. Several commenters expressed the opinion that the number of exemptions allowed under the processed food item definition should be substantially limited so as to allow for labeling of the maximum number of commodities as possible. Some commenters offered specific recommendations as to what should not be included as a processing step such as marinating, breading, canning, smoking, curing, cooking, dividing into portions, etc. Some commenters offered specific recommendations as to what should be included as a processing step such as freezing, removing inedible portions (such as peeling, coring, and chopping a fresh pineapple), restructuring, cooking, curing, and smoking. With respect to recognizing freezing as a processing step, one commenter provided examples of other regulations administered by AMS that recognize freezing as a processing step. The commenter contends that these regulations have established an administrative precedent and a departure from such precedent would not be legally supported. The commenter also contends that imported frozen products are already required to be labeled with the country of origin under the Tariff Act and that requiring the labeling of these products under COOL would be duplicative. Finally, the commenter contends that there was no legislative intent for frozen foods to fall under the COOL labeling requirements.

Several commenters requested that USDA clarify the types of products that would be considered processed food items under the second part of the definition. Some commenters stated that products such as hamburger, beef patties, meatballs, meat loaves, and fabricated steak should be defined as processed food items. Another commenter suggested that ground beef, ground lamb, and ground pork should be defined as processed food items. Several commenters suggested that roasted, dry roasted, and honey roasted peanuts should be defined as processed food items. Several commenters concurred with the agency's definition as published in the interim final rule for fish and shellfish.

One commenter encouraged USDA to retain the definition as published in the fish and shellfish rule, but recognize that processing for perishable agricultural commodities is different than for the other covered commodities. The commenter pointed out that much value added processing occurs with respect to produce and stated that peeling, coring, chopping, and packaging a fresh pineapple for consumers changes the character of the covered commodity from a bristly fruit to a ready-to-eat product. The commenter recommended that USDA should recognize that perishable agricultural commodities that retailers prepare and package for consumers immediate consumption should be considered processed food items.

Other commenters expressed general concern about the proposed definition, but did not offer any alternatives. Other commenters expressed concern that the concept of substantial transformation, which is the basis for determining origin under CBP regulations, the World Trade Organization's Rules of Origin, and the Codex General Standard for the Labeling of Prepackaged Food, is being overwritten. Another commenter expressed their opinion that the addition of salt or sugar represents a change in nutritional properties and therefore should represent a processing step thereby creating a processed food item.

*Agency Response:* In the October 30, 2003, proposed rule, the term "processed food item" was defined as a retail item derived from a covered commodity that has undergone a physical or chemical change, and has a character that is different from that of the covered commodity; or a retail item derived from a covered commodity that has been combined with other covered commodities or other substantive food components. The Agency also contemplated a number of alternative definitions. In promulgating the definition of a processed food item in the interim final rule for fish and shellfish, the Agency reviewed and responded to all of the comments received on the October 30, 2003, proposed rule. The majority of the comments received argued for a broader definition of a processed food item such that more products would be excluded from labeling. Accordingly, under the interim final rule for fish and shellfish, the definition of a processed food item was modified such that cooked products, breaded products, and items that have been imparted with a particular flavor are all considered processed food items. For a more complete discussion of these comments

and the Agency's responses, readers are invited to review the interim final rule for fish and shellfish.

The Agency believes the definition of a processed food item contained in the interim final rule for fish and shellfish has established a bright line standard in terms of what products are covered by the regulation. Therefore, under this interim final rule, the definition of a processed food item is the same as that which was published in the interim final rule for fish and shellfish (69 FR 89708). Further, to provide additional guidance to the industry, the Agency has added additional examples of the types of products that would be excluded in the Questions and Answers section of this rule.

With respect to the issue of substantial transformation, the law specifically defines the criteria for a covered commodity to be labeled as having a United States country of origin. Imported covered commodities do not generally meet this criteria and, therefore, may not bear a declaration that identifies the United States as the sole country of origin.

With regard to excluding ground meat products, the Act defines the term "covered commodity" to specifically include ground beef, ground pork, ground lamb, ground goat as well as ground chicken. Thus, these commodities must be labeled under this regulation. However, items such as meatballs, meat loaf, and similar items that contain seasonings and/or binders, would not meet the definition of "ground beef" as defined in this regulation. With regard to fabricated steak, this product is restructured and therefore would be considered a processed food item under this interim final rule.

With respect to considering freezing as a processing step, freezing is clearly a method of preservation and does not change the character of the product. In addition, in defining the term perishable agricultural commodity, Congress referenced the definition for this term under the Perishable Agricultural Commodities Act of 1930 (PACA). Under PACA, the term perishable agricultural commodity means "any of the following, whether or not frozen or packed in ice \* \* \*" Therefore, it is clear that frozen fruits and vegetables are specifically included as covered commodities under the statute. As the commenter points out, many imported products (in consumer-ready packages) are already required to be labeled under the Tariff Act. This interim final rule does not change these requirements.

With respect to the recommendation to recognize that perishable agricultural

commodities that retailers prepare and package for consumers' immediate consumption should be considered processed food items, many of these preparations must be done prior to a product being ready for consumption. For example, a consumer would not eat a pineapple that wasn't peeled, cored, and sliced and/or chopped. Such processing thus does not change the character of the product but rather prepares it for consumption. This is similar to the process of peeling shrimp. A consumer would not eat shrimp prior to it being peeled and accordingly, peeling shrimp is not considered a processing step under the interim final rule for fish and shellfish.

With respect to roasted, dry roasted, and honey roasted peanuts, because these items are all cooked, under the definition of a processed food item in this interim final rule, these products are excluded from labeling. With regard to excluding items that contain added salt or sugar, the Agency believes the addition of these ingredients merely represent a further step in the preparation of the product for consumption and do not result in a change of character of the covered commodity. Therefore, this recommendation is not adopted.

#### Retailer

*Summary of comments:* Several commenters were concerned that the definition of a retailer in the proposed rule does not conform to what the average consumer thinks of as a retailer because it excludes stores that do not sell fruits and vegetables such as fish markets, meat markets, small green grocers, and convenience stores. These commenters urged USDA to resolve any ambiguities surrounding the definition in a way that maximizes the number of food items and establishments subject to mandatory COOL. Another commenter noted that Congress intended to impose the new labeling requirements on sales conducted by a certain class of business entities (i.e., PACA retailers) but not on all retail sales of covered commodities. They further stated that any person that primarily sells food in wholesale or in bulk to independent businesses (e.g., restaurants and other food service establishments) should be exempt from COOL.

*Agency Response:* The law specifically defines the term retailer as having the meaning given that term in section 1(b) of PACA. Accordingly, fish markets or any other retail entities that either invoice fruits and vegetables at a level below the \$230,000 threshold or do not sell any fruits and vegetables at all are not included. Likewise, the

Agency believes this definition clearly indicates that covered commodities sold by wholesalers to restaurants and other food service establishments are not covered by COOL. Accordingly, no modification to the definition of a retailer has been made.

#### Slaughter

*Summary of Comments:* In the proposed rule, the Agency specifically invited comments on the use of alternative terms for the term "slaughtered." Numerous commenters suggested alternatives including abattoired, processed, harvested, prepared, and initial processing.

*Agency Response:* The Agency believes that the alternative term "harvested" as suggested by several of the commenters is an acceptable alternative for the term "slaughtered" that will be readily understood by consumers. Accordingly, this rule has been modified to allow the use of this term in lieu of the term "slaughtered".

#### Country of Origin Notification

##### *Exemption for Food Service Establishments*

*Summary of Comments:* Several commenters were not in favor of the exemption for food service establishments as it would limit the information available to consumers.

*Agency Response:* The Act expressly states the exemption of food service establishments. Therefore, this exemption is retained in this regulation.

##### *Labeling Covered Commodities of United States Origin*

*Summary of Comments:* One commenter supported labeling only those products derived from animals specifically born, raised, and processed in the United States as eligible for the "product of the United States" designation. This commenter opposed an all-inclusive label such as "product of the United States, Canada, or Mexico" when the commodity meets the specific qualifications for the "product of the United States" label. Another commenter advocated that the "United States origin" designation should only be available for peanut products in which the peanuts have been grown and harvested in the United States and have not been substantially transformed outside the United States. Other commenters supported a presumption of United States origin in which the absence of foreign import markings should be used to identify livestock exclusively born, raised, and processed in the United States. One commenter suggested that in the case of the covered commodities beef, pork, lamb, ground

beef, ground pork, and ground lamb, the retail product should be labeled as "product of the United States" if in fact that product was produced in the United States.

*Agency Response:* The law expressly states the criteria for products to be considered of United States origin, which are included in the definition of this term as stated in § 65.260 of this interim final rule. The specific requirements for covered commodities are as follows: Perishable agricultural commodities, pecans, ginseng, peanuts, and macadamia nuts—covered commodities must be produced in the United States; beef, lamb, pork, chicken, and goat—covered commodities must be derived exclusively from animals (1) born, raised, and slaughtered in the United States (including animals born and raised in Alaska and Hawaii and transported for a period of time not more than 60 days through Canada to the United States and slaughtered in the United States); or (2) present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States. The regulation also states that covered commodities further processed or handled in a foreign country after meeting the requirements to be labeled as United States origin (as defined in § 65.260) may bear the declaration that identifies the United States as the sole country of origin at retail provided the identity of the product is maintained along with records to substantiate the origin claims and the claim is consistent with other applicable Federal legal requirements. Thus, peanuts grown in the United States and processed in another country such that a substantial transformation does not occur are still eligible to bear a United States origin declaration.

In the case of all inclusive labels such as "Product of the United States, Canada, or Mexico", the 2008 Farm Bill provided further direction on country of origin labeling for meat covered commodities. These changes include additional provisions concerning labeling meat covered commodities that have multiple countries of origin. Under this interim final rule, if an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y, where Country X and Country Y represent the actual or possible countries of foreign origin. In addition, the origin declaration may include more specific information

related to production steps provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

With regard to allowing for presumption of United States origin, the law also states that "Any person engaged in the business of supplying a covered commodity to a retailer shall provide information to the retailer indicating the country of origin of the covered commodity." Accordingly, presumption of United States origin is not authorized under the statute.

#### *Labeling Imported Covered Commodities That Have Been Substantially Transformed in the United States*

*Summary of Comments:* Two commenters supported the provisions contained in the interim final rule for fish and shellfish for labeling products that have been imported from country x and substantially transformed in the United States to be labeled as "from country x, processed in the United States" and recommended this provision also be used for other covered commodities. One commenter opposed requiring further itemization of exact production steps that occurred in the United States or in the foreign country. One commenter supported a label that expresses each country's specific role in the production of a product.

*Agency Response:* The 2008 Farm Bill contains labeling provisions for the following categories: United States country of origin, multiple countries of origin, imported for immediate slaughter, foreign country of origin, as well as for labeling ground products. Accordingly, this interim final rule contains labeling provisions for these categories in accordance with the law. A complete discussion on how covered commodities should be labeled is contained in this regulation in the section entitled "Highlights of this Regulation".

#### *Blended Products*

*Summary of Comments:* Several commenters stated that the provision for labeling blended products under the proposed rule, which required an alphabetical listing of countries contained therein and required facilities to document the origin of a product was separately tracked, was excessively costly. Commenters supported language in the interim final rule for fish and shellfish, which stated "the declaration shall indicate the countries of origin contained therein or that may be contained therein." Several commenters supported labeling that indicates several

countries may be represented in the finished product. As an example, the commenters suggested an all-inclusive label stating "product of the United States, Canada, or Mexico." The commenters contend that such a label will provide consumers with a reasonable indication of likely origin while reducing implementation costs.

One commenter requested that USDA clarify what constitutes the "same covered commodity". The commenter stated that the example in the proposed rule referred to green and red leaf lettuce as if they are a single commodity and that the produce industry would consider those two different items. The commenter noted this would render a bag containing red and green leaf lettuce as a processed food item. The commenter recommended that if a commodity has a unique identifier such as a unique price look up code (PLU) related to anything but size or region, it should be considered a unique item.

Other commenters appeared to be confused as to labeling "blended" covered commodities and instead provided comments on labeling commodities of mixed origin. The relevant comments have been addressed in the appropriate sections.

*Agency Response:* In an effort to clarify the labeling requirements for this type of product, the Agency has removed references to the term "blended" covered commodities and has added a definition of "commingled" covered commodities. Under this interim final rule, commingled covered commodities are defined as a single type of covered commodity (e.g., frozen peas), presented for retail sale in a consumer package, that has been prepared from raw material sources having different origins. If the retail product contains two different types of covered commodities (e.g., peas and carrots), it is considered a processed food item and is not subject to mandatory COOL. Further, a commingled covered commodity does not include ground meat products. However, because labeling of ground meat products was included in the blended (commingled) provisions of the proposed rule, for purposes of discussing the comments, they are included under this subheading.

USDA is concerned about the burden imposed by the rule on facilities that produce a commingled retail product as the added costs of implementing this rule will likely be passed on to consumers. The proposed rule would have required such facilities to document that the origin of a product was separately tracked, while in their control, during production and

packaging. The proposed rule also would have required that the labeling of all blended products specify precisely the countries of origin represented within each individually-packaged retail product.

The Department believes that the statutory language makes clear that the purpose of the COOL law is to provide for a retail labeling program for covered commodities—not to impose economic inefficiencies and disrupt the orderly production, processing, and retailing of covered commodities. Therefore, in this interim final rule, the provision to separately track the product has been removed, and the labeling requirements have been made consistent with other Federal labeling requirements (i.e., CBP marking regulations). This interim final rule does not impose any additional burden with respect to the labeling of commingled products for which labeling is also required under CBP regulations.

In the case of perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts, for imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with imported and/or United States origin commodities, the declaration shall indicate the countries of origin for all covered commodities in accordance with CBP marking regulations (19 CFR part 134).

The 2008 Farm Bill states that the origin declaration for ground beef, ground pork, ground lamb, ground goat, and ground chicken covered commodities shall list the countries of origin contained therein or shall list the reasonably possible countries of origin. This interim final provides that when a raw material from a specific origin is not in a processor's inventory for more than 60 days, the country shall no longer be included as a possible country of origin.

In reference to the comment about clarifying the language "the same covered commodity", the Agency has added additional language describing the types of products this labeling provision covers in the preamble. In response to the commenter's recommendation regarding red and green leaf lettuce, the Agency disagrees with the commenter's recommendation to use price lookup codes as the standard for whether or not a covered commodity is considered "the same". While green leaf and red leaf lettuce are different varieties of lettuce, they are both still leaf lettuce and thus would not meet the definition of a processed food item. This is also the case with different varieties of apples or onions as each variety—red delicious, fuji, or

granny smith in the case of apples and red, yellow, and white in the case of onions—has its own PLU code. Thus, the provision for labeling commingled covered commodities applies to products such as a bag that contains frozen strawberries originating from the United States and Mexico, a bag that contains bananas originating from Ecuador and Costa Rica, and a bag of lettuce that contains romaine and iceberg lettuce originating from the United States and Mexico.

#### *Remotely Purchased Products*

*Summary of comments:* One commenter recommended that suppliers should list the country of origin on the sales vehicle. Another commenter recommended that the country of origin notification should be allowed to be made either on the sales vehicle or at the time the product is delivered to the consumer.

*Agency Response:* The Agency agrees that companies should be allowed flexibility in providing the notice of country of origin. As such, under this interim final rule, companies can provide the required notification either on the sales vehicle or at the time the product is delivered to the consumer.

#### *Markings*

##### *Section 60.300(a)*

*Summary of Comments:* Several commenters stated that flexibility is critically important to help minimize costs in complying with the law. These commenters urged AMS to permit the use of the numerous declaration options as listed in the interim final rule for fish and shellfish. Commenters also supported the use of a check box to declare country of origin information on covered commodities. Several commenters recommended that the country of origin declaration be allowed to be made in the form of a statement such as “product of the U.S.” or as simply the country name such as “USA”. The commenters pointed out that this provision was contained within the proposed rule, but was deleted from the interim final rule for fish and shellfish.

*Agency Response:* The Agency believes that the law provides flexibility in providing the country of origin notification and this interim final rule has been drafted accordingly. As such, § 65.400(a) allows for the same flexibility in providing the origin information as allowed in the interim final rule for fish and shellfish, including allowing for the use of a check box. In addition, the use of the name of the country only is permitted

under this interim final rule, provided it is in accordance with other Federal labeling laws. For example, in certain circumstances CBP regulations require the words “product of” or “made in” to precede the name of the country.

##### *Section 60.300(b)*

*Summary of Comments:* Several commenters recommended that the conspicuous location requirement should include any place on the package or product. Several commenters supported the current application of this requirement under the interim final rule for fish and shellfish and recommended that USDA further explain the conspicuous standard to ensure a common understanding across all regulated communities as well as among compliance and enforcement personnel.

*Agency Response:* At the request of the commenters, the Agency has included an additional discussion of this requirement in the preamble of this rule. Declarations must be legible and placed in a conspicuous location as to allow consumers to find the country(ies) of origin easily and read it without strain when making their purchases, and provided that existing Federal labeling requirements must be followed. For example, the country of origin information may be located on the information panel of a package of frozen produce as consumers are familiar with such location for displaying nutritional and other required information.

Likewise, in the case of store overwrap and other similar type products, which is the type of packaging used for fresh meat and poultry products, the information panel of the package is also considered an acceptable location for the origin declaration as this is a location that is currently utilized for providing other Federally-mandated labeling information (i.e., safe handling instructions, nutrition facts, and ingredients statement). However, to the extent practicable, the Agency encourages retailers and suppliers to place this information on the front, also known as the principal display panel, of these types of packages so it will be readily apparent to consumers.

##### *Section 60.300(d)*

*Summary of Comments:* Several commenters expressed support for the provision in both the proposed rule and the interim final rule for fish and shellfish that allows for commingling like items in the same bulk bin even if they are from different origins. Several commenters asserted that it is impossible to label every single item in a bulk bin, that stickering efficacy is not 100%, and that it is likely that some

stickers will fall off during transport and display. These commenters contend that the country of origin notification requirement should be met if the majority of perishable agricultural commodities in a bulk bin have labels as consumers will be able to determine the country of origin.

*Agency Response:* The Agency agrees that flexibility should be provided to retailers to commingle like items from different origins in bulk bins. Thus, under this interim final rule, a bulk container (e.g., display case, shipper, bin, carton, and barrel), used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed. The Agency also understands that stickering efficacy is not 100%. The Agency agrees that consumers would likely be able to discern the country of origin if the majority of items were labeled; however, the Agency encourages retailers to use placards and other signage as a way to more clearly indicate information to consumers as to the origin of the covered commodity. Accordingly, the Agency does not believe it is necessary to change the language for this provision. The Agency will address the issue of preponderance of stickering in its compliance and enforcement procedures, as applicable, to ensure uniform guidance is provided to compliance and enforcement personnel.

##### *Section 60.300(e)*

*Summary of Comments:* Several commenters recommended that the Agency allow for the use of abbreviations for country names as long as the abbreviation clearly indicates the origin of a covered commodity. The commenters made reference to the Agency's policy to follow CBP's interpretation of the Tariff Act with regard to abbreviations and stated their belief that the Agency is not bound by CBP's interpretation. Some commenters recommended that the Agency utilize the country abbreviations established by the International Organization for Standardization. One commenter pointed out the USDA accepts abbreviations from intermediary suppliers and others on records.

*Agency Response:* The Agency believes that the limited application of abbreviations that unmistakably indicate the country of origin is appropriate. The CBP has a long history of administering the Tariff Act and has issued numerous policy rulings with regard to this subject. The Agency concurs with CBP's interpretation that most abbreviations may not be readily

understood by the majority of consumers. The Agency does permit the use of abbreviations in supplier records as long as a key or other similar document explaining what the abbreviations represent is provided. However, the Agency does not believe that providing a key in the store for consumers to have to locate and decipher is appropriate or reasonable. Accordingly, these recommendations are not adopted. However, the Agency has added clarifying language to § 65.400(e).

#### *Section 60.300(f)*

*Summary of Comments:* Numerous commenters recommended that the Agency accept State and regional label designations in lieu of country of origin labeling for commodities produced in the United States. Two commenters recommended that retailers be permitted to substitute more visually appealing and consumer-targeted labels, such as ones with American flags, in lieu of a standard or commodity label.

*Agency Response:* The 2008 Farm Bill modified the Act to allow for the use of State, region, or locality label designations to meet the country of origin notification requirements of the statute for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng that are produced in the United States. The Department believes it is appropriate to expand this provision to also allow State, regional, or locality labels for imported products. Therefore, under this interim final rule, for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng covered commodities, State or regional label designations are acceptable in lieu of country of origin for both domestic and imported products. Accordingly, this recommendation is adopted in part.

With regard to substituting more visually appealing labels, as long as country of origin information is provided in accordance with this regulation, additional labels can be applied to the package that are more eye appealing. In addition, there is no standardized format for labels under this regulation, so suppliers and retailers have flexibility in designing the appearance of the label provided the origin declaration is legible and placed in a conspicuous location.

#### *Recordkeeping*

##### *General*

*Summary of Comments:* Numerous commenters supported the acceptance of existing records used in the normal course of business. These commenters

stated that the rule does not need to establish new document or recordkeeping burdens to verify country of origin claims and that existing records should be sufficient. Several commenters recommended that the Agency provide a list of example documents that would illustrate acceptable normal business records. Some of these commenters offered the following examples of documents: Animal health papers, import or Customs documents, producer affidavits, and records maintained in compliance with assessments and remittances for Federally legislated promotion and research programs. Several commenters supported the use of producer affidavits.

*Agency Response:* The Agency agrees that records kept in the normal course of business likely contain sufficient information to verify origin claims. The Act, as amended by the 2008 Farm Bill, states that records maintained in the course of the normal conduct of business, including animal health papers, import or customs documents, or producer affidavits may serve for verification purposes. The Act, as amended, further states that the Secretary may not require a person that prepares, stores, handles, or distributes a covered commodity to maintain a record of the country of origin of the covered commodity other than those maintained in the course of the normal conduct of the business of such person.

Therefore, under this interim final rule, upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location. In the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the origin claim, provided it is made by someone having first-hand knowledge of the origin of the animal(s) and identifies the animal(s) unique to the transaction. In addition, to further reduce the burden associated with labeling meat covered commodities with origin information, under this interim final rule, slaughter facilities that slaughter animals that are part of a National Animal Identification System (NAIS) compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may choose to rely on the presence of an official ear tag and/or the presence of any accompanying

animal markings (i.e., “Can”, “M”), as applicable, on which to base their origin claims. This provision also applies to such animals officially identified as a group lot.

With regard to providing examples of normal business records that may be useful in verifying origin claims, the Agency has included some examples of records in the regulation and additional examples have been posted on the AMS Web site.

#### *Location of Records*

*Summary of Comments:* Several commenters requested flexibility in the regulation for establishing the manner and location in which regulated firms maintain records. Commenters noted that firms with multiple locations or a corporate headquarters might choose to centralize supplier records. Commenters requested that the rule permit firms to maintain records centrally, provided the information is readily available and that the firm has the capability to transfer it to the specific retail outlet if requested by USDA. The commenters stated that retailers and suppliers could make records available to USDA either electronically by transferring computer files or by facsimiles of paper documents. Some commenters requested that retailers and suppliers be given a reasonable period of time to produce records requested by the Agency.

*Agency Response:* The regulation provides flexibility by allowing electronic or hard copy formats, by not requiring specific records, and by providing flexibility in where the records can be kept. The Agency agrees that retailers and suppliers could make records available to USDA representatives either electronically by transferring computer files or by providing facsimiles of paper documents. The Agency also agrees that retailers and suppliers should be allowed a reasonable amount of time to provide records to USDA representatives upon request. Under this interim final rule, the requirement to maintain records at the retail facility has been removed. Accordingly, the recommendation to allow retailers to provide records to the USDA representative within some reasonable period of time is adopted.

#### *Recordkeeping Retention*

*Summary of Comments:* The Agency received numerous comments regarding the recordkeeping retention requirements. One commenter was in favor of the retention period contained in the proposed rule. Several commenters recommended the one-year

retention period contained in the interim final rule for fish and shellfish. Several commenters recommended that the COOL rule harmonize the record retention requirements with the FDA regulations on Bioterrorism. Several commenters recommended a retention period as short as possible and pointed out that many of the covered commodities are purchased by consumers within a matter of weeks, and in the case of fresh meat products, within 40 to 60 days of production. Another commenter added that even for the minimal amount of frozen meat covered commodities that are sold at retail, the time from production through retail sale would be less than 6 months. Another commenter recommended a retention period of 180 days. Another commenter recommended that the Agency consider a similar recordkeeping retention period as that required by FSIS with respect to HACCP documents for fresh products.

*Agency Response:* Based on the comments received, the Agency agrees that it is appropriate to reduce the record retention requirements contained in the proposed rule. Many of these comments are similar to those that the Agency considered in promulgating the interim final rule for fish and shellfish. Thus, the Agency believes that the recordkeeping provisions in the interim final rule for fish and shellfish, which require a 1-year record retention requirement for suppliers and centrally located retail records, as opposed to the 2-year requirement contained in the proposed rule, is appropriate. In addition, as discussed in more detail in the preamble of this regulation and the preceding responses to comments, the requirement to maintain records at the retail store has been removed. Under this interim final rule, these records may now be kept in any location and must be provided to USDA upon request within 5 business days of the request.

With regard to the recordkeeping retention time implemented by FDA under the Bioterrorism Act, the recordkeeping retention requirements under the final rule (69 FR 71561) issued by FDA vary based on the type of product from six months to two years. Thus, the recordkeeping requirements contained in this interim final rule are similar to those in the FDA regulation and in some cases, are less burdensome. For a more complete discussion of the comments the Agency considered in promulgating the interim final rule for fish and shellfish, readers are invited to review that document.

As to the recommendation for allowing for a shorter record retention period for supplier and centrally-located

retail records, the Agency believes a 1-year period is necessary to provide the Agency with sufficient time to conduct supplier compliance reviews. These reviews often do not commence until several months after the product in question was displayed for retail sale. Accordingly, this recommendation is not adopted.

With regard to the comment that the Agency should adopt the recordkeeping provisions required by FSIS with respect to HACCP documents, the record retention requirements contained in this interim final rule are shorter than those required by FSIS with relation to HACCP. Accordingly, this recommendation is not adopted.

#### *Responsibilities of Suppliers and Retailers*

*Summary of Comments:* Several commenters pointed out that in the case of beef, lamb, and pork, most of the records necessary to verify the origin of the livestock used to produce the covered commodity will not be generated by the supplier of the covered commodity. The commenters contend that it is therefore important that the regulation allow the supplier to either have the records or have access to the records as the records to verify the birth country of the livestock will reside with the livestock producer that sold the livestock months or years earlier, and the animal may have changed hands several times before harvest. Several commenters expressed concern with placing undue recordkeeping and liability burdens on livestock producers. Other commenters noted that only livestock producers have first-hand knowledge of the origin of their animals. One commenter recommended that USDA distinguish between suppliers with first-hand knowledge and intermediary suppliers. The commenter suggested that intermediary suppliers should not be required to keep records beyond those necessary to identify their immediate suppliers and subsequent corporate recipients. Another commenter recommended that importers be required to maintain adequate records to reconcile purchase, inventories, and sales of imported and domestic commodities.

One commenter suggested that the "liability shield" that entitles retailers and others handling covered commodities to rely on the information provided to them should be amended to reflect the statutory standard for liability that applies to retailers under the statute. The commenter contends that because the statute states that retailers are not subject to fines unless the Secretary determines they have willfully

violated the statute, the standard of willfulness is a higher bar to liability than the standard of negligence that is encompassed in the reasonable reliance standard utilized in the "liability shield."

*Agency Response:* The Agency agrees that the provision allowing a supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim to possess or have legal access to records that are necessary to substantiate that claim is necessary. Accordingly, this provision is included in section 65.500(b)(1) of this interim final rule.

With regard to the recommendation that intermediary suppliers be required to keep only those records that identify their immediate suppliers and subsequent recipients, this is the case with products that are pre-labeled with origin information. However, for products that are not pre-labeled, the intermediary supplier must provide the origin information (and identify the product unique to the transaction) in a document that accompanies the product through retail sale. Therefore, the Agency believes it is necessary for intermediary suppliers to also possess records that identify the origin information for compliance verification purposes for products that are not pre-labeled.

With respect to the recommendation to require importers to maintain adequate records to reconcile purchases, inventories, and sales of imported and domestic commodities, the law does not provide the Agency with the authority to require such detailed information nor is such information necessary to substantiate origin claims.

With respect to the safe harbor provision, the 2008 Farm Bill modified the enforcement provisions of the Act such that retailers and suppliers can only be fined if after 30-days of receiving a notice from the Secretary that they are in violation of the Act, the retailer or supplier has not made a good faith effort to comply and continues to willfully violate the Act. Thus, the Agency agrees with the commenter's suggestion that the "liability shield" provides less protection for retailers and suppliers than the statute itself. Accordingly, the "liability shield" language has been deleted from this interim final rule.

#### *Enforcement*

*Summary of Comments:* The Agency received numerous comments on the issue of enforcement. Numerous commenters recommended that the Agency incorporate a transition period prior to the rule taking effect to allow

industries producing, processing, and retailing covered commodities time to clear the channels of commerce before enforcing the rule. Two commenters recommended that AMS implement COOL for all covered commodities no later than January 1, 2009. Several commenters did not offer a specific implementation timeframe other than to request that the Agency establish a "reasonable" period to carry out education and outreach activities. Several commenters referenced the language contained in the House version of the 2008 Farm Bill that states that all animals present in the United States on or before January 1, 2008, shall be considered of United States origin. Other commenters recommended that AMS should presume any meat product or animals in the channels of commerce prior to the rule's implementation date to be of United States origin.

Several commenters urged AMS to establish commodity specific timeframes for the rule's implementation due to unique commercial life-cycle attributes. One commenter suggested an 18-month implementation timeframe for peanuts. One commenter suggested a six to twelve month implementation period and another commenter suggested a one-year timeframe. One commenter suggested timeframes based on the average age of animals at time of harvest. Specifically, the commenter suggested: For imported beef, pork, lamb, ground beef, ground pork and ground lamb, a delayed effective date by at least six months; for beef, pork, lamb, ground beef, ground pork, and ground lamb produced from animals imported for direct harvest, a delayed effective date by at least six months; for beef produced from animals harvested from the United States herd, a delayed effective date by at least 30 months; for ground beef, which is traditionally produced from cull dairy and breeding stock, a delayed effective date of at least 8 years; for pork produced from animals harvested from the United States herd, a delayed effective date by six months; for ground pork, which is traditionally produced from cull breeding stock, a delayed effective date by at least 2 years; and for lamb and ground lamb produced from animals harvested from the United States herd, a delayed effective date by at least 12 months. The commenter further suggested that during the time allowed to clear the channels of commerce, the Agency could encourage retailers to voluntarily label products when the necessary information is available.

Another commenter encouraged the Agency to utilize a similar approach for

implementation as that used in the interim final rule for fish and shellfish. The commenter pointed out that frozen perishable agricultural commodities have a long shelf life and that many such products will have been harvested and frozen well before the rule is issued. The commenter recommended that the Agency allow these products to enter the chain of commerce and only require country of origin information on frozen produce that was harvested and processed after the final rule takes effect. The commenter pointed out that the timing for covered meat commodities is also complicated because of the lifecycle of animals. The commenter recommended that the Agency employ a uniform compliance date policy that is used by both FDA and FSIS for frozen perishable agricultural commodities and meat products, if not for all covered commodities.

One commenter requested that the Agency recognize that a willful violation does not occur where a party is exercising good faith efforts to comply with the statute. The commenter further stated their belief that good faith efforts would include a clear program for providing comprehensive labeling of all covered commodities at the store level, recognizing that for various reasons, some small percentage (perhaps 10 or 15%) of covered commodities might not bear labeling on any given day.

*Agency Response:* The effective date of this regulation is September 30, 2008, because the statute provides for a September 30, 2008, implementation date. However, because some of the affected industries (goat, chicken, pecans, ginseng, and macadamia nuts) did not have prior opportunities to comment on this rulemaking, and the 2008 Farm Bill made changes to several of the labeling provisions for meat covered commodities, it is reasonable to allow time for covered commodities that are already in the chain of commerce and for which no origin information is known or been provided to clear the system. Therefore, the requirements of this rule do not apply to covered commodities produced or packaged before September 30, 2008. In addition, during the six month period following the effective date of the regulation, AMS will conduct an industry education and outreach program concerning the provisions and requirements of this rule. AMS has determined that this allocation of enforcement resources will ensure that the rule is effectively and rationally implemented. This AMS plan of outreach and education should significantly aid the industry in

achieving compliance with the requirements of this rule.

#### *Existing State Programs*

*Summary of Comments:* The Agency invited comment on the proposed rule as it relates to existing State programs. One commenter recommended that USDA clarify the preemption language contained in both the proposed rule and the interim final rule for fish and shellfish. Specifically, the commenter stated that USDA should recognize that the Federal law "occupies the field" and hence, preempts State country of origin labeling laws for all products that are in the ambit of covered commodities. The commenter stated that States should not be able to impose country of origin labeling requirements on covered commodities that are ingredients in processed food items or on those prepared in food service establishments. The commenter believes that Congress has clearly spoken and concluded that labeling shall not apply to these items.

*Agency Response:* In accordance with Executive Order 13132, the Agency does not believe there is basis to allow for preemption of State laws that would encompass commodities that are not regulated under this regulation either because they meet the definition of a processed food item or because they were prepared in food service establishments. No comments from States were received. Accordingly, this recommendation is not adopted.

#### *Miscellaneous*

*Summary of Comments:* Many commenters discussed the use of import markings to differentiate cattle of foreign origin from cattle born and raised in the United States. These commenters noted that current APHIS regulations require live cattle imported from Canada to be branded with the letters "CAN" and live cattle imported from Mexico to be branded with the letter "M." Commenters argued that processors could rely on these brands and other import markings to segregate animals and ensure accurate country of origin notification. Many of these commenters argued that the absence of import markings should indicate a "presumption of United States origin." AMS also received numerous comments expressing concern about the potential for COOL to create obstacles to international trade and possible conflicts with regard to United States trade agreements under the World Trade Organization, the North American Free Trade Agreement, and General Agreements on Tariffs and Trade. Several other commenters expressed their opinions regarding the justification

for COOL as a food safety or animal health measure. Several other commenters asserted that COOL will not ensure food safety or animal health.

*Agency Response:* With respect to using import markings to segregate animals, the Agency believes the labeling provisions contained in § 65.300 of this interim final rule provide flexibility such that the need to segregate animals will be limited to those suppliers that want to provide more specific origin information. However, in an effort to further reduce the burden associated with labeling meat covered commodities with origin information, under this interim final rule, slaughter facilities that slaughter animals that are part of a National Animal Identification System (NAIS) compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag and/or the presence of any accompanying animal markings (i.e., "Can", "M"), as applicable, on which to base their origin claims. This provision also includes such animals officially identified as a group lot.

With regard to presumption of United States origin, the 2008 Farm Bill amended the Act such that animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States will be considered of United States origin.

With respect to the commenters' concern regarding international trade obligations, the Agency has considered these obligations throughout the rulemaking process and concludes that this regulation is consistent with U.S. international trade obligations.

With regard to the comments on COOL serving as a food safety or animal health measure, as stated in the preamble, the purpose of COOL is to provide additional information to consumers on which to base their purchasing decisions. COOL is a retail labeling program and as such does not provide a basis for addressing food safety. Food products, both imported and domestic, must meet the food safety standards of FDA and FSIS.

#### *Preliminary Paperwork Reduction Act*

*Summary of Comments:* USDA received conflicting comments regarding liability burdens and the maintenance of records throughout supply channels between retailers, suppliers and producers. Generally, cattle, pork and lamb producers and their trade associations provided comments supporting protections for

livestock producers from undue recordkeeping and liability burdens placed on them by retailers and packers. On the other hand, meat packers and retailers expressed that the rule should grant them the ability to pass liability for noncompliance with labeling or verification of country of origin back down the supply chain to product sources. Two commenters noted that the interim final rule for fish and shellfish deletes the requirement for chain of custody documentation. One commenter concluded that the rule should not require intermediary suppliers to maintain records beyond those necessary to identify their immediate suppliers and subsequent business customers.

Four commenters advocated that USDA should require importers of designated commodities to maintain adequate records to reconcile purchases, inventories and sales of imported and domestic commodities in order to reduce the need for expensive and burdensome affidavits or audits on United States livestock producers. One commenter noted that the beef industry is more segmented than any other industry affected by COOL and that this segmentation complicates the transfer of origin information for United States beef producers.

Another commenter warned that the requirement to document the country of birth, raising and slaughter of livestock will create a tremendous recordkeeping burden on both packers and producers; and in some cases, it may not even be possible to achieve. This commenter contended that those packers harvesting older animals might find it nearly impossible to find adequate supplies of livestock for which records exist regarding the location of the animal's birth. The commenter added that the recordkeeping burden placed on domestic processors might create a disadvantage relative to imported products, which will have no such requirements to document the animal's origin back to birth.

Two commenters further illuminated this point. One of these noted that it would be more efficient in the lamb industry to focus on tracking the one to three percent of United States slaughter representing Canadian lambs imported by a handful of individuals or firms. The commenter also pointed out that due to recordkeeping requirements for assessments and remittances for the Lamb Promotion Research and Information (check-off) order, a current audit trail exists for country of origin of domestic sheep. The other commenter contended that imported meat, by its nature, is likely to have passed through

more handling stages than domestic product by the time it reaches the point of final United States retail sale. The commenter stated that because imported beef, lamb and pork passes through at least two countries, and through handling by ranchers, exporters, importers, processors, and distributors, imported products will require a longer audit trail that demands more, and potentially more detailed, recordkeeping.

*Agency Response:* The Agency has already addressed many of these comments earlier in this Comment and Response section. In general, the Agency has reduced the recordkeeping burden to the extent possible while still maintaining a verifiable audit trail.

Compared to the proposed rule, this interim final rule reduces the length of time that records must be kept, revises the recordkeeping requirements for pre-labeled products, and removes the requirement to maintain records at the retail store. Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction. Under the proposed rule, records would have been required to be kept for 2 years.

For retailers, records and other documentary evidence relied upon at the point of sale by the retailer to establish a covered commodity's country(ies) of origin must be maintained for one year from the date the origin declaration is made at retail and, upon request, provided to any duly authorized representatives of USDA within 5 business days of the request. Under the proposed rule, retailers were required to maintain these records at the retail store for 7 days following the sale of the product.

For pre-labeled products, the interim final rule provides that the label itself is sufficient evidence on which the retailer may rely to establish a product's origin. The proposed rule did not provide for this method of substantiation. Under the interim final rule, records that identify the covered commodity, the supplier, and for products that are not pre-labeled, the country of origin information must be maintained for a period of 1 year from the date the origin designations are made at retail. Under the proposed rule, these records would have been required to be maintained for 2 years.

In addition to these burden reducing changes made by the Agency, the 2008

Farm Bill also made several burden reducing changes. Accordingly, some of the concerns expressed by the commenters have been addressed by the 2008 Farm Bill and by this interim final rule. For example, the statute expressly allows for the use of producer affidavits, so packers will be able to rely on affidavits to base the origin claims for covered commodities. This will alleviate many of the concerns expressed by producers. Likewise, under the 2008 Farm Bill, the Secretary is prohibiting from requiring the creation of records not already maintained in the normal course of business, which will also reduce the recordkeeping burden. In addition, the 2008 Farm Bill contains a provision such that all animals present in the United States on or before July 15, 2008, will be considered of United States origin, which addresses the concerns of commenters regarding adequate supplies of livestock for which origin is documented back to birth. A complete discussion of the changes made as a result of the 2008 Farm Bill can be found earlier in this document.

#### *Preliminary Regulator Impact Analysis*

*Summary of Comments:* Numerous comments were submitted stating that USDA underestimated the implementation and maintenance costs of the COOL program. One commenter stated that the implementation costs plus two years of maintenance costs totaled \$49 million. Another commenter provided an estimated total implementation cost of \$236,000 for planning, software, training, and capital. It provided an estimated annual maintenance cost of \$279,300 for maintenance of hardware/software, operation costs, and packaging. They reported net economic impact was –\$516,200. A third commenter stated that retailers experienced actual first year implementation costs of \$9,000 to \$16,500 per store for seafood labeling, and intermediary suppliers experienced costs between \$200,000 and \$250,000 per firm. They reported that one retailer saw a \$0.07 per pound (less than 2 percent) increase in cost of goods from its suppliers directly attributable to the requirements necessary to comply with country of origin labeling. A fourth commenter discussed the capital expenditures necessary to meet the product segregation requirements for beef and pork slaughter plants. This commenter estimated that cost to exceed \$2 billion. The commenter stated their belief that even with those plants that can be identified as “All-American” and exempt from the segregation

requirement, the cost still could exceed \$1 billion.

*Agency Response:* While the Agency believes its analysis conducted in the PRIA in 2003 was accurate for that time, the Agency has conducted a new economic impact analysis because economic conditions have changed, updated data are available, and additional commodities have been added. The commodities to be regulated by this regulation are muscle cuts of beef, lamb, goat, pork, and chicken; ground beef, ground lamb, ground chicken, ground goat, and ground pork; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans.

The results of this updated analysis show estimated first-year incremental cost for growers, producers, processors, wholesalers, and retailers at \$2.5 billion. The estimated cost to the United States economy in higher food prices and reduced food production in the tenth year after implementation of the rule is \$211.9 million. The Agency also re-estimated the paperwork costs and estimated those to be \$126 million in initial and startup costs during the first year and \$499 million per year to store and maintain the records thereafter.

With regard to the commenters’ statements regarding segregation, this interim final rule provides flexibility in how products of multiple origin can be labeled. Thus, the costs associated with labeling products of multiple origin will likely be less than the upper range estimate in the PRIA as the proposed rule did not contain this flexibility. A complete discussion on labeling products of multiple origin is contained in the Highlights of this Interim Final Rule section earlier in this document.

*Summary of Comments:* One commenter stated their belief that statute is intended to disadvantage imported meat.

*Agency Response:* Both importers and domestic suppliers are required to meet the requirements of the rule. The Agency believes that firms will find efficient ways to comply with the requirements of the rule.

*Summary of Comments:* One commenter stated that the authorizing legislation was not a “Pro-Consumer” safety measure.

*Agency Response:* As discussed in more detail in the preamble and in other responses to comments earlier in this section, COOL is not a food safety measure. COOL provides more information to consumers on which to base their purchasing decisions.

*Summary of Comments:* Several commenters believe that COOL will have an adverse impact on beef demand.

Another commenter believes COOL will hurt consumers because it will discourage the use of imported beef, which will result in less ground beef being produced and driving up the price. Other commenters stated their belief that consumers think domestic products are superior and are willing to pay more for it. One commenter included a paper written by an economics professor entitled, “An Overview of the Impact of COOL on Production Costs for the U.S. Cattle Producer and Results of the TFOG Experiment” who concluded, in part, that the impact of COOL on the demand for beef in the United States is uncertain. The paper referenced different opinions expressed by economists and others and stated that there is really no consensus about the impact of COOL on the demand for beef in the United States.

*Agency Response:* The Agency interprets all of these comments as discussing COOL’s impact on the demand for covered commodities. The Agency maintains its position concerning the impact of COOL on the demand for all the covered products as presented in the Regulatory Impact Analysis.

*Summary of Comments:* One commenter stated that COOL implementation and maintenance costs can be minimized by streamlining regulatory requirements.

*Agency Response:* As previously discussed, the Agency has made changes that streamline both the regulatory and paperwork burden aspects of COOL. For example, the definition of a processed food item has been changed such that a greater number of products are now exempt from COOL requirements. The fewer the number of products that must be labeled, the lower implementation and maintenance costs will be for many affected entities. Another example is that the overall recordkeeping retention period for retailers and suppliers is reduced from 2 years to 1 year for centrally located records and the requirement to maintain records at the retail store has been removed. These records can now be maintained in any location.

In addition to the changes made by the Agency in an effort to reduce the burden of complying with this rule, changes have also been made as a result of the 2008 Farm Bill. For example, the 2008 Farm Bill and this interim final rule provide for flexibility in labeling products of multiple origin. In addition, the 2008 Farm Bill allows for the use of producer affidavits and prohibits the Secretary from requiring the creation of

records that are not already maintained as part of the normal course of business. A complete discussion of the changes made by the Agency, including the changes made as a result of the 2008 Farm Bill, can be found earlier in this document. The Agency believes these changes as a whole have greatly reduced the burden on affected industries and the cost estimates for the implementation of this rule have been lowered significantly as discussed in the RIA.

*Summary of Comments:* Several commenters pointed out that many products are already labeled as to country of origin pursuant to existing laws. One commenter illustrated that retailers provide origin labeling on more than 60 percent of the top 20 fruits and top 20 vegetables (by consumption). This commenter added that the industry is now providing such labeling and will continue to do so. These same commenters also contended that additional country of origin labeling requirements are unnecessary and would impose enormous additional costs on all segments of the food chain. They argued that the cost of mandatory country of origin labeling is significant and will not provide consumer benefit.

*Agency Response:* If 60 percent of the top 20 fruits and the top 20 vegetables are already labeled with origin information as stated by the commenter, the Agency would expect that the cost of implementing COOL for the remaining fruit and vegetable products may be less than what the Agency is estimating. However, it is difficult to quantify the associated cost savings. As for the cost of implementing and maintaining COOL, these commenters did not offer any quantitative data to support their claim.

*Summary of Comments:* One commenter reported that they implemented COOL without burden or noticeable expense. This commenter is a retailer who believed its customers are demanding to know the origin of the foods they see for sale. They have completed labeling the country of origin on all of its beef, pork, lamb, peanuts and fresh produce (in addition to seafood) without any burden or noticeable expense. They believe this improved traceability reduced their risk.

*Agency Response:* The Agency views this comment as supporting the Agency's contention that firms will adapt their existing infrastructure as needed to comply with COOL and that firms will find the most cost effective way of doing so.

*Summary of Comments:* In support of the benefits of the mandatory COOL program, one commenter noted that

USDA Economic Research Service (ERS) data revealed that United States origin lamb enjoyed a \$.40 per pound price advantage compared to imported lamb products. The commenter further stated that using ERS retail data released in January 2003, the two-year combined volume-weighted average price of domestic lamb was \$4.30 per pound. For imported lamb, it was \$3.90 per pound.

*Agency Response:* The Agency has determined that the relationship between domestic and imported lamb prices change over time. In some years domestic prices will be higher and in other years imported prices will be higher. The commenter was examining 2001 and 2002 data. An examination of monthly retail scanner prices provided by ERS from January 2004 through December 2005 indicates that imported lamb prices per pound sold as a premium as compared to domestic lamb for this time period. Thus, it cannot be assumed that origin information consistently provides a net benefit in the form of higher prices for domestic lamb.

*Summary of Comments:* One commenter cited three studies (surveys) that found consumers overwhelmingly desire COOL and believe they have a right to know such information. One study, conducted in early June 2007, found that 92 percent thought that imported food should be labeled as to its country of origin. Another study (survey), conducted in March 2007, found that 82 percent of the people polled supported mandatory COOL. Finally, a study (survey) conducted in mid-July 1997 found that 88 percent of those polled said all retail food should have COOL. This study also showed that 94 percent believe that consumers have a right to know the country of origin of the foods they purchase.

*Agency Response:* The Agency does not believe that these types of studies provide a sufficient basis to estimate the quantitative benefits, if any, of COOL. As discussed in the Regulatory Impact Analysis, there are several limitations with the willingness-to-pay studies that call into question the appropriateness of using this approach to make determinations about the benefits of this rule. First, consumers in such studies often overstate their willingness to pay for a product. Second, in most of these willingness-to-pay studies, consumers are not faced with the actual choices they would face at retail outlets. Third, consumers' willingness-to-pay as elicited from a survey is a function of the questions asked. Different questionnaires will yield different results. Finally, the results reported

from these studies do not take into account changes in consumers' preferences for a particular product or product attribute over time.

*Summary of Comments:* One commenter noted that COOL could serve as a risk management measure. Some countries, which may not have as stringent food safety regulations and/or have not implemented/enforced those regulations as rigorously as the U.S., may export hazardous food products. COOL could allow consumers to avoid such food items as the need arose.

*Agency Response:* As previously discussed in the preamble of this rule and in other responses to comments, COOL provides consumers with more information on which to base their purchases. Food products, both imported and domestic, must meet the food safety standards of FDA and FSIS. COOL will permit consumers to choose the origin of the foods they purchase.

*Summary of Comments:* Two commenters asserted their belief that the utility of COOL is unsubstantiated and that it imposes onerous costs on covered commodities with no quantifiable benefits. The commenters believe that mandatory COOL should thus be repealed and replaced with a voluntary program.

*Agency Response:* While it may be difficult to quantify the benefits associated with mandatory COOL, the COOL program must be implemented on September 30, 2008, in accordance with the statute.

#### *Preliminary Regulatory Flexibility Analysis*

*Summary of Comments:* Several commenters urged the Agency to ensure that small businesses were not burdened with unnecessary recordkeeping requirements. One commenter noted that paperwork and recordkeeping burdens continue to be top concerns for small businesses.

*Agency Response:* In the initial regulatory flexibility analysis, the Agency noted that costs of implementation may be proportionately higher for smaller versus larger firms given the potential scale of economies associated with the operation of systems to comply with the requirements of mandatory country of origin labeling. In particular, larger firms would have the ability to spread fixed costs of implementation over a greater number of units of production, thereby incurring lower average costs per unit.

However, the Agency has drafted this rule to provide as much regulatory relief for small entities as possible within the limits of the discretionary authority provided by the law. For example, the

Agency has reduced the recordkeeping retention period and has provided flexibility in labeling commingled covered commodities and commodities of multiple origin. In addition, the rule allows market participants to decide how best to implement COOL in their operations. And, market participants other than those retailers defined by the statute can decide to sell products through marketing channels not subject to the rule. The Agency further assumes that in the longer run, higher costs will be passed on to consumers in the form of higher prices for the covered commodities.

*Summary of Comments:* Several commenters said that recordkeeping and other costs of compliance will fall disproportionately on smaller, independent farmers. One of these commenters noted that the position of small, independent farmers may be weakened due to this additional burden.

*Agency Response:* As noted in the Agency's previous response, the initial regulatory flexibility analysis showed that costs of implementation may be proportionately higher for smaller versus larger firms. However, the Agency believes smaller farmers may have some implementation cost advantages over larger farms. Smaller farms likely have simpler recordkeeping systems, and thus would incur lower development costs relative to larger farms. The rule does not prescribe a particular recordkeeping system; so for example, a small fruit and vegetables operation likely would be able to maintain records in hardcopy form rather than developing a complicated electronic recordkeeping system.

*Summary of Comments:* Several commenters asserted their belief that COOL would provide benefits to small producers and consumers at reasonable implementation costs. One commenter explained that for truly small producers (less than 50 animals), mandatory COOL will create a niche market.

*Agency Response:* The Agency believes that the firms within each of the industries will competitively adjust to the provisions of COOL. Some may create niche markets while others may provide covered commodities to retailers, the food service industry, and the away from home food markets which are not covered by COOL.

#### Executive Order 12866—Regulatory Impact Analysis

USDA has examined the economic impact of this interim final rule as required by Executive Order 12866. USDA has determined that this regulatory action is economically significant, as it is likely to result in a

rule that would have an effect on the economy of \$100 million or more in any one year. This rule has been reviewed by the Office of Management and Budget (OMB). Executive Order 12866 requires that a regulatory impact analysis be performed on all economically significant regulatory actions.

This interim final rule defines covered commodities as muscle cuts of beef, lamb, goat, pork, and chicken; ground beef, ground lamb, ground pork, ground goat, and ground chicken; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans. This interim final rule together with the interim final rule for fish and shellfish that was published in the October 5, 2004, **Federal Register** (69 FR 89708) define the full scope of covered commodities as defined by law.

This regulatory impact assessment reflects revisions to the Preliminary Regulatory Impact Assessment (PRIA)(68 FR 61944). Revisions to the PRIA were made as a result of changes to the rule relative to the October 30, 2003, proposed rule, and comments received on the proposed rule for all covered commodities.

The Comments and Responses section lists the comments received and provides the Agency's responses to the comments. Where substantially unchanged, results of the PRIA are summarized herein, and revisions are described in detail. Interested readers are referred to the text of the PRIA for a more comprehensive discussion of the assumptions, data, methods, and results.

#### Summary of the Economic Analysis

The estimated benefits associated with this interim final rule are likely to be small. The estimated first-year incremental costs for growers, producers, processors, wholesalers, and retailers are \$2.5 billion. The estimated cost to the United States economy in higher food prices and reduced food production in the tenth year after implementation of the rule is \$211.9 million.

Note that this analysis does not quantify certain costs of the rule such as the cost of the rule after the first year, or the cost of any supply disruptions or any other "lead-time" issues. Except for the recordkeeping requirements, there is insufficient information to distinguish between first-year startup and maintenance costs versus ongoing maintenance costs for this interim final rule. Maintenance costs beyond the first year are expected to be lower than the combined startup and maintenance costs required in the first year.

USDA finds little evidence that consumers are willing to pay a price premium for country of origin labeling (COOL). USDA also finds little evidence that consumers are likely to increase their purchase of food items bearing the United States origin label as a result of this rulemaking. Current evidence does not suggest that United States producers will receive sufficiently higher prices for United States-labeled products to cover the labeling, recordkeeping, and other related costs. The lack of widespread participation in voluntary programs for labeling products of United States origin provides evidence that consumers do not have strong enough preferences for products of United States origin to support price premiums sufficient to recoup the costs of labeling.

#### Statement of Need

Justification for this interim final rule remains unchanged from the PRIA. This rule is the direct result of statutory obligations to implement the COOL provisions of the 2002 and 2008 Farm Bills. There are no alternatives to Federal regulatory intervention for implementing this statutory directive.

The COOL provisions of the Act change current Federal labeling requirements for muscle cuts of beef, pork, lamb, goat, and chicken; ground beef, ground pork, ground lamb, ground goat, and ground chicken; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans (hereafter, covered commodities). Under current Federal laws and regulations, COOL is only universally required for wild and farm-raised fish and shellfish covered commodities. In particular, labeling of United States origin is not currently mandatory for the other commodities and labeling of imported products at the consumer level is required only in certain circumstances.

As described in the PRIA, the conclusion remains that there does not appear to be a compelling market failure argument regarding the provision of country of origin information. Comments received on the PRIA and subsequent requests for comments elicited no evidence of significant barriers to the provision of this information other than private costs to firms in the supply chain and low expected returns. Thus, from the point of view of society, market mechanisms would ensure that the optimal level of country of origin information would be provided.

#### Alternative Approaches

The PRIA noted that many aspects of the mandatory COOL provisions

contained in the Act are prescriptive and provide little regulatory discretion for this rulemaking. Some commenters suggested that USDA explore more opportunities for less costly regulatory alternatives. Specific suggestions focused on methods for identifying country of origin, recordkeeping requirements, and the scope of products required to be labeled.

A number of comments on the PRIA suggested that USDA adopt a "presumption of United States origin" standard for identifying commodities of United States origin. Under this standard, only imported livestock and covered commodities would be required to be identified and tracked according to their respective countries of origin. Any livestock or covered commodity not so identified would then be considered by presumption to be of United States origin. A presumption of origin standard would require mandatory identification of products not of United States origin. The law, however, specifically prohibits USDA from using a mandatory identification system to verify the country of origin of a covered commodity. In addition, as discussed in the proposed rule, the Agency does not believe that a presumption of United States origin standard provides a means of providing country of origin information that is credible and can be verified. Comments on the proposed rule did not identify how to overcome these obstacles. Thus, a presumption of United States origin standard is not a viable alternative.

With regard to alternatives for recordkeeping, a number of commenters suggested that USDA reduce the recordkeeping burden for the rule. In this interim final rule, the requirement to maintain records at the retail store has been removed. In addition, the overall recordkeeping retention period for retailers and suppliers is reduced from 2 years to 1 year.

The interim final rule also "streamlines" the required recordkeeping for items that are pre-labeled (i.e., labeled by the manufacturer/first handler) with the required country of origin information. Records that demonstrate the chain of custody (immediate previous source and subsequent recipient) for all covered items must be maintained, but the underlying records (e.g., invoices, bills of lading, production and sales records, etc.) do not need to identify the country of origin of these pre-labeled products. For example, if a processor labels the country of origin on a bag of apples, and the apples ultimately are sold in that package at retail, then that label may serve as sufficient evidence on which

the retailer may rely to establish the product's origin. Thus, the retailer's records would not need to show country of origin information for that bag of apples, but the retailer's records would need to include information to allow the source of those apples to be tracked back through the system to allow the country of origin claim to be verified at the point in the system at which the claim was initiated. Under the proposed rule, the retailer would have also been required to identify the country of origin of the bag of apples within its recordkeeping system; the information provided on the bag itself would not have been sufficient. This change in recordkeeping requirements should lessen the number of changes that entities in the distribution chain need to make to their recordkeeping systems and should lessen the amount of data entry that is required.

This interim final rule changes the definition of a processed food item such that a greater number of products are now exempt from COOL requirements. The fewer the number of products that must be labeled, the lower implementation and maintenance costs for many affected entities.

The 2008 Farm Bill contains a number of provisions that amended the COOL provisions in the Act. In general, these changes provide for greater flexibility in labeling by retailers and suppliers and reduces the burden on livestock producers. For example, the 2008 Farm Bill provides for flexibility in labeling ground products by allowing the notice of country of origin to include a list of countries contained therein or that may reasonably be contained therein. In addition, the law provides flexibility in labeling meat covered commodities derived from animals of multiple countries of origin. For example, under this interim final rule, if an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y where Country X and Country Y represent the actual or possible countries of foreign origin.

The law also provides that meat from animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States, may be labeled as having a United States origin. Additionally, the law states that producer affidavits shall be considered sufficient records documenting animals'

The law also states that for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng produced in the United States, designation of the State, region, or locality of the United States where such commodity was produced shall be sufficient to identify the country of origin.

As noted in the PRIA, the law stated that COOL applies to the retail sale of a covered commodity beginning September 30, 2004. Subsequent to the publication of the proposed rule, the law was amended to change the implementation date to September 30, 2008, for all covered commodities except farm-raised and wild fish and shellfish. The implementation date for fish and shellfish covered commodities was September 30, 2004. The delay of the effective date of the labeling requirements under the law provides affected entities with additional time to adjust their systems to comply with the requirements of the law and this rule.

#### Analysis of Benefits and Costs

As in the PRIA, the baseline for this analysis is the present state of the affected industries absent mandatory COOL. USDA recognizes that some affected firms have already begun to implement changes in their operations to accommodate the law and the expected requirements of this interim final rule.

Because the Act contains an implementation date of September 30, 2004, for wild and farm-raised fish and September 30, 2008, for all other covered commodities, the economic impacts of the rule will be staggered by four years. The analysis herein of economy wide costs of the rule abstracts away from the staggered dates of implementation and treats all commodities as having the same effective date of implementation. As discussed more fully below, a two-pronged approach was used to estimate the costs of this rule. While direct fish costs are not specifically included and discussed in this analysis, they have been updated using more recent data and used to estimate the overall impacts of this rule on the United States economy even though labeling of fish was implemented in 2004 and no new regulations for fish are forthcoming from this rule. This was done to take into account all the cross-commodity effects of this rule. The results of the analysis are not significantly affected by this simplifying assumption.

*Benefits:* The expected benefits from implementation of this rule are difficult to quantify. The Agency's conclusion remains unchanged, which is that the

benefits will be small and will accrue mainly to those consumers who desire country of origin information. Several analysts conclude that the main benefit is the welfare effect resulting from removing informational distortions associated with not knowing the origin of products (Ref. 1). Numerous comments received on previous COOL rulemaking actions indicate that there clearly is interest by some consumers in the country of origin of food. The mandatory COOL program may provide additional benefits to these consumers. However, commenters provided no additional substantive evidence to alter the Agency's conclusion that the measurable economic benefits of mandatory COOL will be small. Additional information and studies cited by commenters were of the same type identified in the PRIA—namely, consumer surveys and willingness-to-pay studies, including the most recent studies reviewed for this analysis (Ref. 2; Ref. 3). The Agency does not believe that these types of studies provide a sufficient basis to estimate the quantitative benefits, if any, of COOL.

There are several limitations with the willingness-to-pay studies that call into question the appropriateness of using this approach to make determinations about the benefits of this rule. First, consumers in such studies often overstate their willingness to pay for a product. This typically happens because survey participants are not constrained by their normal household budgets when they are deciding which product or product feature they most value. Second, in most of these willingness-to-pay studies, consumers are not faced with the actual choices they would face at retail outlets. Third, consumers' willingness-to-pay as elicited from a survey is a function of the questions asked. Different questionnaires will yield different results. Finally, the results reported from these studies do not take into account changes in consumers' preferences for a particular product or product attribute over time.

As was the case in the interim final rule for fish and shellfish, a number of commenters pointed to additional food safety incidents that occurred in 2007, suggesting that mandatory COOL would provide food safety benefits to consumers. As discussed in the PRIA, however, mandatory COOL does not address food safety issues. Appropriate preventative measures and effective mechanisms to recall products in the event of contamination incidents are the means used to protect the health of the entire consuming public regardless of the form in which a product is consumed or where it is purchased. In

addition, foods imported into the United States must meet food safety standards equivalent to those required of products produced domestically.

*Costs:* To estimate the costs of this rule, a two-pronged approach was employed. First, implementation costs for firms in the industries directly affected by the rule were estimated. The implementation costs on directly affected firms represent increases in capital, labor, and other input costs that firms will incur to comply with the requirements of the rule. These costs are expenses that these particular firms must incur, and thus represent the opportunity costs of the rulemaking.

These costs, however, are not necessarily dead weight losses to the United States economy, as measured by the value of goods and services that are produced. This is simply because increases in capital, labor, and other inputs necessary to comply with the rule will benefit the providers of such inputs. In order to estimate the net decrease in economic activity as a result of this rulemaking, the implementation cost estimates were applied to a general equilibrium model to estimate overall impacts on the United States economy after a 10-year period of economic adjustment. The general equilibrium model provides a means to estimate the change in overall consumer purchasing power after the economy has adjusted to the requirements of the rule. In addition, since the Department has not identified a market failure associated with this rulemaking and therefore does not believe the rule would have measurable benefits, we believe this net decrease in economic activity can be considered the overall net costs (benefits minus costs) of this rulemaking.

Details of the data, sources, and methods underlying the cost estimates are provided in the PRIA. This section provides the revised cost estimates and describes revisions made to the PRIA.

In the PRIA, a range of estimated implementation costs were developed to reflect the likely range of first-year costs for directly affected firms to comply with the proposed rule. The lower range of incremental cost estimates reflected the costs to modify and maintain current recordkeeping systems, while the upper range of estimates reflected other capital and operational costs to comply with the proposed rule. We concluded in the PRIA that costs likely would fall in the middle to upper end of the range of estimated costs. Taking into account comments received on the proposed rule and the PRIA, as was the case in the regulatory impact analysis in the interim final rule for fish and

shellfish, this revised regulatory impact assessment presents only a single set of anticipated costs. Comments representing affected entities clearly described that compliance with the rule would require changes beyond recordkeeping alone. The revised incremental cost estimates reflect not only the revised definition of a processed product but the changes made as a result of the 2008 Farm Bill, the additional recordkeeping costs and additional payments by the directly affected firms for capital, labor, and other expenses that will be incurred as a result of operational changes to comply with the rule.

First-year incremental costs for directly affected firms are estimated at \$2.5 billion, a reduction of \$1.4 billion or 36 percent from the upper range estimate presented in the proposed rule. Costs per firm are estimated at \$376 for producers, \$53,948 for intermediaries (such as handlers, importers, processors, and wholesalers), and \$235,551 for retailers.

To assess the overall net impacts of the higher costs of production resulting from the rule, we used a computational general equilibrium (CGE) model of the United States economy developed by USDA's Economic Research Service (ERS) (Ref 4). The model was adjusted by imposing the estimated implementation costs on the directly impacted segments of the economy. That is, the costs of implementation increase costs of production for directly impacted firms, and these increased costs of production were imposed on the CGE model. The model estimates changes in prices, production, exports, and imports as the directly impacted industries adjust to higher costs of production over the longer run (10 years). The CGE model covers the whole United States economy, and estimates how other segments of the economy adjust to changes emanating from the directly affected segments and the resulting change in overall productivity of the economy.

Overall net costs to the United States economy in terms of reduced purchasing power resulting from a loss in productivity after a decade of adjustment are estimated at \$211.9 million in the tenth year. Domestic production for all of the covered commodities at the producer and retail levels, except for fruits and vegetables, is estimated to be lower, and prices are estimated to be higher, compared to the absence of this rulemaking. Fruit and vegetable production, exports, and imports are estimated to increase even though costs increase due to this rulemaking, likely due to substitution

effects attributable to the differential cost impacts of the rule. In addition, United States exports are estimated to decrease for all covered commodities except for fruits and vegetables. Compared to the baseline of no mandatory COOL, United States imports are estimated to increase for fruits and vegetables, cattle and sheep, hogs, chicken, and fish. United States imports of broilers, beef and veal, and pork are estimated to decrease.

The findings indicate that, consistent with standard economic theory, directly affected industries recover a portion of the higher costs imposed by the rule through slightly higher prices for their products. With higher prices, the

quantities of their products demanded also decline. Consumers pay slightly more for the products and purchase less of the covered commodities. Overall, the model indicates that the net loss to society, or the “deadweight” burden of the rule, is considerably smaller than the incremental opportunity costs to directly affected firms that were imposed on the model. The remainder of this section describes in greater detail how the estimated direct, incremental costs and the overall net costs to the United States economy are developed.

*Cost assumptions:* This rule directly regulates the activities of retailers (as defined by the law) and their suppliers. Retailers are required by the rule to

provide country of origin information for the covered commodities that they sell, and firms that supply covered commodities to these retailers must provide them with this information. In addition, virtually all other firms in the supply chain for the covered commodities are potentially affected by the rule because country of origin information will need to be maintained along the entire supply chain.

*Number of firms and number of establishments affected:* This rule is estimated to directly or indirectly affect approximately 1,256,000 establishments owned by approximately 1,222,000 firms. Table 1 provides estimates of the affected firms and establishments.

TABLE 1—ESTIMATED NUMBER OF AFFECTED ENTITIES

Type	Firms	Establishments
<b>Beef, Lamb, Pork, and Goat:</b>		
Cattle and Calves .....	971,400	971,400
Sheep and Lamb .....	69,090	69,090
Hogs and Pigs .....	65,540	65,540
Goats .....	9,146	9,146
Stockyards, Dealers & Market Agencies .....	6,807	6,807
Livestock Processing & Slaughtering .....	2,943	3,207
Meat & Meat Product Wholesale .....	2,509	2,706
<b>Chicken:</b>		
Chicken Producer and Processor .....	38	168
Chicken Wholesaler/Distributor .....	510	564
<b>Perishable Agricultural Commodities:</b>		
Fruits & Vegetables .....	79,800	79,800
Ginseng Farms .....	190	190
Ginseng Dealers .....	46	46
Frozen fruit, juice & vegetable mfg .....	155	247
Fresh fruit & vegetable wholesale .....	4,654	5,016
<b>Peanuts, Pecans, &amp; Macadamia Nuts:</b>		
Peanut Farming .....	650	650
Macadamia Farming .....	53	53
Pecan Farming .....	1,119	1,119
Roasted nuts & peanut butter mfg .....	8	9
Peanuts, Pecans, & Macadamia Wholesalers .....	5	5
General line grocery wholesalers .....	3,037	3,436
Retailers .....	4,040	36,392
<b>Totals:</b>		
Producers .....	1,197,026	1,197,156
Handlers, Processors, & Wholesalers .....	20,674	22,043
Retailers .....	4,040	36,392
<b>Grand Total .....</b>	<b>1,221,740</b>	<b>1,255,591</b>

Information in the PRIA for the numbers of affected producers has been updated with more recent information. Other changes from the PRIA are reductions in the numbers of affected entities in the peanut sector, and consequently, in the totals. In addition, affected entities in the chicken, goat, ginseng, macadamia nut, and pecan industries have been added. The rule covers only ginseng root. As previously discussed, the rule does not cover most product forms of peanuts, macadamia nuts, and pecans sold at retail, such as

roasted and dry-roasted peanuts. Only green and raw nuts are required by COOL because other product forms are not covered by this regulation due to the definition of a processed food item. Market shares for green and raw nuts sold at affected retailers are not available, but the volume of sales is certainly very small in comparison to roasted peanuts. For purposes of estimation, the numbers of affected entities at each level of the peanut, macadamia nuts, and pecan sectors were reduced to 5 percent of their totals,

consistent with levels reported in the PRIA (as applicable) due to the large percentage of product forms not covered by this rule. The number of peanut producers is reduced from 13,000 to 650, the number of macadamia nut producers is estimated at 53, the number of pecan producers is estimated at 1,119, the number of peanut, macadamia nut and pecan processing (which includes drying) firms is estimated at 8, and the number of peanut, macadamia nut, and pecan wholesaling firms is estimated at 5.

The chicken industry is somewhat different from the other covered commodities. One major difference is that chicken firms are highly vertically integrated and the integrators own the birds from the time they hatch to the time they sell the birds directly to retailers or to another processor or distributor. There are 38 chicken companies in the United States operating 168 slaughtering plants. The integrators dictate all aspects of the production process to the growers who are under contractual obligation to grow-out chickens for one of the integrators. All decisions from when to populate a grower's farm, to feed formulation, veterinarian services, and harvesting the mature chickens are made by the integrator. The grower supplies the chicken houses and the labor.

Of all the chicken sold to retailers, 68.9 percent comes directly from the integrator, 27.7 percent through a distributor, and the remaining from brokers and further processors. With 95 percent of the chickens produced/processed under vertical integration, keeping track of the product should be less burdensome than for other covered commodities. For the vertically integrated firms, the main cost will be stepping-up their on-going tracking system, if they do not have an adequate system already, more labeling, and more involvement in ensuring the required information is sent to retailers for each load of product, if the product is not already pre-labeled for COOL.

It is assumed that all firms and establishments identified in Table 1 will be affected by the rule, although some may not produce or sell products ultimately within the scope of the rule. While this assumption may overstate the number of affected firms and establishments, we nevertheless believe the assumption is reasonable. Detailed data are not available on the number of entities categorized by the marketing channels in which they operate and the specific products that they sell.

*Source of cost estimates:* To develop estimates of the cost of implementing this rule, comments on the proposed rule as well as the interim final rule for fish and shellfish were reviewed and available economic studies were also examined. No single source of information, however, provided comprehensive coverage of all economic benefits and costs associated with mandatory COOL for all of the covered commodities. Available information and knowledge about the operation of the supply chains for the covered commodities were used to synthesize

the findings of the available studies about the rule's potential costs.

*Cost drivers:* This rule is a retail labeling requirement. Retail stores subject to this rule will be required to inform consumers as to the country of origin of the covered commodities that they sell. To accomplish this task, individual package labels or other point-of-sale materials will be required. If products are not already labeled by suppliers, the retailer will be responsible for labeling the items or providing the country of origin information through other point-of-sale materials. This may require additional retail labor and personnel training. Modification to existing recordkeeping systems likely will be required to ensure that products are labeled accurately and to permit compliance and enforcement reviews. For most retail firms of the size defined by the statute (i.e., those retailing fresh and frozen fruits and vegetables with an invoice value of at least \$230,000 annually), we assume that recordkeeping will be accomplished primarily by electronic means. Modifications to recordkeeping systems will require software programming and may entail additional computer hardware. Retail stores are also expected to undertake efforts to ensure that their operations are in compliance with the rule.

Prior to reaching retailers, most covered commodities move through distribution centers or warehouses. Direct store deliveries (such as when a local truck farmer delivers fresh produce directly to a retail store) are an exception. Distribution centers will be required to provide retailers with country of origin information. This likely will require modification of existing recordkeeping processes to ensure that the information passed from suppliers to retail stores permits accurate product labeling and permits compliance and enforcement reviews. Additional labor and training may be required to accommodate new processes and procedures needed to maintain the flow of country of origin information through the distribution system. There may be a need to further separate products within the warehouse, add storage slots, and alter product stocking, sorting, and picking procedures.

Packers and processors of covered commodities will also need to inform retailers and wholesalers as to the country of origin of the products that they sell. To do so, their suppliers will need to provide documentation regarding the country of origin of the products that they sell. Maintaining country of origin identity through the packing or processing phase may be

more complex if products are from more than one country. The efficiency of operations may be affected as products move through the receiving, storage, processing, and shipping operations. For packers and processors handling products from multiple origins, there may also be a need to separate shifts for processing products from different origins, to split processing within shifts, or to alter labels to correctly identify the country or countries of origin. However, in the case of meat covered commodities, there is flexibility in labeling covered commodities of multiple origins under this interim final rule. In the case where products of different origins are segregated, costs are likely to increase. Records will need to be maintained to ensure that accurate country of origin information is retained throughout the process and available to permit compliance and enforcement reviews. In the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the country of origin claim.

Processors handling only domestic origin products or products from a single country of origin may have lower implementation costs compared with processors handling products from multiple origins. Procurement costs also may be unaffected in this case, if the processor is able to continue sourcing products from the same suppliers. Alternatively, a processor that currently sources products from multiple countries may choose to limit its source to fewer countries or a single country. In this case, such cost avoidance would be partially offset by additional procurement costs to source supplies from a single or narrower country of origin. Additional procurement costs may include higher transportation costs due to longer shipping distances and higher acquisition costs due to supply and demand conditions for products from a particular country of origin, whether domestic or foreign.

At the production level, agricultural producers need to maintain information in existing records to establish country of origin information for the products they produce and sell. Country of origin information will need to be transferred to the first handler of their products, and records sufficient to allow the source of the product to be traced back will need to be maintained as the products move through the supply chains. In the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the country of origin

claim. In general, additional producer costs include the cost of modifying and maintaining a recordkeeping system for country of origin information, animal or

product identification, and labor and training.

*Incremental cost impacts on affected entities:* To estimate the direct costs of this rule, the focus is on those units of

production that are affected (Table 2). Relative to the PRIA, estimated quantities are reduced for peanut producers and for all commodities at the intermediary and retailer levels.

TABLE 2—ESTIMATED ANNUAL UNITS OF PRODUCTION AFFECTED BY MANDATORY COUNTRY OF ORIGIN LABELING

	Beef	Pork	Lamb and goat	Chicken	Fruit, vegetable, and ginseng	Peanuts, pecans, and macadamia nuts
	<b>Million Head</b>			<b>Million Pounds</b>		
Producer .....	33.9	104.8	2.9	45,012.9	120,388.5	212.7
	<b>Million Pounds</b>					
Intermediary .....	24,890	6,721	354	27,710	99,449	11
Retailer .....	8,193	2,330	133	17,645	47,078	5

For livestock, the relevant unit of production is an animal because there will be costs associated with maintaining country of origin information on each animal. These costs may include recordkeeping and ear tagging and other related means of identification on either an individual animal or lot basis. Annual domestic slaughter numbers are used to estimate the flow of animals through the live animal production segment of the supply chain. Estimates have changed from the PRIA due to the addition of the new commodities (chicken, goats, macadamia nuts, pecans, and ginseng), the use of more up-to-date information for previously included commodities, the revised definition of a processed product and of ground beef, and changes made to the COOL provisions by the 2008 Farm Bill.

For chicken producers, production is measured by round weight (live weight) pounds.

For fruits and vegetables, we assume that essentially all production is predestined for either fresh or processing use. That is, growers know before the crop is produced whether it will be sold for fresh consumption or for processing. However, producers do not know whether their products ultimately will be sold to retailers, foodservice firms, or exporters. Therefore, it is assumed that all fresh fruit and vegetable production and production destined for frozen processors at the producer level will be affected by this rule. Ginseng production has been included with the fruit and vegetable production. The total fruit and vegetable production has been updated with 2006 data from the PRIA.

As previously discussed, only green and raw peanuts, macadamia nuts, and

pecans sold at retail are subject to the requirements of this rule because of the definition of a processed food item. Green and raw peanuts are specialty items typically sold at roadside stands, through mail order, and at specialty shops. These items frequently are not carried by many of the retailers subject to this rule. Statistics on the size of this niche market are not readily available. We assume that no more than 5 percent of the sales of peanuts at subject retailers are sold as green or raw peanuts. Therefore, the initial estimates of the volume of peanuts affected by this rule are reduced to 5 percent of the amounts estimated in the PRIA. Macadamia nuts and pecans have been included with peanuts.

We assume that all sales by intermediaries such as handlers, packers, processors, wholesalers, and importers will be affected by the rule. Although some product is destined exclusively for foodservice or other channels of distribution not subject to the rule, we believe these intermediaries will seek to keep their marketing options open for possible sales to subject retailers. Estimated units of production for most commodities at the intermediary level are reduced from the PRIA due to the definition of a processed food item.

Beef production at the intermediary level is reduced 10 percent from the PRIA estimate to account for the change in the definition of a processed food item. Data are not readily available on the sales of beef in different product forms. Based on discussions with industry experts, it is assumed that approximately 10 percent of beef products are sold in forms exempt from this rule (e.g., cooked products, seasoned products).

Pork production at the intermediary level is reduced by 12.2 billion pounds. Unlike beef and lamb, much of the pork carcass typically is processed into products that would not be covered under the COOL rule. For example, most of the ham and bacon are cured, and other cuts such as picnic meat are used for sausage and other processed products. Thus, a factor of 0.375 is applied to pork production at both the intermediary and retailer levels, which is the estimate of the proportion of the retail-weight pork carcass that is used for fresh pork cuts that would require country of origin labeling under the rule. The cuts assumed to be covered commodities are fresh ham, all of the loin cuts, spareribs, and the entire Boston butt. We recognize that some of these cuts will be processed into items not covered by the rule, while other cuts will be sold in unprocessed forms that would be covered by the rule. In the PRIA, the 37.5 percent adjustment factor was applied at the retailer level, but not at the intermediary level. In this analysis, we have also applied the adjustment at intermediary levels, because products destined for items exempt from the rule would not require COOL. In addition to the 37.5 percent adjustment factor, a further reduction of 10 percent is applied to account for the increase in the number of items exempt from the labeling requirements due to the revised definition of a processed food item.

Lamb production at the intermediary level is unchanged from the PRIA, as there are relatively few of the value-added types of products that would be excluded from labeling. Goat meat has been included with lamb.

Fruit and vegetable production at the intermediary level is reduced by 21.2

billion pounds to exclude products not covered by this rule under the definition of a processed food item. The revised estimate includes only frozen, plain vegetables in the frozen vegetables category because items such as mixed frozen vegetables and vegetables with sauce are not covered by this rule. Frozen, plain vegetable sales at retail are estimated at 5.5 billion pounds (Ref. 5).

Information and data on ginseng is limited. However, the Wisconsin Department of Agriculture reports the number of growers at 190, the number of dealers at 46, and grower sales at 282,055 dry root pounds for 2006 (Ref. 6). While some other regions in the country likely produce ginseng, information could not be found and it is believed that Wisconsin is the largest producing state. The information from Wisconsin likely underestimates the total number of farms, dealers, and production of ginseng. However, we believe that Wisconsin represents most of the ginseng production; therefore, this information is used for this rule. Since the number of entities and production are likely underestimated and the production is relatively small as compared to other covered commodities, the production was not adjusted for retail consumption.

The Census of Agriculture provides an estimate of the number of macadamia nut farming operations. The total number of macadamia farms is estimated at 1,059 [Ref. 7]. Businesses that husk and crack macadamia nuts are unofficially estimated by the Hawaii Field Office of the National Agricultural Statistical Service (NASS) at 8 firms and establishments. Businesses that

wholesale macadamia nuts are estimated by the Hawaii Department of Agriculture at 21 firms and establishments. Similar to peanuts, the rule exempts most product forms of macadamia nuts sold at retail. While data on macadamia nuts sold at retail that are covered by this rule are not available, the volume of sales is certainly very small. For purposes of estimation, the number of affected entities at each level of the macadamia nut sector has been reduced to 5 percent of the total estimated. The number of farms has been reduced from 1059 to 53 and the number of wholesalers has been reduced from 21 to 1.

The Census of Agriculture provides an estimate of 22,371 pecan farming operations [Ref. 7]. Similar to peanuts and macadamia nuts, the rule exempts most product forms of pecans sold at retail. For purposes of estimation, the number of affected entities at each level of the pecan sector has been reduced to 5 percent of the total 22,371 farms to 1,119 farms.

As with peanut, macadamia nut, and pecan production at the producer level, peanut, macadamia nut, and pecan production at the intermediary level is also reduced by 95 percent. The estimate of peanut, macadamia nut, and pecan production is intended to include only green and raw peanuts, macadamia nuts, and pecans.

For retailers, food disappearance figures are adjusted to estimate consumption through retailers as defined by the statute. For each covered commodity, disappearance figures are multiplied by 0.470, which represents the estimated share of production sold

through retailers covered by this rule. To derive this share, the factor of 0.622 is used to remove the 37.8 percent food service quantity share of total food in 2006 (Ref. 8). This factor is then multiplied by 0.756, which was the share of sales by supermarkets, warehouse clubs and superstores of food for home consumption in 2006 (Ref 9). In other words, supermarkets, warehouse clubs and superstores represent the retailers as defined by PACA, and these retailers are estimated to account for 75.6 percent of retail sales of the covered commodities.

Estimated beef and pork volumes at the retailer level are reduced by 10 percent from the PRIA to account for the larger number of items exempt from labeling under the revised definition of a processed food item. Lamb volume is unchanged from the PRIA estimate. Goat meat has been included with lamb.

Estimated total retailer volume is increased by 18.0 billion pounds because chicken was not a covered commodity in the PRIA.

Fruit and vegetable retailer volume is reduced by 8.5 billion pounds from the PRIA estimate because of the exclusion of a large volume of frozen vegetable products under the revised definition of a processed food item. Retailer peanut volume is reduced 95 percent from the PRIA estimate due to the revised definition of a processed food item.

Table 3 summarizes the direct, incremental costs that firms will incur during the first year as a result of this rule. These estimates are derived primarily from the available studies that addressed cost impacts of mandatory COOL.

TABLE 3—ESTIMATES OF FIRST-YEAR IMPLEMENTATION COSTS PER AFFECTED INDUSTRY SEGMENT  
[Million dollars]

	Beef	Pork	Lamb & goat	Chicken	F & V	Peanuts, pecans, & macadamia nuts <sup>1</sup>	Total
Producer .....	305	105	10	0	30	0	450
Intermediary .....	373	101	5	139	497	0	1,115
Retailer .....	574	93	5	44	235	0	952
Total .....	1,252	299	21	183	763	0	2,517

<sup>1</sup> Indicates a value greater than zero, but less than 0.5.

Assumptions and procedures underlying the cost estimates are described fully in the discussion of the “upper range” estimates presented in the PRIA. Changes from the PRIA estimates are highlighted herein. One of the major changes is that all the data from the PRIA has been updated by using more recent data.

Considering all producer segments together, we have estimated a \$9 per head cost to cattle producers to implement the rule. This estimate reflects the expectation of relatively small implementation costs at the cow-calf level of production, but relatively higher costs each time cattle are resold. Typically, fed steers and heifers change

hands two, three, or more times from birth to slaughter, and each exchange will require the transfer of country of origin information. Thus, total costs for beef producers are estimated at \$305 million, a 16 percent reduction from the PRIA upper range estimate due to the lower level of slaughter in 2006 and the slightly lower per head cost estimate. In

addition, as provided in the 2008 Farm Bill, in the case of livestock, a producer affidavit shall be considered acceptable evidence on which a packer may rely to initiate an origin claim.

We assume that intermediaries will face increased costs associated with tracking cattle and the covered beef commodities produced from these animals and providing this information to subsequent purchasers, which may be other intermediaries or covered retailers. Incremental costs for beef packers may include additional capital and labor expenditures to enable cattle from different origins to be tracked for slaughter, fabrication, and processing. As previously mentioned, under this interim final rule, if an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y where Country X and Country Y represent the actual or possible countries of foreign origin. In addition, the rule also provides for flexibility in labeling ground products by allowing the notice of country of origin to include a list of countries contained therein or that may reasonably be contained therein. However, we believe that some segregation will still occur in order to provide the marketplace with product strictly of United States origin. Considering the costs likely to be faced by intermediaries in the beef sector, \$0.015 per pound is adopted as an estimate of costs, which is consistent with estimates from the available studies. Total costs are thus estimated at \$373 million, a 31 percent reduction from the PRIA upper range estimate due to the reduced estimate of the volume of production affected and the slightly lowered per pound cost estimate. The cost per pound was lowered due to the increasing use of pre-packaged and pre-labeled beef products, which lowers costs for retailers as well as intermediaries.

The implementation costs are estimated at \$0.07 per pound for beef retailers, for a total of \$574 million. This figure reflects the costs for individual package labels, meat case segmentation, record keeping and information technology changes, labor, training, and auditing. In addition, there likely will be increased costs for in-store butcher department operations related to cutting, repackaging, and grinding operations. As with the estimate for intermediaries, the estimate for retailers

is reduced by 10 percent from the PRIA upper range estimate.

Total costs for affected entities in the beef sector are thus estimated at \$1,252 million, a 26 percent reduction from the PRIA estimate.

Costs for pork producers are estimated at \$1.00 per head. With annual slaughter of 104.8 million head, total costs for producers are estimated at \$105 million, which is a 30 percent reduction from the PRIA estimate due to a slightly lower per head slaughter estimate.

Costs for all pork sector intermediaries (including handlers, processors, and wholesalers) should be similar to costs for beef sector intermediaries. These estimated costs for pork industry intermediaries are \$0.015 per pound, for a total of \$101 million, a reduction of \$267 million from the PRIA estimate. The reduction is due to the downward revision of the volume of pork production estimated to be affected at the intermediary level and a slightly lower per pound cost estimate.

Costs for retailers of pork are estimated to be \$0.04 per pound. The per-pound cost estimate for pork is lower than for beef primarily to reflect the higher costs incurred by in-store grinding operations to produce ground beef. Although ground pork may also be produced in-store, most ground pork is processed into sausage and other products not covered by the rule. Total estimated costs for pork retailers are \$93 million, a 40 percent decrease from the PRIA estimate. Total costs for the pork sector are estimated at \$299 million, which is \$374 million less than the PRIA upper range estimate.

Costs per head for lamb and goat producers are estimated at \$3.50 per head. Total costs for lamb and goat producers are estimated at \$10 million, which is \$5 million less than the PRIA estimate even with the addition of goat.

Intermediaries in the lamb and goat sector will likely face per-pound costs similar to costs faced by beef and pork sector intermediaries, which are estimated at \$0.015 per pound. Total costs for lamb and goat sector intermediaries are thus estimated at \$5 million, which is \$2 million less than the PRIA upper range estimate.

Costs to retailers for lamb and goat should be similar to costs borne for pork, which was estimated at \$0.04 per pound. Total costs for retailers of lamb and goat are estimated at \$5 million, which is \$4 million lower than the PRIA upper range estimate.

Summing the estimates for producers, intermediaries, and retailers results in estimated costs of \$21 million for the lamb and goat industries. This total is \$11 million less than the PRIA upper

range estimate even with the inclusion of goat as a covered commodity.

Costs for chicken producers who grow-out chicken for an integrator (the firm that will slaughter and possibly further process the chickens) is \$0.00 because these individuals do not own or control the movement of the chickens they are raising. All chickens produced are owned, and their movement is controlled, by the integrator, which is the main intermediary in the chicken supply chain. We do not expect that producers will need change any current practices and thus will not incur any additional costs due to this rule.

Costs for the intermediaries in the chicken supply chain are estimated to be \$0.005 per pound. Since the integrators own their chickens from the time they hatch to time they are sold to a retailer or distributor, there is no need to "collect" country of origin information. Costs to the integrator are mainly due to system changes to incorporate COOL information into existing recordkeeping systems and supplying required information to the retailers and food distributors. Approximately 69 percent of chicken covered by COOL is supplied directly to the retailer from the integrator. The vast majority, if not all, of the chicken supplied by the integrator is pre-labeled. The bulk of the rest is supplied by the distributors whose costs will be slightly higher since they are receiving product from integrators and selling product to retailers. Total costs for intermediaries are estimated at \$139 million.

Costs for retailers are estimated to be \$0.0025 per pound. As noted above, most, if not all, chicken is purchased directly from integrators and will have been pre-labeled. This will significantly lower the retailers cost in terms of meeting COOL requirements. Most of the costs retailers will bear will be from distributors. Total cost for retailers are \$44 million.

Total estimated costs for chicken producers, intermediaries, and retailers are \$183 million. Since chicken costs were not included in the PRIA, the total estimated costs for chicken is an increase in the total cost of covered commodities in the PRIA.

Although fruit, vegetable, and ginseng producers maintain the types of records that will be required to substantiate United States origin claims, it is believed that this information is not universally transferred by producers to purchasers of their products. Producers will have to supply this type of information in a format that allows handlers and processors to maintain country of origin information so that it can be accurately transferred to retailers.

For fruit, vegetable, and ginseng producers, costs are estimated at \$0.00025 per pound to make and substantiate COOL claims, which equates to \$0.01 for a 40 pound container. Because fruits and vegetables only have a single point of origin, which is where they are grown, substantiating country of origin claims is substantially simpler for fruit and vegetable producers than for livestock producers. Total costs for fruit, vegetable, and ginseng producers are estimated at \$30 million, which is \$6 million higher than the PRIA upper range estimate for fruits and vegetables due to higher levels of production in 2006.

Fruit, vegetable, and ginseng intermediaries will shoulder a sizeable portion of the burden of tracking and substantiating country of origin information. Intermediaries will need to obtain information to substantiate COOL claims by producers and suppliers; maintain COOL identity throughout handling, processing, and distribution; and supply retailers with COOL information through product labels and records. The estimated cost for these activities for fruit and vegetable sector intermediaries is \$0.005 per pound, resulting in total estimated costs of \$497 million. This amount is \$83 million less than the PRIA upper range estimate because of the lowered estimate of the volume of production affected by the rule.

Because intermediaries will bear a large portion of the burden of COOL tracking and labeling, implementation costs for retailers will be reduced. It is believed that virtually all frozen fruits and vegetables will be labeled by suppliers, thus imposing minimal incremental costs for retailers. In addition, over 60 percent of fresh fruits and vegetables arrive at retail with labels or stickers that may be used to provide COOL information. It is believed that fresh fruit and vegetable suppliers will provide COOL information on these labels and stickers, again imposing minimal incremental costs for retailers. Costs for retailers are estimated at \$0.005 per pound of fresh and frozen fruits and vegetables, \$0.005 less than the amount assumed for the PRIA upper range estimates. The lower per-unit cost is supported by the revised recordkeeping requirements. For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish a product's country of origin. For these pre-labeled products, the product label or sticker carries the required country of origin information, while the recordkeeping system maintains the information necessary to track the product back

through the supply chain. Total costs for fruits, vegetables, and ginseng at retail are estimated at \$235 million, a reduction of \$485 million from the PRIA. The lowered cost estimate is attributable to both a lowered estimate of the volume of affected production and a lowered estimated cost per unit for retailers.

Costs per pound for each segment of the peanut, macadamia nut, and pecan industries is estimated at \$0.00025 for producers, \$0.005 for intermediaries and \$0.015 for retailers. As a result, costs for the peanut, macadamia nut, and pecan industries are estimated at about \$400,000, with negligible costs for producers and costs of less than \$200,000 at the intermediary and retailer levels. Total upper range costs for all the peanut sectors were estimated at \$8 million in the PRIA. The reduced estimates are due to the drastically lowered estimates of the volumes of affected peanut, macadamia nut, and pecan production.

Total incremental costs are estimated for this rule at \$450 million for producers, \$1,115 million for intermediaries and \$952 million for retailers for the first year. Total incremental costs for all supply chain participants are estimated at \$2,517 million for the first year, a reduction of \$1,365 million from the PRIA upper range estimate even though a number of new commodities have been added for COOL coverage. The reduced estimates are due to lower volumes of affected products at the intermediary as well as the retailer level and slightly lower cost estimates.

There are wide differences in average estimated implementation costs for individual entities in different segments of the supply chain (Table 4). With the exception of a small number of chicken producers, producer operations are single-establishment firms. Thus, average estimated costs per firm and per establishment are somewhat similar. Retailers subject to the rule operate an average of just over nine establishments per firm. As a result, average estimated costs per retail firm also are just over nine times larger than average costs per establishment.

TABLE 4—ESTIMATED IMPLEMENTATION COSTS PER FIRM AND ESTABLISHMENT

	Cost estimates per	
	Firm	Establishment
Producer .....	\$376	\$376
Intermediary .....	53,948	50,598
Retailer .....	235,551	26,149

Average estimated implementation costs per producer are relatively small at \$376. This is \$67 per firm lower than the PRIA estimates. The difference is attributable to the reduction in the number of peanut producers. Estimated costs for intermediaries are substantially larger, averaging \$53,948 per firm and \$50,598 per establishment. The average cost per firm is \$3,862 higher than the PRIA upper range estimated cost, with the higher cost attributable to the lower number of estimated firms. Similarly, the average cost per intermediary establishment is \$7,996 higher than PRIA the upper range estimate due to the lower number of establishments. At an average of \$235,551 per firm, retailers have the highest average estimated costs per firm. This is \$160,538 lower than the PRIA upper range estimate. The lower estimated cost per retailer is attributable to the reduction in the number of retailing firms from the PRIA time period and the lower total estimated costs. Retailers' average estimated costs per establishment are \$26,149. This amount is \$21,924 lower than the PRIA upper range estimate.

The costs per firm and per establishment represent industry averages for aggregated segments of the supply chain. Large firms and establishments likely will incur higher costs relative to small operations due to the volume of commodities that they handle and the increased complexity of their operations. In addition, different types of businesses within each segment are likely to face different costs. Thus, the range of costs incurred by individual businesses within each segment is expected to be large, with some firms incurring only a fraction of the average costs and other firms incurring costs many times larger than the average.

Average costs per producer operation can be calculated according to the commodities that they produce (Table 5). Average estimated costs are lowest for lamb and goat producers (\$128) and highest for hog operations (\$1,599). Again, chicken "producers" do not own or control the movement of the birds they are growing-out. We do not expect that the rule will result in any changes in their current production practices, and thus their average cost is zero. Because average production volume per hog operation is large relative to other types of producer operations, estimated costs per hog operation are large relative to other producer operations.

TABLE 5—ESTIMATED FIRST-YEAR IMPLEMENTATION COSTS PER PRODUCER OPERATION

Producer	Average cost
Beef .....	\$314
Lamb & Goats .....	128
Pork .....	1,599
Chicken .....	0
Fruits, Vegetables & Ginseng ..	376
Peanuts, Pecans, & Macadamia Nuts .....	258

It is believed that the major cost drivers for the rule occur when livestock or covered commodities are transferred from one firm to another, when livestock or covered commodities are commingled in the production or marketing process, and when products are assembled and then redistributed to retail stores. In part, some requirements of the rule will be accomplished by firms using essentially the same processes and practices as are currently used, but with information on country of origin claims added to the processes. This adaptation generally would require relatively small marginal costs for recordkeeping and identification systems. In other cases, however, firms may need to revamp current operating processes to implement the rule. For example, a processing or packing plant may need to sort incoming products by country of origin in addition to weight, grade, color, or other quality factors. This may require adjustments to plant operations, line processing, product handling, and storage. Ultimately, it is anticipated that a mix of solutions will be implemented by industry participants to effectively meet the requirements of the rule. Therefore, it is anticipated that direct, incremental costs for the rule likely will fall within a reasonable range of the estimated total of \$2,517 million.

In the PRIA, one regulatory alternative considered by AMS would be to narrow the definition of a processed food item, thereby increasing the scope of commodities covered by the rule. This alternative is not adopted in this rule. An increase in the number of commodities that would require COOL would increase implementation costs of the rule with little expected economic benefit. Additional labeling requirements may also slow some of the innovation that is occurring with various types of value-added, further processed products.

A different regulatory alternative would be to broaden the definition of a processed food item, thereby decreasing the scope of commodities covered by

the rule. Accordingly, such an alternative would decrease implementation costs for the rule. At the retail level and to a lesser extent at the intermediary level, cost reductions would be at least partly proportional to the reduction in the volume of production requiring retail labeling, although if the broader definition excluded products for which incremental costs are relatively high, such as beef products, the impact could be more than proportional. Start-up costs for retailers and many intermediaries likely would be little changed by a narrowing of the scope of commodities requiring labeling because firms would still need to modify their recordkeeping, production, warehousing, distribution, and sales systems to accommodate the requirements of the rule for those commodities that would require labeling. Ongoing maintenance and operational costs, however, likely would decrease in some proportion to a decrease in the number of items covered by the rule. On the other hand, implementation costs for the vast majority of agricultural producers would not be affected by a change in the definition of a processed food item. This is because it is assumed that virtually all affected producers would seek to retain the option of selling their products through supply channels for retailers subject to the rule. Agricultural producers generally would have little influence on the ultimate product form in which their products are sold at retail, and thus would be little affected by changes in the definition of a processed food item.

The definition of a processed food item developed for this rule has taken into account comments from affected entities and has resulted in excluding products that would be more costly and troublesome for retailers and suppliers to provide country of origin information. Total incremental costs for this rule are estimated at \$1,365 million less than the upper range costs estimated in the PRIA, with much of the reduction attributable to the revised definition of a processed food item.

*Net Effects on the economy:* The previous section estimated the direct, incremental costs of the rule to the affected firms in the supply chains for the covered commodities. While these costs are important to those directly involved in the production, distribution, and marketing of covered commodities, they do not represent net costs to the United States economy or net costs to the affected entities for that matter.

With respect to assessing the net effect of this rule on the economy as a

whole, it is important to understand that a significant portion of the costs directly incurred by the affected entities take the form of expenditures for additional production inputs, such as payments to others whether for increased hours worked or for products and services provided. As such, these direct, incremental costs to affected entities represent opportunity costs of the rule, but they do not represent net losses to the economy. As a result, the direct costs incurred by the participants in the supply chains for the covered commodities do not measure the net impact of this rule on the economy as a whole. Instead, the relevant measure of net impact is the extent to which the rule reduces the amount of goods and services that can be produced throughout the United States economy from the available supply of inputs and resources.

Even from the perspective of the directly affected entities, the direct, incremental costs do not present the whole picture. Initially, the affected entities will have to incur the operational adjustments and expenses necessary to implement the rule. However, over time as the economy adjusts to the requirements of the rule, the burden facing suppliers will be reduced as their production level and the prices they receive change. What is critical in assessing the net effect of this rule on the affected entities over the longer run is to determine the extent to which the entities are able to pass these costs on to others and consequently how the demand for their commodities is affected.

Conceptually, suppose that all the increases in costs from the rule were passed on to consumers in the form of higher prices and that consumers continued to purchase the same quantity of the affected commodities from the same marketing channels. Under these conditions, the suppliers of these commodities would not suffer any net loss from the rule even if the increases in their operating costs were quite substantial. However, other industries might face losses as consumers would spend less on other commodities. It is unlikely, however, absent the rule leading to changes in consumers' preferences for the covered commodities that consumers will maintain their consumption of the covered commodities in the face of increased prices. Rather, many or most consumers will likely reduce their consumption of the covered commodities. The resulting changes in consumption patterns will in turn lead to changes in production patterns and the allocation of inputs and resources

throughout the economy. The net result, once all these changes have occurred, is that the total amount of goods and services produced by the United States economy will be less than before.

To analyze the effect of the changes resulting from the rule on the total amount of goods and services produced throughout the United States economy in a global context, a computable general equilibrium (CGE) model developed by the Economic Research Service (ERS) is utilized (Ref. 4). The ERS CGE model includes all the covered commodities and the products from which they are derived, as well as non-covered commodities that will be indirectly affected by the rule, such as feed grains. Even though COOL for fish was implemented in 2004, the costs for fish and shellfish are included here to account for the cross-commodity effects between covered commodities. Ignoring the costs for fish and shellfish would result in assuming that COOL did not apply to fish and the cross-commodity effects may be distorted. Peanuts, however, are aggregated with oilseeds in the model, and there is no meaningful way to modify the model to account for the impacts of the rule on peanut production, processing, and consumption. Given the revised definition of a processed food item, almost all peanut products are exempt from this rule. As a consequence, the peanut sector accounts for only a negligible fraction of the total estimated incremental costs for all directly affected entities. Thus, omitting the small direct costs on the peanut sector

is expected to have negligible impacts with respect to estimated net impacts on the overall United States economy.

The ERS CGE model traces the impacts from an economic "shock," in this case a permanent incremental increase in costs of production, through the U.S agricultural sector and the U.S economy to the rest of the world and back through the inter-linking of economic sectors. By taking into account the linkages among the various sectors of the United States and world economies, a comprehensive assessment can be made of the economic impact on the United States economy of the rule implementing COOL. The model reports economic changes resulting after a ten-year period of adjustment.

The results of this analysis indicate that the rule implementing COOL after the economy has had a period of ten years to adjust will have a smaller net impact on the overall United States economy than the incremental costs for directly affected entities for the first year. Under the assumption that COOL will not change consumers' preferences for the covered commodities, it is estimated that the overall net costs to the United States economy due to the rule, in terms of a reduction in consumers' purchasing power, will be \$211.9 million. This represents the net cost to the United States economy after all transfers and adjustments in consumption and production patterns have occurred.

Overall net costs to the United States economy after a decade of adjustment are significantly smaller than the

implementation costs to directly affected firms. This result does not imply that the implementation costs for directly affected firms have been substantially reduced from the initial estimates. While some of the increase in their costs will be offset by reduced production and higher prices over the longer term, the suppliers of the covered commodities will still bear direct implementation costs.

The estimates of the overall net costs to the United States economy are based on the estimates of the incremental increases in operating costs to the affected firms. The model does not permit supply channels for covered commodities that require country of origin information to be separated from supply channels for the same commodities that do not require COOL. Thus, the direct cost impacts must be adjusted to accurately reflect changes in operating costs for all firms supplying covered commodities. Table 6 reports these adjusted estimates in terms of their percentage of total operating costs for each of the directly affected sectors. The percentages used are based on the estimate of the percentage change in operating costs for the entire supply channel and are adjusted between the various segments of each covered commodities' supply chain (producers, processors, importers, and retailers) based on the estimate of how the costs of the regulation will be distributed among them. As a result, the cost changes shown in Table 6 only approximate the direct cost estimates previously described.

		Beef, Lamb, & Goat	Pork	Chicken	Fish	Fresh Produce
		percent change				
Farm Supply	Domestic	1.30	1.30	0.00	0.60	0.10
	Imported	1.30	1.30	1.00	0.60	0.10
Processing	Domestic	2.10	1.00	1.10	n.a.	n.a.
	Imported	2.10	1.00	1.10	n.a.	n.a.
Retail	Domestic	2.20	0.40	0.60	0.40	0.60
	Imported	2.20	0.40	0.60	0.40	0.60
n.a. - Not Applicable.						

In addition, it is assumed that domestic and foreign suppliers of the affected commodities located at the same level or segment of the supply chain face the same percentage increases in their operating costs. In reality, the incremental costs for some imported covered commodities may be lower, as a portion of those products already enter the United States with country of origin labels.

The percentage changes in operating costs reported in Table 6 differ from the percentage changes in operating costs reported for the High Cost scenario as listed in Table 8 in the PRIA. The differences in percentage changes reported in the PRIA and those reported here are attributable to changes in implementation costs of the rule as well as recalibration of our estimates of total operating costs for the various segments of the supply channels of the directly affected sectors. Thus, for example, even though changes in the rule reduced our estimate of the incremental costs incurred by intermediaries and retailers in the beef and lamb sectors, the recalibration of our estimate of their operating costs causes the estimated percentage change in costs applied to

processing and retailing segments of these sectors to increase.

As discussed above, consumption and production patterns will change as the incremental increases in operating costs outlined above are passed on, at least partially, to consumers in the form of higher prices by the affected firms. The increases in the prices of the covered commodities will in turn cause exports and domestic consumption and ultimately domestic production to fall. The results of our analysis indicate that United States production of all the covered commodities combined will decline 0.02 percent and that the overall price level for these commodities (a weighted average index of the prices received by suppliers for their commodities) will increase by 0.02 percent.

The structure of the model does not enable changes in net revenues to suppliers of the covered commodities to be determined. Likewise, the model cannot be used to determine the extent to which the reductions in production arise from some firms going out of business or all firms cutting back on their production. To provide an indication of what effect this will have on the suppliers of the covered commodities, changes in revenues using

the model results are estimated. The result of this calculation shows that revenues to suppliers of the covered commodities will decrease by \$461 million. This decrease in revenue is due to the decrease in estimated revenues in all the covered commodities; all affected sectors show a small revenue decrease due to the increased costs of the rule.

The costs of the rule will not be shared equally by all suppliers of the covered commodities. The distribution of the costs of the rule will be determined by several factors in addition to the direct costs of complying with the rule. These are the availability of substitute products not covered by the rule and the relative competitiveness of the affected suppliers with respect to other sectors of the U.S. and world economies.

Although the increases in operating costs are the initial drivers behind the changes in consumption and production patterns resulting from this rule, they do not, as can be seen by examining Table 7, determine which commodity sector will be most affected. Table 7 contains the percentage changes in prices, production, exports, and imports for the three main segments of the marketing chain by covered commodities.

TABLE 7—ESTIMATED IMPACT OF RULE ON U.S. PRODUCTION, PRICES AND TRADE OF IMPACTED SECTORS

Commodity	Price	Production	Exports (volume)	Imports (volume)
Fruits and Vegetables .....	0.21	-0.20	-0.39	0.04
Cattle and Sheep .....	0.52	-0.94	-1.18	0.25
Broilers .....	0.03	-0.56	-0.36	-0.03
Hogs .....	0.26	-0.46	-0.60	0.16
Beef and Veal .....	0.99	-1.09	-1.93	-2.32
Chicken .....	0.82	-0.90	-1.54	0.29
Pork .....	0.68	-0.81	-1.37	-0.86
Fish .....	0.50	-0.68	-0.06	0.04

As mentioned previously, peanuts, macadamia nuts, and pecans are included with oilseed products in the ERS CGE model. As a result, they are not included in this analysis.

The rule increases operating costs for the supply chains of the covered commodities. As shown in Table 7, the increased costs result in higher prices for these products. The quantity demanded at these higher prices falls, with the result that the production of all of the covered commodities decreases.

Imports of fruits, vegetables, cattle, sheep, chicken, fish, and hogs increase because United States domestic suppliers respond more to changes in

their operating costs than do foreign suppliers. The resulting gap between the supply response of United States and foreign producers provides foreign suppliers with a cost advantage in United States markets that enables them to increase their exports to the United States even though they face similar increases in operating costs.

To put these impacts in more meaningful terms, the percentage changes reported in Table 7 were converted into changes in current prices and quantities produced, imported, and exported (Table 8). The base values in Table 8 vary from those reported in Table 2 above because they are derived

from projected levels reported in the USDA Agricultural Baseline for 2006 (Ref. 18), while values in Table 2 represent actual reported values for 2006 as compiled by USDA's NASS. Baseline values were used to accommodate the structure of the model.

Increases in prices for all covered commodities are small, less than one cent per pound. Production changes are similarly small, less than 100 million pounds for all covered commodities. The declines in the production of cattle, broilers, and hogs mirrors the declines in the production of beef, chicken, and pork.

TABLE 8—ESTIMATED CHANGES IN U.S. PRODUCTION PRICES, AND TRADE FOR AFFECTED COMMODITIES

Indicator	Units	Base	Change from base
<b>U.S. Production:</b>			
Veg. & Fruits .....	Mil. Lbs .....	191,523	-383
Cattle .....	Thous. Hd .....	32,229	-303
Broilers .....	Mil. Hd .....	6,503	-36
Hogs .....	Thous. Hd .....	103,015	-474
Beef .....	Mil. Lbs .....	24,784	-270
Chicken .....	Mil. Lbs .....	35,733	-322
Pork .....	Mil. Lbs .....	20,706	-168
Fish .....	Mil. Lbs .....	7,997	-54
<b>U.S. Price:</b>			
Veg. & Fruits .....	\$/Lb .....	0.25	0.0005
Cattle and sheep .....	\$/Cwt .....	89.55	0.4657
Broilers .....	\$/Lb .....	0.43	0.0001
Hogs .....	\$/Cwt .....	49.62	0.1290
Beef and veal .....	\$/Lb .....	4.09	0.0405
Chicken .....	\$/Lb .....	1.74	0.0143
Pork .....	\$/Lb .....	2.83	0.0192
Fish .....	\$/Lb .....	0.93	0.0047
<b>U.S. Exports (volume):</b>			
Fruits & Vegetables .....	Mil. Lbs .....	19,990	-78
Beef .....	Mil. Lbs .....	697	-13
Chicken .....	Mil. Lbs .....	5,203	-80
Pork .....	Mil. Lbs .....	2,498	-34
Fish .....	Mil. Lbs .....	6,384	-4
<b>U.S. Imports (volume):</b>			
Fruits & Vegetables .....	Mil. Lbs .....	37,573	15
Beef .....	Thous. Hd .....	2,502	-58
Chicken .....	Mil. Hd .....	0	0
Pork .....	Thous. Hd .....	5,741	-49

TABLE 8—ESTIMATED CHANGES IN U.S. PRODUCTION PRICES, AND TRADE FOR AFFECTED COMMODITIES—Continued

Indicator	Units	Base	Change from base
Fish .....	Mil. Lbs .....	10,158	4

Sources: Base values for meat and fruits and vegetables come from USDA Agricultural Baseline Projections to 2016, Staff Report WAOB-2007-1. USDA, Office of the Chief Economist, 2007. Changes are derived from applying percentage changes obtained from the ERS CGE model to the base values. <sup>a</sup> Live animal estimates derived from baseline values for meat product using 2005 average dress weight for cattle, hogs and broilers. <sup>b</sup> Base values for fish come from Fisheries of the United States, 2005. National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 2006. <sup>c</sup> Fruit and vegetable price derived by dividing the total value of fruit and vegetable production by total quantity of fruit and vegetables produced as reported in USDA baseline for 2005. <sup>d</sup> Fish price derived by dividing total value of commercial and aquaculture production, excluding other, by total commercial and aquaculture production.

The estimated changes in prices and production cause revenues for the fruit and vegetable industry to increase an estimated \$5 million. The small revenue increase in the fruit and vegetable industry is attributed to the fact that the price increase just offsets the production decrease. The estimated changes in production and prices result in revenues decreasing by \$94 million for beef cattle producers while revenues from production and sale of beef decrease by an estimated \$112 million dollars. Revenues for broiler production decline by \$91 million and revenues for the production and sale of chicken decrease by \$54 million. In addition, revenues for hog production decrease by \$21 million and revenues from production and sale of pork decrease by \$79 million. Finally, revenues to the fish industry fall by nearly \$14 million.

The increase in the prices of all affected commodities causes exports to decline (Table 8). These declines are small; they are for the most part smaller than the declines in United States production of these commodities.

The ERS CGE model assumes that firms behave as though they have no influence on either their input or output prices. On the other hand, a model that assumed that processors could influence their input and output prices could find that prices received by agricultural producers decreased because processors passed their cost increases down to their suppliers rather than increase the price they charged their customers.

The estimates of the net economic impact of the rule on the United States are based on the assumption that country of origin labeling does not shift consumer demand toward the covered commodities of United States origin. This assumption is based on the earlier finding that there was no compelling evidence to support the view that mandatory COOL will increase the demand for United States products. Despite this lack of evidence, we examine how much of a shift or increase in demand for commodities of United States origin would have to occur to offset the costs imposed on the economy

by the rule. Consumer demand for the covered commodities would have to increase 0.90 percent to offset the costs to the economy of COOL as outlined in the rule.

The hypothetical 0.90 percent increase in demand for covered commodities represents the overall increase (shift) in demand from all outlets. If there were such a demand increase for domestically produced covered commodities, however, it would presumably occur at those retailers required to provide country of origin information. As previously discussed, the percentage share of covered commodities sold by retailers subject to this rule is estimated at 47.0 percent of total consumption. This indicates that demand at covered retailers would need to increase by 1.9 percent for purposes of this hypothetical exercise, assuming no change in demand at other domestic outlets or in export demand.

As previously mentioned, the estimates of the overall net economic effects of the rule are derived from a CGE model developed by ERS. The results from this model show the changes in production and consumption patterns after the economy has adjusted to the incremental increase in costs (medium run results). Such changes occur over time and the economy does not adjust instantaneously.

The results of this analysis describe and compare the old production and consumption patterns to the new ones, but do not reflect any particular adjustment process. The purpose of using the ERS CGE model is not to forecast what prices and production will be over any particular time frame, but to explore the net implications of COOL on the United States economy and capture the direction of the changes.

The ERS CGE model is global in the sense that all regions in the world are covered. Production and consumption decisions in each region are determined within the model following behavior that is consistent with economic theory. Multilateral trade flows and prices are determined simultaneously by world

market clearing conditions. This permits prices to adjust to ensure that total demand equals total supply for each commodity in the world.

The general equilibrium feature of the model means that all economic sectors—agricultural and non-agricultural—are included. Hence, resources can move among sectors, thereby ensuring that adjustments in the feed grains and livestock sectors, for example, are consistent with adjustments in the processed sectors.

The model is static and this implies that gains (or losses) from stimulating (or inhibiting) investment and productivity growth are not captured. The model allows the existing resources to move among sectors, thereby capturing the effects of re-allocation of resources that are the result of policy changes. However, because the model fixes total available resources, it likely significantly underestimates the long-run effects of policies on aggregate output. For example, the 10-year average real growth of GDP between 1997 and 2007 was approximately 3.1% (Ref 8). If applied to the next 10 years, this implies an economy approximately 36% larger at the end of this analysis than at the beginning of this analysis.

The ERS CGE model uses data from the Global Trade Analysis Project (GTAP database, version 7.2). The database represents the world as of 2004 and includes information on macroeconomic variables, production, consumption, trade, demand and supply elasticities, and policy measures. The GTAP database includes 57 commodities and 101 countries/regions. For this analysis, the regions were represented by the following country/regions: The United States, Canada, Mexico, the European Union-25 (EU), Oceania, China, Other East Asian Countries, India, Other South Asian Countries, South America and Central America, OPEC Countries, Russia, Africa and the rest of the World. The agricultural sector is subdivided into the following 7 commodity aggregations: Rice, wheat, corn, other feed grains (barley, sorghum), soybeans, sugar (cane

and beets), vegetables and fresh fruits, other crops (cotton, peanuts), cattle and sheep, hogs and goats, poultry, and fish. The food processing sectors are subdivided into the following 6 commodity aggregations, bovine cattle and sheep meat, pork meat, chicken meat, vegetable oils and fats, other processed food products, beverages and tobacco, and fish. The remaining sectors in the database were represented by 18 aggregated non-agricultural sectors.

#### Interim Final Regulatory Flexibility Analysis

This rule has been reviewed under the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). The purpose of RFA is to consider the economic impact of a rule on small businesses and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the marketplace. The Agency believes that this rule will have a significant economic impact on a substantial number of small entities. As such, the Agency has prepared the following regulatory analysis of the rule's likely economic impact on small entities pursuant to the RFA. The Comments and Responses section lists the comments received on the preliminary RFA and provides the Agency's responses to the comments.

The rule is the direct result of statutory obligations to implement the COOL provisions of the 2002 and 2008 Farm Bills. The Act requires USDA to issue regulations to implement a mandatory COOL program for the remaining covered commodities not later than September 30, 2008. The intent of this law is to provide consumers with additional information on which to base their purchasing decisions. Specifically, the law imposes additional Federal labeling requirements for covered commodities sold by retailers subject to the law. Covered commodities include muscle cuts of beef (including veal), lamb, pork, chicken, and goat; ground beef, ground lamb, ground pork, ground goat, and ground chicken; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans.

Under preexisting Federal laws and regulations, COOL is not universally required for the commodities covered by this rule. In particular, labeling of United States origin is not mandatory, and labeling of imported products at the consumer level is required only in certain circumstances. Thus, the Agency has not identified any Federal rules that

would duplicate or overlap with this rule.

Many aspects of the mandatory COOL provisions are prescriptive and provide little regulatory discretion in rulemaking. The law requires a statutorily defined set of food retailers to label the country of origin of covered commodities. The law also prohibits USDA from using a mandatory identification system to verify the country of origin of covered commodities. However, the rule provides flexibility in allowing market participants to decide how best to implement mandatory COOL in their operations. Market participants other than those retailers defined by the statute may decide to sell products through marketing channels not subject to the rule. Taking into account comments received on the proposed rule, the rule decreases the length of time that records are required to be kept, providing some relief to affected entities both large and small. A complete discussion of the information collection and recordkeeping requirements and associated burdens appears in the Paperwork Reduction Act section. In addition, although recent amendments have added additional covered commodities, the number of products required to be labeled is reduced because the definition of a processed food item has been broadened, thus providing additional regulatory relief.

The objective of the rule is to regulate the activities of retailers (as defined by the law) and their suppliers so that retailers will be able to fulfill their statutory obligations. The rule requires retailers to provide country of origin information for all of the covered commodities that they sell. It also requires all firms that supply covered commodities to these retailers to provide the retailers with the information needed to correctly label the covered commodities. In addition, all other firms in the supply chain for the covered commodities are potentially affected by the rule because country of origin information will need to be maintained and transferred along the entire supply chain. In general, the supply chains for the covered commodities consist of farms, processors, wholesalers, and retailers. A listing of the number of entities in the supply chains for each of the covered commodities can be found in Table 1.

Retailers covered by this rule must meet the definition of a retailer as defined by the Perishable Agricultural Commodities Act of 1930 (PACA). The PACA definition includes only those retailers handling fresh and frozen fruits and vegetables with an invoice value of

at least \$230,000 annually. Therefore, the number of retailers affected by this rule is considerably smaller than the total number of retailers nationwide. In addition, there is no requirement that firms in the supply chain must supply their products to retailers subject to the rule.

Because country of origin information will have to be passed along the supply chain and made available to consumers at the retail level, it is assumed that each participant in the supply chain as identified in Table 1 will likely encounter recordkeeping costs as well as changes or modifications to their business practices. Absent more detailed information about each of the entities within each of the marketing channels, it is assumed that all such entities will be affected to some extent even though some producers and suppliers may choose to market their products through channels not subject to the requirements of this rule. Therefore, it is estimated that approximately 1,256,000 establishments owned by approximately 1,222,000 firms will be either directly or indirectly affected by this rule. The only changes from the Preliminary Regulatory Impact Analysis (PRIA) are reductions in the numbers of affected firms and establishments in the peanut sector and the addition of chicken, goat, ginseng, macadamia nuts, and pecans as covered commodities. These changes and the use of more up-to-date information resulted in the number of establishments and firms decreasing from the PRIA.

This rule potentially will have an impact on all participants in the supply chain, although the nature and extent of the impact will depend on the participant's function within the marketing chain. The rule likely will have the greatest impact on retailers and intermediaries (handlers, processors, wholesalers, and importers), while the impact on individual producers is likely to be relatively small.

The direct incremental costs are estimated for the rule at approximately \$2,517 million. The decrease in the direct incremental cost in the rule as compared to the PRIA is mainly the result of broadening the definition of a processed food item, which exempts more products from the labeling requirements of the rule.

There are two measures used by the Small Business Administration (SBA) to identify businesses as small: Sales receipts or number of employees. In terms of sales, SBA classifies as small those grocery stores with less than \$25 million in annual sales and specialty food stores with less than \$6.5 million

in annual sales (13 CFR 121.201). Warehouse clubs and superstores with less than \$25 million in annual sales are also defined as small. SBA defines as small those agricultural producers with less than \$750,000 in annual receipts. Of the other businesses potentially affected by the rule, SBA classifies as small those manufacturing firms with less than 500 employees and wholesalers with less than 100 employees.

**Retailers:** While there are many potential retail outlets for the covered commodities, food stores, warehouse clubs, and superstores are the primary retail outlets for food consumed at home. In fact, food stores, warehouse clubs, and superstores account for 75.6 percent of all food consumed at home (Ref. 9). Therefore, the number of these stores provides an indicator of the number of entities potentially affected by this rule. The 2002 Economic Census (Ref. 10) shows there were 42,318 food store, warehouse club, and superstore firms operated for the entire year. Most of these firms, however, would not be subject to the requirements of this rule.

The law defines the term retailer as having the meaning given that term in section 1(b) of the Perishable Agricultural Commodities Act of 1930 (PACA). Thus, under this interim final rule, a retailer is defined as any person licensed as a retailer under PACA. The number of such businesses is estimated from PACA data (Ref. 11). The PACA definition of a retailer includes only those retailers handling fresh and frozen fruits and vegetables with an invoice value of at least \$230,000 annually. Therefore, the number of retailers affected by this rule is considerably smaller than the number of food retailers nationwide. USDA data indicate that there are 4,040 retail firms as defined by PACA that would thus be subject to the rule. As explained below, most small food store firms have been excluded from mandatory COOL based on the PACA definition of a retailer.

The 2002 Economic Census data provide information on the number of food store firms by sales categories. Of the 42,318 food stores, warehouse club, and superstore firms, an estimated 41,629 firms had annual sales meeting the SBA definition of a small firm plus 689 other firms that would be classified as above the \$25 million threshold. USDA has no information on the identities of these firms, and the PACA database does not identify firms by North American Industry Classification System code that would enable matching with Economic Census data. USDA assumes, however, that all or nearly all of the 689 large firms would

meet the definition of a PACA retailer because most of these larger food retailers likely would handle fresh and frozen fruits and vegetables with an invoice value of at least \$230,000 annually. Thus, an estimated 83 percent (3,351 out of 4,040) of the retailers subject to the rule are small. However, this is only 8.0 percent of the estimated total number of small food store retailers. In other words, an estimated 92.0 percent of small food store retailers would not be subject to the requirements of the rule.

Retailer costs under the rule are estimated at \$952 million. Costs are estimated at \$235,551 per retail firm and \$26,149 per retail establishment. These estimated costs are lower than the PRIA upper range estimates. Retailers will face recordkeeping costs, costs associated with supplying country of origin information to consumers, and possibly additional handling costs. These cost increases may result in changes to retailer business practices. The rule does not specify the systems that affected retailers must put in place to implement mandatory COOL. Instead, retailers will be given flexibility to develop or modify their own systems to comply with the rule. There are many ways in which the rule's requirements may be met and firms will likely choose the least cost method in their particular situation to comply with the rule.

**Wholesalers:** Any establishment that supplies retailers with one or more of the covered commodities will be required by retailers to provide country of origin information so that retailers can accurately supply that information to consumers. Of wholesalers potentially affected by the rule, SBA defines those having less than 100 employees as small. Importers of covered commodities will also be affected by the rule and are categorized as wholesalers in the data.

The 2004 Statistics of U.S. Businesses (Ref. 12) provides information on wholesalers by employment size. For meat and meat products wholesalers there is a total of 2,509 firms. Of these, 2,401 firms have less than 100 employees. This indicates that approximately 96 percent of meat wholesalers are considered as small firms using the SBA definition.

There are 510 chicken wholesaler/distributor firms operating 564 facilities. Of these, there are 332 firms which have less than 100 employees, resulting in approximately 65 percent of the chicken wholesalers/distributors being classified as small businesses.

For fresh fruit and vegetable wholesalers there are a total of 4,654 firms. Of these, 4,418 firms have less

than 100 employees, resulting in approximately 95 percent of the fresh fruit and vegetable wholesalers being classified as small businesses.

While information on ginseng wholesalers is not available, 46 dealers have been identified and they would all be considered as small businesses.

In addition to specialty wholesalers that primarily handle a single covered commodity, there are also general-line wholesalers that handle a wide range of products. It is assumed that these general-line wholesalers likely handle at least one and possibly all of the covered commodities. Therefore, the number of general-line wholesale businesses is included among entities affected by the rule.

The 2004 Statistics of U.S. Businesses provides information on general-line grocery wholesalers by employment size. There were 3,037 firms in total, and 2,858 firms had less than 100 employees. This results in approximately 94 percent of the general-line grocery wholesalers being classified as small businesses.

In general, over 94 percent of the wholesalers are classified as small businesses. This indicates that most of the wholesalers affected by mandatory COOL may be considered as small entities as defined by SBA.

It is estimated that intermediaries (importers and domestic wholesalers, handlers, and processors) will incur costs under the rule of approximately \$1,115 million. Costs are estimated at \$53,948 per intermediary firm and \$50,598 per establishment.

Wholesalers will encounter increased costs in complying with mandatory COOL. Wholesalers will likely face increased recordkeeping costs, costs associated with supplying country of origin information to retailers, and possibly costs associated with segmenting products by country of origin, and additional handling costs. Some of the comments received on the proposed rule from wholesalers and retailers have indicated that retailers may choose to source covered commodities from a single supplier that procures the covered commodity from only one country in an attempt to minimize the costs associated with complying with mandatory COOL. These changes in business practices could lead to the further consolidation of firms in the wholesaling sector. The rule does not specify the systems that affected wholesalers must use to implement mandatory COOL. Instead, wholesalers will be given flexibility to modify or develop their own systems to comply with the rule. There are many ways in which the rule's requirements

may be met. In addition, wholesalers have the option of supplying covered commodities to retailers or other suppliers that are not covered by the rule.

*Manufacturers:* Any manufacturer that supplies retailers or wholesalers with a covered commodity will be required to provide country of origin information to retailers so that the information can be accurately supplied to consumers. Most manufacturers of covered commodities will likely print country of origin information on retail packages supplied to retailers. Of the manufacturers potentially affected by the rule, SBA defines those having less than 500 employees as small.

The 2004 Statistics of U.S. Businesses (Ref. 12) provides information on manufacturers by employment size. For livestock processing and slaughtering there is a total of 2,943 firms. Of these, 2,834 firms have less than 500 employees. This suggests that 96 percent of livestock processing and slaughtering operations would be considered as small firms using the SBA definition.

For chicken processing there are a total of 38 firms, only two of which are classified as small. Thus, only 5 percent of the chicken processors are small businesses.

For frozen fruit, juice, and vegetable manufacturers there is a total of 155 firms. There are 132 of these firms that are considered to be small. This suggests that 85 percent of the frozen fruit, juice, and vegetable manufacturers would be considered as small using the SBA definition.

There are a total of 161 roasted nuts and peanut butter manufacturers, which includes firms that do drying. Because only green and raw peanuts, macadamia nuts, and pecans will require retail country of origin labeling under this rule, it is estimated that no more than 5 percent of peanut, macadamia nut, and pecan manufacturing firms will be affected. Therefore, 8 peanut, macadamia nut, and pecan manufacturers are estimated to be affected, most if not all of which likely could be considered as small.

In general, approximately 95 percent of the manufacturers are classified as small businesses. This indicates that most of the manufacturers of covered commodities impacted by the rule would be considered as small entities as defined by SBA.

Manufacturers are included as intermediaries and additional costs for these firms are discussed in the previous section addressing wholesalers. Manufacturers of covered commodities will encounter increased

costs in complying with mandatory COOL. Manufacturers like wholesalers will likely face increased recordkeeping costs, costs associated with supplying country of origin information to retailers, and possibly costs associated with segmenting products by country of origin and additional handling costs. Some of the comments received on the proposed rule from manufacturers have indicated that they may limit the number of sources from which they procure raw products. These changes in business practices could lead to the further consolidation of firms in the manufacturing sector. The rule does not specify the systems that affected manufacturers must use to implement mandatory COOL. Instead, manufacturers will be given flexibility to modify or develop their own systems to comply with the rule. There are many ways in which the rule's requirements may be met.

*Producers:* Producers of perishable agricultural commodities, peanuts, macadamia nuts, pecans, and ginseng are directly affected by mandatory COOL. Producers of cattle, hogs, sheep, and goats while not directly covered by this rule, will nevertheless be affected because covered meat commodities are produced from livestock. Whether directly or indirectly affected, these producers will more than likely be required by handlers and wholesalers to maintain country of origin information and transfer it to them so that they can readily transfer this information to retailers. Individuals who grow-out chickens for an integrator are not expected to be affected by this rule.

SBA defines a small agricultural producer as having annual receipts less than \$750,000. The 2002 U.S. Census of Agriculture (Ref. 13) shows there are 1,018,359 farms that raise beef cows, and 2,458 are estimated to have annual receipts greater than \$750,000. Thus, at least 99 percent of these beef cattle farms would be classified as small businesses according to the SBA definition. Similarly, an estimated 82 percent of hog farms would be considered as small and an estimated 99 percent of sheep, lamb, and goat farms would be considered as small.

Based on 2002 U.S. Census of Agriculture information, 92 percent of vegetable farms, 94 percent of fruit, nut, and berry farms, and 91 percent of peanut, macadamia nut, and pecan farms could be classified as small.

At the production level, agricultural producers will need to maintain records to establish country of origin for the products they sell. This information will need to be conveyed as the products move through the supply chains. In

general, additional producer costs include the cost of modifying and maintaining a recordkeeping system for the country of origin information, animal or product identification, and labor and training. Based on our knowledge of the affected industries as well as comments received on the proposed rule and the voluntary guidelines, it is believed that producers already have much of the information available that could be used to substantiate country of origin claims. Cattle, hog, lamb, sheep, chicken, and goat producers may have a slightly larger burden for recordkeeping than fruit, vegetable, ginseng, peanut, macadamia nut, and pecan producers because animals can be born in one country and fed and slaughtered in another country. However, this rule provides flexibility in labeling meat covered commodities of multiple origins.

The costs for producers are expected to be relatively limited and should not have a larger impact on small producers than large producers. Producer costs are estimated at \$450 million, or an estimated \$376 per firm.

*Economic impact on small entities:* Information on sales or employment is not available for all firms or establishments shown in Table 1. However, it is reasonable to expect that this rule will have a substantial impact on a number of small businesses. At the wholesale and retail levels of the supply chain, the efficiency of these operations may be affected. For packers and processors handling products sourced from multiple countries, there may also be a desire to operate separate shifts for processing products from different origins, or to split processing within shifts. In either case, costs are likely to increase. Records will need to be maintained to ensure that accurate country of origin information is retained throughout the process and to permit compliance and enforcement reviews.

Even if only domestic origin products or products from a single country of origin are handled, there may be additional procurement costs to source supplies from a single country of origin. Additional procurement costs may include higher transportation costs due to longer shipping distances and higher acquisition costs due to supply and demand conditions for products from a particular country of origin, whether domestic or foreign.

These additional costs may result in consolidations within the processor, manufacturer, and wholesaler sectors for these covered commodities. Also, to comply with the rule, retailers may seek to limit the number of entities from

which they purchase covered commodities.

*Additional alternatives considered:* As previously mentioned, the COOL provisions of the Act leave little regulatory discretion in defining who is directly covered by this rule. The law explicitly identifies those retailers required to provide their customers with country of origin information for covered commodities (namely, retailers as defined by PACA).

The law also requires that any person supplying a covered commodity to a retailer provide information to the retailer indicating the country of origin of the covered commodity. Again, the law provides no discretion regarding this requirement for suppliers of covered commodities to provide information to retailers.

The rule has no mandatory requirement, however, for any firm other than statutorily defined retailers to make country of origin claims. In other words, no producer, processor, wholesaler, or other supplier is required to make and substantiate a country of origin claim provided that the commodity is not ultimately sold in the form of a covered commodity at the establishment of a retailer subject to the rule. Thus, for example, a processor and its suppliers may elect not to maintain country of origin information nor to make country of origin claims, but instead sell products through marketing channels not subject to the rule. Such marketing alternatives include foodservice, export, and retailers not subject to the rule. It is estimated that 47.0 percent of United States food sales occur through retailers subject to the rule, with the remaining 53.0 percent sold by retailers not subject to the rule or sold as food away from home. Additionally, food product sales into export markets provide marketing opportunities for producers and intermediaries that are not subject to the provisions of the rule. The majority of product sales are not subject to the rule, and there are many current examples of companies specializing in production of commodities for foodservice, export markets, and other channels of distribution that would not be directly affected by the rule.

The rule does not dictate systems that firms will need to put in place to implement the requirements. Thus, different segments of the affected industries will be able to modify or develop their own least-cost systems to implement COOL requirements. For example, one firm may depend primarily on manual identification and paper recordkeeping systems, while another may use automated

identification and electronic recordkeeping systems.

The rule has no requirements for firms to report to USDA. Compliance audits will be conducted at firms' places of business. As stated previously, required records may be kept by firms in the manner most suitable to their operations and may be hardcopy documents, electronic records, or a combination of both. In addition, the rule provides flexibility regarding where records may be kept. If the product is pre-labeled with the necessary country of origin information, records documenting once-forward and once-back chain of custody information are sufficient as long as the source of the claim can be tracked and verified. Such flexibility should reduce costs for small entities to comply with the rule.

The rule requires that covered commodities at subject retailers be labeled with country of origin information, that suppliers of covered commodities provide such information to retailers, and that retailers and their suppliers maintain records and information sufficient to verify all country of origin claims. The rule provides flexibility regarding the manner in which the required information may be provided by retailers to consumers. The rule provides flexibility in the manner in which required country of origin information is provided by suppliers to retailers, and in the manner in which records and information are maintained to substantiate country of origin claims. Thus, the rule provides the maximum flexibility practicable to enable small entities to minimize the costs of the rule on their operations.

The recordkeeping burden associated with this rule was reduced based on public comments. USDA seeks comments on whether the regulatory impact analysis accurately reflects the potential population of impacted small entities and the extent to which the regulation economically impacts those entities.

#### Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), the information collection provisions associated with this interim final rule have been submitted to OMB for approval as a new collection. The Comments and Responses section lists the comments received on the preliminary PRA analysis contained in the October 30, 2003, proposed rule and provides the Agency's responses to the comments. A description of these provisions is given below with an

estimate of the annual recordkeeping burden.

*Title:* Recordkeeping and Records Access Requirements for Producers and Food Facilities

*OMB Number:* 0581–new

*Type of Request:* New collection.

*Expiration Date:* Three years from the date of approval.

*Abstract:* The COOL provisions in the 2002 and 2008 Farm Bills require that specified retailers inform consumers as to the country of origin of covered commodities. Covered commodities included in this rulemaking are: Muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.

The key changes from the preliminary PRA analysis are reductions in the numbers of affected firms and establishments in the peanut sector and the addition of chicken, goat, ginseng, macadamia nuts, and pecans as covered commodities. These changes, and the use of more recent data for the other covered commodities, results in the number of establishments and firms decreasing from the preliminary PRA. In addition, as discussed in more detail below, the recordkeeping retention period has been reduced for both supplier and retailer records. Further, the 2008 Farm Bill specifically allows for the use of producer affidavits and prohibits the Secretary from requiring the maintenance of additional records not already maintained in the normal course of business.

While the Agency believes there will be savings to firms as a result of these changes, such savings are difficult to quantify. In addition, a number of affected firms commented that the initial paperwork burden estimates published in the proposed rule were too low. Therefore, the estimated labor hours per firm and per establishment remain unchanged in this PRA analysis. Comments are specifically invited on this issue.

Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location. Any person engaged in the business of supplying a covered commodity to a retailer (i.e., including but not limited to producers, distributors, handlers, packers, and processors), whether directly or indirectly, must make

country of origin information available to the retailer and must maintain records to establish and identify the immediate previous source and immediate subsequent recipient of a covered commodity for a period of one year from the date of the transaction. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of beef, lamb, chicken, goat, and pork is the slaughter facility, must possess or have legal access to records that are necessary to substantiate that claim. In the case of beef, lamb, chicken, pork, and goat, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the origin claim, provided it is made by someone having first-hand knowledge of the origin of the animal(s) and identifies the animal(s) unique to the transaction. For an imported covered commodity, the importer of record must ensure that records provide clear product tracking from the port of entry into the United States to the immediate subsequent recipient. In addition, the records must accurately reflect the country of origin in relevant CBP entry documents and

information systems and must be maintained for a period of 1 year from the date of the transaction. As previously mentioned, upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location. In addition, records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled the country of origin information must be maintained for a period of one year from the date the origin declaration is made at retail. Such records may be located at the retailer's point of distribution, or at a warehouse, central office or other off-site location. *Description of Recordkeepers:* Individuals who supply covered commodities, whether directly to retailers or indirectly through other participants in the marketing chain, are required to establish and maintain country of origin information for the covered commodities and supply this information to retailers. As a result,

producers, handlers, manufacturers, wholesalers, importers, and retailers of covered commodities will be affected by this rule. *Burden:* Approximately 1,255,591 establishments owned by approximately 1,221,740 firms are estimated to be either directly or indirectly affected by this rule. As previously discussed in previous sections of this document, several changes have been made in this interim final rule compared to the October 30, 2003, proposed rule. These changes are a result of changes made by the Agency in an effort to reduce the burden on regulated entities as well as changes made by the 2008 Farm Bill. In general, the supply chain for each of the covered commodities includes agricultural producers, processors, wholesalers, importers, and retailers. Imported products may be introduced at any level of the supply chain. Other intermediaries, such as auction markets, may be involved in transferring products from one stage of production to the next. The rule's paperwork burden will be incurred by the number and types of firms and establishments listed in Table 9, which follows.

TABLE 9—COSTS ASSOCIATED WITH PAPERWORK BURDEN

Type	Firms	Initial costs	Establishments	Maintenance costs	Total costs
<b>Producers:</b>					
Cattle & Calves .....	971,400	75,699,259	971,400	145,651,716	221,350,975
Sheep & Lambs .....	69,090	5,384,046	69,090	10,359,355	15,743,400
Hogs & Pigs .....	65,540	5,107,401	65,540	9,827,068	14,934,469
Goats .....	9,146	715,745	9,146	1,371,381	2,084,126
Chicken Producer and Processor .....	38	2,961	168	25,190	28,151
Fruits & Vegetables .....	79,800	6,218,654	79,800	3,788,984	10,007,638
Ginseng .....	190	14,806	190	9,021	23,828
Peanuts .....	650	50,653	650	30,863	81,516
Pecans .....	1,119	87,192	1,119	53,130	140,323
Macadamia .....	53	4,130	53	2,516	6,647
<b>Handlers, Processors, &amp; Wholesalers:</b>					
Stockyards, Dealers & Market Agencies .....	6,807	8,910,363	6,807	6,589,040	15,499,403
Livestock Processing & Slaughtering .....	2,943	3,852,387	3,207	62,086,237	65,938,624
Meat & Meat Product Wholesale .....	2,509	3,284,281	2,706	2,619,354	5,903,635
Chicken Processor and Wholesaler .....	510	667,590	564	545,941	1,213,531
Frozen Fruit, Juice & Vegetable Mfg .....	155	202,895	247	239,091	441,986
Fresh Fruit & Vegetable Wholesale .....	4,654	6,092,086	5,016	4,855,388	10,947,474
Ginseng Dealers .....	46	60,214	46	44,527	104,741
Roasted Nuts & Peanut Butter Mfg .....	8	10,472	9	8,712	19,184
Peanut, Pecans, & Macadamia Nut Wholesalers .....	5	6,545	5	4,840	11,385
General Line Grocery Wholesalers .....	3,037	3,975,433	3,436	3,325,979	7,301,412
Retailers .....	4,040	5,288,360	36,392	247,264,534	252,552,894
<b>Totals:</b>					
Producers .....	1,197,026	93,281,849	1,197,156	171,119,224	264,401,073
Handlers, Processors, & Wholesalers .....	20,674	27,062,266	22,043	80,319,108	107,381,374
Retailers .....	4,040	5,288,360	36,392	247,264,534	252,552,894
<b>Grand Total .....</b>	<b>1,221,740</b>	<b>125,632,475</b>	<b>1,255,591</b>	<b>498,702,866</b>	<b>624,335,341</b>

The affected firms and establishments will broadly incur two types of costs. First, firms will incur initial or start-up

costs to comply with the rule. Initial costs will be borne by each firm, even though a single firm may operate more

than one establishment. Second, enterprises will incur additional recordkeeping costs associated with

storing and maintaining records on an ongoing basis. These activities will take place in each establishment operated by each affected business.

Compared to the proposed rule, this rule reduces the length of time that records must be kept and revises the recordkeeping requirements for pre-labeled products. Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction. Under the proposed rule, records would have been required to be kept for 2 years.

Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location. Under the proposed rule, retailers would have to have maintained these records at the retail store for 7 days following the sale of the product.

For pre-labeled products, the rule provides that the label itself is sufficient evidence on which the retailer may rely to establish a product's origin. The proposed rule did not provide for this method of substantiation. The rule now requires that records identify the covered commodity, the supplier and for products that are not pre-labeled, the country of origin information. This information must be maintained for a period of 1 year from the date the origin and production designations are made at retail. Under the proposed rule, these records would have been required to be maintained for 2 years.

With respect to initial recordkeeping costs, it is believed that most producers currently maintain normal business that would contain the information needed to substantiate country of origin claims. However, producers do not typically pass along country of origin information to subsequent purchasers. Therefore, producers likely will incur some additional incremental costs to record, maintain, and transfer country of origin information to substantiate required claims made at retail. Because much of the necessary recordkeeping has already been developed during typical farm and ranch operations, it is estimated that the incremental costs for producers to supplement existing records with country of origin information will be relatively small per firm. Examples of

initial or start-up costs would be any additional recordkeeping burden needed to record the required country of origin information and transfer this information to handlers, processors, wholesalers, or retailers via records used in the normal course of business.

Producers will need an estimated 4 hours to modify an established system for organizing records to carry out the purposes of this regulation. This additional time would be required to modify existing recordkeeping systems to incorporate any added information needed to substantiate country of origin claims. Although not all farm products ultimately will be sold at retail establishments covered by this rule, it is assumed that virtually all producers will wish to keep their marketing options as flexible as possible. Thus, all producers of covered commodities or livestock (in the case of the covered meat commodities) will modify recordkeeping systems sufficient to substantiate country of origin claims. It is also recognized that some operations will require substantially more than 4 hours modifying their recordkeeping systems. In particular, it is believed that livestock backgrounders, stockers, and feeders will face a greater burden in modifying recordkeeping systems. These types of operations will need to track country of origin information for animals brought into the operation as well as for animals sold from the operation via records used in the normal course of business, increasing the burden of substantiating country of origin claims. Conversely, operations such as fruit and vegetable farms that produce only United States products likely will require little if any change to their existing recordkeeping systems in order to substantiate country of origin claims. Overall, it is believed that 4 hours represents a reasonable estimate of the average additional time that will be required per year across all types of producers.

In estimating initial recordkeeping costs, 2001 wage rates and benefits published by the Bureau of Labor Statistics from the National Compensation Survey were used. Subsequently, the National Compensation Survey has been updated and 2006 wage rates and benefits are now available. These updated wage rates and benefits are used in estimating the recordkeeping costs and results in an increase in the estimated costs.

For producers, it is assumed that the added work needed to initially adapt an existing recordkeeping system for country of origin information is primarily a bookkeeping task. This task may be performed by independent

bookkeepers, or in the case of operations that perform their own bookkeeping, an individual with equivalent skills. The Bureau of Labor Statistics (BLS) publishes wage rates for bookkeepers, accounting, and auditing clerks (Ref. 15). It is assumed that this wage rate represents the cost for producers to hire an independent bookkeeper. In the case of producers who currently perform their own bookkeeping, it is assumed that this wage rate represents the opportunity cost of the producers' time for performing these tasks. The May 2006 wage rate, the most recent data available, is estimated at \$15.28 per hour. For this analysis, an additional 27.5 percent is added to the wage rate to account for total benefits which includes social security, unemployment insurance, workers compensation, etc. The estimate of this additional cost to employers is published by the BLS (Ref. 15). At 4 hours per firm and a cost of \$19.48 per hour, initial recordkeeping costs to producers are estimated at approximately \$93.3 million to modify existing recordkeeping systems in order to substantiate country of origin claims.

The recordkeeping burden on handlers, processors, wholesalers, and retailers is expected to be more complex than the burden most producers face. These operations will need to maintain country of origin information on the covered commodities purchased and subsequently furnish that information to the next participant in the supply chain. This will require adding additional information to a firm's bills of lading, invoices, or other records associated with movement of covered commodities from purchase to sale. Similar to producers, however, it is believed that most of these operations already maintain the types of necessary records in their existing systems. Thus, it is assumed that country of origin information will require only modification of existing recordkeeping systems rather than development of new systems.

The Label Cost Model Developed for FDA by RTI International (Ref. 16; Ref. 17) is used to estimate the cost of including additional country of origin information to an operation's records. It is assumed that a limited information, one-color redesign of a paper document will be sufficient to comply with the rule's recordkeeping requirements. The number of hours required to complete the redesign is estimated to be 29 with an estimated cost at \$1,309 per firm. While the cost will be much higher for some firms and lower for others, it is believed that \$1,309 represents a reasonable estimate of average cost for all firms. Based on this, it is estimated

that the initial recordkeeping costs to intermediaries such as handlers, processors, and wholesalers (importers are included with wholesalers) will be approximately \$27 million, and initial recordkeeping costs at retail will be approximately \$5 million. The recordkeeping cost to producers increases due to the increase in the number of firms from the additional covered commodities; goat, chicken, macadamia nuts, pecans, and ginseng. The recordkeeping cost to intermediaries and retailers declines slightly from the initial recordkeeping cost estimate in the proposed rule due to the reduction in the number of intermediaries and retailers from continuing consolidation in those sectors.

The total initial recordkeeping costs for all firms are thus estimated at approximately \$125 million. This increase in the recordkeeping cost as compared to the initial recordkeeping costs in the proposed rule is due to the higher estimated wage rates and benefits.

In addition to these one-time costs to modify recordkeeping systems, enterprises will incur additional recordkeeping costs associated with storing and maintaining records. These costs are referred to as maintenance costs in Table 9. Again, the marginal cost for producers to maintain and store any additional information needed to substantiate country of origin claims is expected to be relatively small.

For fruit, vegetable, ginseng, peanut, macadamia nut, and pecan producers, country of origin generally is established at the time that the product is harvested, and thus there is no need to track country of origin information throughout the production lifecycle of the product. Likewise, this is also the case for chicken as the vast majority of chicken products sold by covered retailers are from chickens that are produced in a controlled environment in the United States. This group of producers is estimated to require an additional 4 hours a year, or 1 hour per quarter, to maintain country of origin information.

Compared to chicken, fruit, vegetable, ginseng, peanut, macadamia nut, and pecan producers, it is expected that livestock producers will incur higher costs to maintain country of origin information. Chicken, fruits, vegetables, ginseng, peanuts, and macadamia nuts are generally harvested once and then shipped by the producer to the first handler. In contrast, livestock can and often do move through several geographically dispersed operations prior to sale for processing or slaughter.

Cattle, for example, typically change ownership between 2 to 3 times before they are slaughtered and processed. Livestock may be acquired from other countries by United States producers, which may complicate the task of tracking country of origin information. Because animals are frequently sorted and regrouped at various stages of production and may change ownership several times prior to slaughter, country of origin information will need to be maintained on animals as they move through their lifecycle. Thus, it is expected that the recordkeeping burden for livestock producers will be higher than it will be for producers of other covered commodities. It is estimated that these producers will require an additional 12 hours a year, or 1 hour per month, to maintain country of origin records. Again, this is an average for all enterprises.

It is assumed that farm labor will primarily be responsible for maintaining country of origin information at producers' enterprises. NASS data (Ref. 18) are used to estimate average farm wage rates—\$9.80 per hour for livestock workers and \$9.31 per hour for other crops workers. Applying the rate of 27.5 percent to account for benefits results in an hourly rate of \$12.50 for livestock workers and \$11.87 for other crops workers. Assuming 12 hours of labor per year for livestock operations and 4 hours per year for all other operations, the estimated total annual maintenance costs to producers is \$171 million, which is higher than the initial maintenance costs in the proposed rule. The increase in the estimated maintenance cost is due to the higher estimated wage rates and benefits and the increase in the number of producers due to the inclusion of chickens, goats, ginseng, macadamia nuts, and pecans as covered commodities.

It is expected that intermediaries such as handlers, processors, and wholesalers will face higher costs per enterprise to maintain country of origin information compared to costs faced by producers. Much of the added cost is attributed to the larger average size of these enterprises compared to the average producer enterprise. In addition, these intermediaries will need to track products both coming into and going out of their businesses.

With the exception of livestock processing and slaughtering establishments, the maintenance burden hours for country of origin recordkeeping is estimated to be 52 hours per year per establishment. For this part of the supply chain, the recordkeeping activities are on-going and are estimated to require an

additional hour a week. It is expected, however, that livestock processing and slaughtering enterprises will experience a more intensive recordkeeping burden. These enterprises disassemble carcasses into many individual cuts, which must maintain their country of origin identity. In addition, businesses that produce ground beef, lamb, goat and pork may commingle product from multiple origins, which will require some monitoring and recordkeeping to ensure accurate labeling and to substantiate the country of origin information provided to retailers. Maintenance of the recordkeeping system at these establishments is estimated to total 1,040 hours per establishment, or 20 hours per week.

Maintenance activities will include inputting, tracking, and storing country of origin information for each covered commodity. Since this is mostly an administrative task, the cost is estimated by using the May 2006 BLS wage rate from the National Compensation Survey for Administrative Support Occupations (\$14.60 per hour with an additional 27.5 percent added to cover overhead costs for a total of \$18.62 per hour). This occupation category includes stock and inventory clerks and record clerks. Coupled with the assumed hours per establishment, the resulting total annual maintenance costs to handlers, processors, and wholesalers and other intermediaries are estimated at approximately \$80 million.

Retailers will need to supply country of origin information for each covered commodity sold at each store. Therefore, additional recordkeeping maintenance costs are believed to affect each establishment. Because tracking of the covered commodities will be done daily, it is believed that an additional hour of recordkeeping activities for country of origin information will be incurred daily at each retail establishment. These additional activities result in an estimated 365 additional hours per year per establishment. Using the BLS wage rate for administrative support occupations (\$14.60 per hour with an additional 27.5 percent added to cover overhead costs for a total of \$18.62 per hour) results in total estimated annual maintenance costs to retailers of \$247 million. This estimated cost is higher than the initial maintenance cost for retailers in the proposed rule due to the higher wage rate and benefits from the updated BLS information.

The total maintenance recordkeeping costs for all enterprises are thus estimated at approximately \$499 million. The increase in the total maintenance cost over the initial

maintenance cost estimate in the proposed rule is due to the higher wage rates and benefits which were updated with more recent information and the addition of more covered commodities.

The total first-year recordkeeping burden is calculated by summing the initial and maintenance costs. The total recordkeeping costs are estimated for producers at approximately \$264 million; for handlers, processors, and wholesalers at approximately \$107 million; and for retailers at approximately \$253 million. The total recordkeeping cost for all participants in the supply chain for covered commodities is estimated at \$624 million for the first year, with subsequent maintenance costs of \$499 million per year.

*Annual Reporting and Recordkeeping Burden for the First Year (Initial):* Public reporting burden for this initial recordkeeping set up is estimated to average 4.5 hours per year per individual recordkeeper.

*Estimated Number of Firms Recordkeepers:* 1,221,740.

*Estimated Total Annual Burden:* 5,504,811 hours.

*Annual Reporting and Recordkeeping Burden (Maintenance):* Public reporting burden for this recordkeeping storage and maintenance is estimated to average 24.9 hours per year per individual recordkeeper.

*Estimated Number of Establishments Recordkeepers:* 1,255,591.

*Estimated Total Annual Burden:* 31,909,210 hours.

AMS is committed to implementation of the Government Paperwork Elimination Act (GPEA) to provide the public with the option to submit or transact business electronically to the extent practicable. This new information collection has no forms and is only for recordkeeping purposes. Therefore, the provisions of an electronic submission alternative are not required by GPEA.

AMS is soliciting comments from all interested parties concerning these recordkeeping requirements. Comments are specifically invited on: (1) Whether the recordkeeping is necessary for the proper operation of this program, including whether the information would have practical utility; (2) the accuracy of USDA's estimate of the burden of the recordkeeping requirements, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the records to be maintained; and (4) ways to minimize the burden of the recordkeeping on those who are to maintain and/or make the records available, including the use

of appropriate automated, electronic, mechanical, or other technological recordkeeping techniques or other forms of information technology. Comments concerning the recordkeeping requirements contained in this interim final rule should be submitted through the Internet at <http://www.regulations.gov>. Written comments should be sent to Country of Origin Labeling Program, Room 2607-S; Agricultural Marketing Service (AMS), USDA; STOP 0254; 1400 Independence Avenue, SW.; Washington, DC 20250-0254, or by facsimile to 202/354-4693.

Comments sent to the above location should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503. All responses to this action will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

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Executive Order 12988

The contents of this rule were reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. States and local jurisdictions are preempted from creating or operating country of origin labeling programs for the commodities specified in the Act and these regulations. With regard to other Federal statutes, all labeling claims made in conjunction with this regulation must be consistent with other applicable Federal requirements. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

#### Civil Rights Review

AMS considered the potential civil rights implications of this rule on minorities, women, or persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities that are subject to these regulations. This interim final rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this rule will not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

## Executive Order 13132

This rule has been reviewed under Executive Order 13132, Federalism. This Order directs agencies to construe, in regulations and otherwise, a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence to conclude that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. This rule is required by the 2002 Farm Bill, as amended by the 2008 Farm Bill.

While this statute does not contain an express preemption provision, it is clear from the language in the statute that Congress intended preemption of State law. The law assigns enforcement responsibilities to the Secretary and encourages the Secretary to enter into partnerships with States with enforcement infrastructure to assist in the administration of the program. The law provides for a 30-day period in which retailers and suppliers may take the necessary corrective action after receiving notice of a nonconformance. The Secretary can impose a civil penalty only if the retailer or supplier has not made a good faith effort to comply and only after the Secretary provides notice and an opportunity for a hearing. Allowing private rights of actions would frustrate the purpose of this comprehensive enforcement system in which Congress struck a delicate balance of imposing a requirement, but ensuring that the agency had wide latitude in enforcement discretion. Thus, it is clear that State laws and other actions were intended to be preempted.

Several States have implemented mandatory programs for country of origin labeling of certain commodities. For example, Alabama, Arkansas, Mississippi, and Louisiana have origin labeling requirements for certain seafood products. Other States including Wyoming, Idaho, North Dakota, South Dakota, Louisiana, Kansas, and Mississippi have origin labeling requirements for certain meat products. In addition, the State of Florida and the State of Maine have origin labeling requirements for fresh produce items.

To the extent that these State country of origin labeling programs encompass commodities that are not governed by this regulation, the States may continue to operate them. For those State country of origin labeling programs that encompass commodities that are governed by this regulation, these

programs are preempted. In most cases, the requirements contained within this rule are more stringent and prescriptive than the requirements of the State programs. With regard to consultation with States, as directed by the law, AMS has consulted with the States that have country of origin labeling programs. Further, States were expressly invited to comment on the proposed regulation as it related to existing State programs. No States submitted any comments pertaining to this issue.

This interim final rule contains those provisions of the October 30, 2003 (68 FR 61944), proposed rule that pertain to muscle cuts of beef, lamb and pork; ground beef, ground lamb, ground pork; perishable agricultural commodities; and peanut covered commodities as well as the additional commodities that were added by the 2008 Farm Bill: Chicken, macadamia nuts, pecans, ginseng, and goat meat. Modifications to these provisions have been made as discussed herein.

This interim final rule is made effective on September 30, 2008. The requirements of this rule do not apply to covered commodities produced or packaged before September 30, 2008. This will allow existing product to clear through the channels of commerce and permit AMS to conduct an industry education and outreach program concerning the provisions contained within this rulemaking.

Further, pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impractical, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect. This action is authorized under the Agricultural Marketing Act of 1946, as amended. This interim final rule reflects changes made as a result of comments received in response to the 2003 proposed rule and the 2004 interim final rule on fish and shellfish, as well as the changes made by the 2008 Farm Bill. After issuance of this interim final rule, the Department will provide all affected persons, including the newly affected industries—goat, chicken, macadamia nuts, pecans, and ginseng—the opportunity to provide additional comments prior to issuing a final rule. In addition, this action is needed to meet the statutory implementation date. Further, this rule provides for a 60-day comment period.

**List of Subjects in 7 CFR Part 65**

Agricultural commodities, Food labeling, Meat and meat products, Macadamia nuts, Peanuts, Pecans, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR chapter I is amended by adding part 65 to read as follows:

**PART 65—COUNTRY OF ORIGIN LABELING OF BEEF, PORK, LAMB, CHICKEN, GOAT MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADAMIA NUTS, and PEANUTS**

**Subpart A—General Provisions****Definitions**

## Sec.

65.100	Act.
65.105	AMS.
65.110	Beef.
65.115	Born.
65.120	Chicken.
65.125	Commingled covered commodities.
65.130	Consumer package.
65.135	Covered commodity.
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65.155	Ground beef.
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65.175	Ground pork.
65.180	Imported for immediate slaughter.
65.185	Ingredient.
65.190	Lamb.
65.195	Legible.
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65.205	Perishable agricultural commodity.
65.210	Person.
65.215	Pork.
65.220	Processed food item.
65.225	Produced.
65.230	Production step.
65.235	Raised.
65.240	Retailer.
65.245	Secretary.
65.250	Slaughterer.
65.255	United States.
65.260	United States country of origin.
65.265	USDA.

**Country of Origin Notification**

65.300	Country of origin notification.
65.400	Markings.

**Recordkeeping**

65.500	Recordkeeping requirements.
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**Subpart B—[Reserved]**

Authority: 7 U.S.C. 1621 *et seq.*

**Subpart A—General Provisions****Definitions****§ 65.100 Act.**

*Act* means the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*).

**§ 65.105 AMS.**

*AMS* means the Agricultural Marketing Service, United States Department of Agriculture.

**§ 65.110 Beef.**

*Beef* means meat produced from cattle, including veal.

**§ 65.115 Born.**

*Born* in the case of chicken means hatched from the egg.

**§ 65.120 Chicken.**

*Chicken* has the meaning given the term in 9 CFR 381.170(a)(1).

**§ 65.125 Commingled covered commodities.**

*Commingled covered commodities* means covered commodities (of the same type) presented for retail sale in a consumer package that have been prepared from raw material sources having different origins (e.g., bag of frozen strawberries).

**§ 65.130 Consumer package.**

*Consumer package* means any container or wrapping in which a covered commodity is enclosed for the delivery and/or display of such commodity to retail purchasers.

**§ 65.135 Covered commodity.**

(a) *Covered commodity* means:

- (1) Muscle cuts of beef, lamb, chicken, goat, and pork;
- (2) Ground beef, ground lamb, ground chicken, ground goat, and ground pork;
- (3) Perishable agricultural commodities;
- (4) Peanuts;
- (5) Macadamia nuts;
- (6) Pecans; and
- (7) Ginseng.

(b) Covered commodities are excluded from this part if the commodity is an ingredient in a processed food item as defined in § 65.220.

**§ 65.140 Food service establishment.**

*Food service establishment* means a restaurant, cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, or other similar facility operated as an enterprise engaged in the business of selling food to the public. Similar food service facilities include salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

**§ 65.145 Ginseng.**

*Ginseng* means ginseng root of the genus *Panax*.

**§ 65.150 Goat.**

*Goat* means meat produced from goats.

**§ 65.155 Ground beef.**

*Ground beef* has the meaning given that term in 9 CFR 319.15(a), i.e., chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, and

containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders, and also includes products defined by the terms "hamburger" in 9 CFR 319.15(b) and "beef patties" in 9 CFR 319.15(c).

**§ 65.160 Ground chicken.**

*Ground chicken* means comminuted chicken of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

**§ 65.165 Ground goat.**

*Ground goat* means comminuted goat of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

**§ 65.170 Ground lamb.**

*Ground lamb* means comminuted lamb of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

**§ 65.175 Ground pork.**

*Ground pork* means comminuted pork of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

**§ 65.180 Imported for immediate slaughter.**

*Imported for immediate slaughter* means imported into the United States for "immediate slaughter" as that term is defined in 9 CFR 93.400, i.e., consignment directly from the port of entry to a recognized slaughtering establishment and slaughtered within 2 weeks from the date of entry.

**§ 65.185 Ingredient.**

*Ingredient* means a component either in part or in full, of a finished retail food product.

**§ 65.190 Lamb.**

*Lamb* means meat, other than mutton (or yearling mutton), produced from sheep.

**§ 65.195 Legible.**

*Legible* means text that can be easily read.

**§ 65.200 NAIS-compliant system.**

*NAIS-compliant system* means Animal and Plant Health Inspection Service (APHIS)/Veterinary Services (VS) official animal identification numbers, tags, devices, or protocols, and location identifiers that are consistent with any APHIS/VS official disease program or activity, and animal tracking databases that have been reviewed and approved by APHIS/VS Chief

Information Officer for utilizing NAIS standards regarding animal movement information.

**§ 65.205 Perishable agricultural commodity.**

*Perishable agricultural commodity* means fresh and frozen fruits and vegetables of every kind and character that have not been manufactured into articles of a different kind or character and includes cherries in brine as defined by the Secretary in accordance with trade usages.

**§ 65.210 Person.**

*Person* means any individual, partnership, corporation, association, or other legal entity.

**§ 65.215 Pork.**

*Pork* means meat produced from hogs.

**§ 65.220 Processed food item.**

*Processed food item* means 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), except 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. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding). Examples of items excluded include teriyaki flavored pork loin, roasted peanuts, breaded chicken tenders, and fruit medley.

**§ 65.225 Produced.**

*Produced* in the case of a perishable agricultural commodity, peanuts, ginseng, pecans, and macadamia nuts means grown.

**§ 65.230 Production step.**

*Production step* means, in the case of beef, pork, goat, chicken, and lamb, born, raised, or slaughtered.

**§ 65.235 Raised.**

*Raised* means, in the case of beef, pork, chicken, goat, and lamb, the period of time from birth until slaughter or in the case of animals imported for immediate slaughter as defined in § 65.180, the period of time from birth

until date of entry into the United States.

**§ 65.240 Retailer.**

*Retailer* means any person licensed as a retailer under the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(b)).

**§ 65.245 Secretary.**

*Secretary* means the Secretary of Agriculture of the United States or any person to whom the Secretary's authority has been delegated.

**§ 65.250 Slaughter.**

*Slaughter* means the point in which a livestock animal (including chicken) is prepared into meat products (covered commodities) for human consumption. For purposes of labeling under this part, the word harvested may be used in lieu of slaughtered.

**§ 65.255 United States.**

*United States* means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, the Northern Mariana Islands, and any other Commonwealth, territory, or possession of the United States.

**§ 65.260 United States country of origin.**

*United States country of origin* means in the case of:

(a) Beef, pork, lamb, chicken, and goat:

(1) From animals exclusively born, raised, and slaughtered in the United States;

(2) From animals born and raised in Alaska or Hawaii and transported for a period of not more than 60 days through Canada to the United States and slaughtered in the United States; or

(3) From animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States.

(b) Perishable agricultural commodities, peanuts, ginseng, pecans, and macadamia nuts: From products produced in the United States.

**§ 65.265 USDA.**

*USDA* means the United States Department of Agriculture.

**Country of Origin Notification**

**§ 65.300 Country of origin notification.**

In providing notice of the country of origin as required by the Act, the following requirements shall be followed by retailers:

(a) *General.* Labeling of covered commodities offered for sale whether individually, in a bulk bin, carton, crate, barrel, cluster, or consumer package

must contain country of origin as set forth in this regulation.

(b) *Exemptions.* Food service establishments as defined in § 65.135 are exempt from labeling under this subpart.

(c) *Exclusions.* A covered commodity is excluded from this subpart if it is an ingredient in a processed food item as defined in § 65.220.

(d) *Labeling covered commodities of United States origin.*

(1) A covered commodity may bear a declaration that identifies the United States as the sole country of origin at retail only if it meets the definition of United States country of origin as defined in § 65.260.

(2) Covered commodities further processed or handled in a foreign country after meeting the requirements to be labeled as United States origin as defined in § 65.260 (e.g., born, raised, and slaughtered or produced) may bear a declaration that identifies the United States as the sole country of origin at retail provided the identity of the product is maintained along with records to substantiate the origin claims and the claim is consistent with other applicable Federal legal requirements.

(e) *Labeling muscle cut covered commodities of multiple countries of origin that include the United States.*

(1)(i) If an animal was born, raised, and/or slaughtered in the United States and was not imported for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal may be designated as Product of the United States, Country X, and/or (as applicable) Country Y where Country X and Country Y represent the actual or possible countries of foreign origin.

(ii) If an animal was imported into the United States for immediate slaughter as defined in § 65.180, the origin of the resulting meat products derived from that animal shall be designated as Product of Country X and the United States.

(2) In both cases of paragraph (e)(1)(i) and (e)(1)(ii) of this section, the origin declaration may include more specific information related to production steps provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

(f) *Labeling imported covered commodities.* Imported covered commodities for which origin has already been established as defined by this law (e.g., born, raised, slaughtered or grown) and for which no production steps have occurred in the United States, shall retain their origin, as declared to U.S. Customs and Border

Protection (CBP) at the time the product entered the United States, through retail sale.

(g) *Labeling commingled covered commodities.* In the case of perishable agricultural commodities; peanuts; pecans; ginseng; and macadamia nuts: For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with covered commodities sourced from a different origin that have not been substantially transformed (as established by CBP) in the United States, and/or covered commodities of United States origin, the declaration shall indicate the countries of origin in accordance with existing Federal legal requirements.

(h) *Labeling ground beef, ground pork, ground lamb, ground goat, and ground chicken.* The declaration for ground beef, ground pork, ground lamb, ground goat, and ground chicken covered commodities shall list all countries of origin contained therein or that may be reasonably contained therein. In determining what is considered reasonable, when a raw material from a specific origin is not in a processor's inventory for more than 60 days, that country shall no longer be included as a possible country of origin.

(i) *Remotely purchased products.* For sales of a covered commodity in which the customer purchases a covered commodity prior to having an opportunity to observe the final package (e.g., Internet sales, home delivery sales, etc.), the retailer may provide the country of origin notification either on the sales vehicle or at the time the product is delivered to the consumer.

**§ 65.400 Markings.**

(a) Country of origin declarations can either be in the form of a placard, sign, label, sticker, band, twist tie, pin tag, or other format that allows consumers to identify the country of origin. The declaration of the country of origin of a product may be in the form of a statement such as "Product of USA," "Produce of the USA," or "Grown in Mexico," may only contain the name of the country such as "USA" or "Mexico," or may be in the form of a check box provided it is in conformance with other Federal labeling laws.

(b) The declaration of the country of origin (e.g., placard, sign, label, sticker, band, twist tie, pin tag, or other display) must be legible and placed in a conspicuous location, so as to render it likely to be read and understood by a customer under normal conditions of purchase.

(c) The declaration of country of origin may be typed, printed, or handwritten provided it is in conformance with other Federal labeling laws and does not obscure other labeling information required by other Federal regulations.

(d) A bulk container (e.g., display case, shipper, bin, carton, and barrel), used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed.

(e) In general, abbreviations are not acceptable. Only those abbreviations approved for use under CBP rules, regulations, and policies, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland", "Luxemb" for Luxembourg, and "U.S." for the "United States" are acceptable. The adjectival form of the name of a country may be used as proper notification of the country of origin of imported commodities provided the adjectival form of the name does not appear with other words so as to refer to a kind or species of product. Symbols or flags alone may not be used to denote country of origin.

(f) With the exception of perishable agricultural commodities, peanuts, pecans, and ginseng, State or regional label designations are not acceptable in lieu of country of origin labeling.

### Recordkeeping

#### § 65.500 Recordkeeping requirements.

(a) General.

(1) All records must be legible and may be maintained in either electronic or hard copy formats. Due to the variation in inventory and accounting documentary systems, various forms of documentation and records will be acceptable.

(2) Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make

available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location.

(b) Responsibilities of Suppliers.

(1) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must make available information to the buyer about the country(ies) of origin of the covered commodity. This information may be provided either on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of beef, lamb, chicken, goat, and pork is the slaughter facility, must possess or have legal access to records that are necessary to substantiate that claim. For that purpose, in the case of beef, lamb, chicken, goat, and pork, a producer affidavit shall be considered acceptable evidence on which the slaughter facility may rely to initiate the origin claim, provided it is made by someone having first-hand knowledge of the origin of the animal(s) and identifies the animal(s) unique to the transaction. Packers that slaughter animals that are part of a NAIS compliant system or other recognized official identification system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag and/or the presence of any accompanying animal markings (i.e., "Can", "M"), as applicable, on which to base their origin claims. This provision also applies to such animals officially identified as a group lot.

(2) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly (i.e., including but not limited to growers, distributors,

handlers, packers, and processors), must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction.

(3) For an imported covered commodity (as defined in § 65.300(f)), the importer of record as determined by CBP, must ensure that records: Provide clear product tracking from the port of entry into the United States to the immediate subsequent recipient and accurately reflect the country of origin of the item as identified in relevant CBP entry documents and information systems; and must maintain such records for a period of 1 year from the date of the transaction.

(c) Responsibilities of Retailers.

(1) Records and other documentary evidence relied upon at the point of sale to establish a covered commodity's country(ies) of origin must be provided to any duly authorized representative of USDA in accordance with § 65.500(a)(2), and maintained for a period of 1 year from the date the origin declaration is made at retail. For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish the product's origin.

(2) Records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled, the country of origin information, must be maintained for a period of 1 year from the date the origin declaration is made at retail.

### Subpart B—[Reserved]

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**Lloyd C. Day,**

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