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## Part II

### Department of Agriculture

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**Agricultural Marketing Service  
7 CFR Parts 60 and 65**

**Mandatory Country of Origin Labeling of  
Beef, Pork, Lamb, Chicken, Goat Meat,  
Wild and Farm-Raised Fish and Shellfish,  
Perishable Agricultural Commodities,  
Peanuts, Pecans, Ginseng, and Macadamia  
Nuts; Final Rule**

**DEPARTMENT OF AGRICULTURE****Agricultural Marketing Service****7 CFR Parts 60 and 65**

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

RIN 0581-AC26

**Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Wild and Farm-Raised Fish and Shellfish, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts**

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

**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 contained a number of provisions that amended the COOL provisions in the Act. These changes included the addition of chicken, goat, macadamia nuts, pecans, and ginseng as covered commodities, the addition of provisions for labeling products of multiple origins, as well as a number of other changes. 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, on August 1, 2008, the Department published an interim final rule with a request for comments for all of the covered commodities other than wild and farm-raised fish and shellfish. The Agency is issuing this final rule for all covered commodities. This final rule contains definitions, the requirements for consumer notification and product

marking, and the recordkeeping responsibilities of both retailers and suppliers for covered commodities.

**DATES:** This final rule is effective March 16, 2009.

**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 about this final rule. The second section provides a discussion of the rule's requirements, including a summary of changes from the October 5, 2004, interim final rule for fish and shellfish and the August 1, 2008, interim final rule for the remaining covered commodities 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 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 interim final rule for the remaining covered commodities that was published in the August 1, 2008, **Federal Register** (73 FR 45106). 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***Prior Documents in This Proceeding*

This 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 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).

On August 1, 2008, AMS published an interim final rule for covered commodities other than fish and shellfish (73 FR 45106) with a 60-day comment period.

**II. Summary of Changes From the Interim Final Rules***Definitions*

In the regulatory text for fish and shellfish (7 CFR part 60), a definition for "commingled covered commodities" has been added for clarity and to conform to the regulatory text for the other covered commodities.

In the regulatory text for the remaining covered commodities (7 CFR part 65), the definition of "ground beef" has been modified in response to

comments. Under this 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 term “hamburger” in 9 CFR 319.15(b). A full explanation of this change is discussed in the Comments and Responses section.

In 7 CFR part 65, the definition of “lamb” has been modified in response to comments to include mutton. Under this final rule, the term “lamb” means meat produced from sheep.

In 7 CFR part 65, the definition of “NAIS-compliant system” has been deleted in response to comments received as it is no longer needed.

A definition of “pre-labeled” has been added to both 7 CFR part 60 and 7 CFR part 65 for clarity in response to comments received. Under this final rule, the term “pre-labeled” means a covered commodity that has the commodity’s country of origin, and, as applicable, method of production information, and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

In 7 CFR part 65, the definition of “produced” has been modified for clarity in response to comments. Under this final rule, the term “produced” in the case of perishable agricultural commodities, peanuts, ginseng, pecans, and macadamia nuts means harvested.

#### *Country of Origin Notification*

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

The August 1, 2008, interim final rule contained an express provision allowing U.S. origin covered commodities to be further processed or handled in a foreign country and retain their U.S. origin. The Agency received numerous comments requesting further clarification of this provision as well as comments requesting that it be deleted. Accordingly, under this final rule, this provision has been deleted. To the extent that it is allowed under existing Customs and Border Protection (CBP) and Food Safety and Inspection Service (FSIS) regulations, U.S. origin covered commodities may still be eligible to bear a U.S. origin declaration if they are

processed in another country such that a substantial transformation (as determined by CBP) does not occur. In addition, to the extent that additional information about the production steps that occurred in the U.S. is permitted under existing Federal regulations (e.g., CBP, FSIS), nothing in this final rule precludes such information from being included. A full explanation of this change is discussed in the Comments and Responses section.

##### *Country of Origin Notification for Muscle Cuts*

Under the August 1, 2008, 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 could have been 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.

During the comment period, the Agency received extensive feedback from livestock producers, members of Congress, and other interested parties expressing concern about the provision in the interim final rule that allowed U.S. origin product to be labeled with a mixed origin label. It was never the intent of the Agency for the majority of product eligible to bear a U.S. origin declaration to bear a multiple origin designation. The Agency made additional modifications for clarity.

Under this final rule, for muscle cut covered commodities derived from animals that were born in Country X or (as applicable) Country Y, raised and slaughtered in the United States, and were not derived from animals imported for immediate slaughter as defined in § 65.180, the origin may be designated as Product of the U.S., Country X, and (as applicable) Country Y.

For muscle cut covered commodities derived from animals born, raised, and slaughtered in the U.S. that are commingled during a production day with muscle cut covered commodities derived from animals that were raised and slaughtered in the United States, and were not derived from animals imported for immediate slaughter as defined in § 65.180, the origin may be designated, for example, as Product of the United States, Country X, and (as applicable) Country Y.

For muscle cut covered commodities derived from animals that are born in Country X or Country Y, raised and slaughtered in the United States, that are commingled during a production day with muscle cut covered

commodities that are derived from animals that are imported into the United States for immediate slaughter as defined in § 65.180, the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y.

In all of the cases above, the countries of origin may be listed in any order. In addition, if animals are raised in another country and the United States, provided the animals are not imported for immediate slaughter as defined in § 65.180, the raising that occurs in the United States takes precedence over the minimal raising that occurred in the animal’s country of birth.

A full explanation of these changes is discussed in the Comments and Responses section.

##### *Markings*

Under the October 5, 2004, interim final rule for fish and shellfish and the August 1, 2008, interim final rule for the remaining covered commodities, only those abbreviations approved for use under CBP rules, regulations, and policies were acceptable. The 2008 Farm Bill and the August 1, 2008, interim final rule expressly authorized 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. In response to comments received, under this final rule, abbreviations may be used for state, regional, or locality label designations for these commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP. A full explanation of this change is discussed in the Comments and Responses section.

##### *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 were made in the August 1, 2008, interim final rule to reduce the recordkeeping burden. Further changes are being made in this final rule in response to comments received.

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 and method of production (wild and/or farm-raised), as applicable, to be either maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA, upon request, within 5 business days of the request. For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and method of production, as applicable, and no additional records documenting origin and method of production information are necessary. Under the August 1, 2008, interim final rule, retailers were required to maintain these records for a period of 1 year.

Under this final rule, upon request by USDA representatives, suppliers and retailers shall make available to USDA representatives, records maintained in the normal course of business that verify an origin and method of production (wild and/or farm-raised) claim, as applicable. Such records shall be provided within 5 business days of the request and may be kept in any location.

Under this final rule, producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims for all covered commodities, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction.

#### *Responsibilities of Retailers and Suppliers*

With regard to the "safe harbor" language that was contained in the October 30, 2003, proposed rule and the October 5, 2004, interim final rule, which allowed retailers and suppliers to rely on the information provided unless they could have been reasonably expected to have knowledge otherwise, based on comments received, similar "safe harbor" language has been included in this final rule. A complete discussion is contained in the Comments and Responses section of this final rule.

With regard to the recordkeeping provision concerning livestock that are part of a NAIS-compliant system, in response to comments received, the Agency has clarified that packers who slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking indicating the origin as being a country

other than the U.S. (i.e., "CAN" or "M") may use that information as a basis for a U.S. origin claim. In addition, packers that slaughter animals that are part of another country's recognized official system (e.g. Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims.

#### Highlights of This Final Rule

##### Covered Commodities

As defined in the statute, 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; wild and farm-raised fish and shellfish; perishable agricultural commodities (fresh and frozen fruits and vegetables); peanuts; pecans; ginseng; and macadamia nuts.

##### Exemption for Food Service Establishments

Under the statute and therefore this 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 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, 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 (cold or hot), and restructuring (e.g., emulsifying and extruding).

With regard to determining what is considered an "other covered commodity" with respect to fruits and vegetables, the Agency will generally rely on U.S. Grade Standards for fruits and vegetables to make the distinction of whether or not the retail item is a combination of "other covered commodities". For example, different colored sweet peppers combined in a package will require country of origin notification because there is one U.S. Grade Standard for sweet peppers, regardless of the color. As another example, there are separate U.S. Grade Standards for iceberg lettuce and romaine lettuce. Therefore, this type of salad mix will not be required to be labeled with country of origin information. While the Agency previously used this example in the preamble of the August 1, 2008, interim final rule and concluded that such a salad mix would be subject to COOL, the Agency now believes the use of U.S. Grade Standards in determining when a perishable retail item is considered a processed food item provides a bright line to the industry and is an easy and straightforward approach as regulated entities are already familiar with U.S. Grade Standards.

There are limited exceptions to this policy. One exception occurs when there are different grade standards for the same commodity based on the region of production. For example, although there are separate grade standards for oranges from Florida, Texas, and California/Arizona, combining oranges from these different regions would not be considered combining "other covered commodities" and therefore, a container with oranges from Texas and Florida is required to be labeled with country of origin information.

As examples of processing steps that are considered to further prepare product for consumption, meat products that have been needle-tenderized or chemically tenderized using papain or other similar additive are not considered processed food items. Likewise, meat products that have been injected with sodium phosphate or other similar solution are also not considered processed food items as the solution has not changed the character of the covered commodity. In contrast, meat products that have been marinated with a particular flavor such as lemon-

pepper, Cajun, etc. have been changed in character and thus are considered processed food items.

While the definition of a processed food item does exclude a number of products from labeling under the COOL program, many imported items are still required to be marked with country of origin information under the Tariff Act of 1930 (19 U.S.C. 1304) (Tariff Act). For example, while a bag of frozen peas and carrots is considered a processed food item under this final rule, if the peas and carrots are of foreign origin, the Tariff Act requires that the country of origin information be marked on the bag. Likewise, while roasted peanuts, pecans, and macadamia nuts are also considered processed food items under this final rule, under the Tariff Act, if the nuts are of foreign origin, the country of origin information must be indicated to the ultimate purchaser. This also holds true for a variety of fish and shellfish items. For example, salmon imported from Chile that is smoked in the United States as well as shrimp imported from Thailand that is cooked in the United States are also required to be labeled with country of origin information under the Tariff Act. In addition, items such as marinated lamb loins that are imported in consumer-ready packages would also be required to be labeled with country of origin information as both CBP and FSIS regulations require meat that is imported in consumer-ready packages to be labeled with origin information on the package.

Examples of items excluded from country of origin labeling include teriyaki flavored pork loin, meatloaf, roasted peanuts, breaded chicken tenders, breaded fish sticks, flank steak with portabella stuffing, steakhouse sirloin kabobs with vegetables, cooked and smoked meats, blue cheese angus burgers, cured hams, bacon, corned beef briskets, prosciutto rolled in mozzarella cheese, a salad that contains iceberg and romaine lettuce, a fruit cup that contains cantaloupe, watermelon, and honeydew, 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.

(c) Farm-raised fish and shellfish—covered commodities must be derived exclusively from fish or shellfish hatched, raised, harvested, and processed in the United States, and that has not undergone a substantial transformation (as established by CBP) outside of the United States.

(d) Wild fish and shellfish—covered commodities must be derived exclusively from fish or shellfish either harvested in the waters of the United States or by a U.S. flagged vessel and processed in the United States or aboard a U.S. flagged vessel, and that has not undergone a substantial transformation (as established by CBP) outside of the United States.

#### Labeling Country of Origin for Imported Products

Under this final rule, a fish or shellfish imported covered commodity shall retain its origin as declared to CBP at the time the product enters the United States, through retail sale, provided it has not undergone a substantial transformation (as established by CBP) in the United States. Similarly, for the other covered commodities, an imported covered commodity for which origin has already been established as defined by the Act (e.g., born, raised, slaughtered or harvested) and for which no production steps have occurred in the United States shall retain its origin as declared to 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. This final rule does not change these requirements.

#### Labeling Fish and Shellfish Imported Products That Have Been Substantially Transformed in the United States

Under this final rule, in the case of wild fish and shellfish, if a covered commodity was imported from country

X and substantially transformed (as established by CBP) in the United States or aboard a U.S. flagged vessel, the product shall be labeled at retail as "From [country X], processed in the United States." Alternatively, the product may be labeled as "Product of country X and the United States". The covered commodity must also be labeled to indicate that it was derived from wild fish or shellfish.

In the case of farm-raised fish, if a covered commodity was imported from country X at any stage of production and substantially transformed (as established by CBP) in the United States, the product shall be labeled at retail as "From [country X], processed in the United States." Alternatively, the product may be labeled as "Product of country X and the United States". The covered commodity shall also be labeled to indicate that it was derived from farm-raised fish or shellfish.

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

Under this final rule, for muscle cut covered commodities derived from animals that were born in Country X or (as applicable) Country Y, raised and slaughtered in the United States, and were not derived from animals imported for immediate slaughter as defined in § 65.180, the origin may be designated, for example, as Product of the U.S., Country X, and (as applicable) Country Y. The countries of origin may be listed in any order.

For muscle cut covered commodities derived from animals born, raised, and slaughtered in the U.S. that are commingled during a production day with muscle cut covered commodities derived from animals that were raised and slaughtered in the United States, and were not derived from animals imported for immediate slaughter as defined in § 65.180, the origin may be designated as, for example, Product of the United States, Country X, and (as applicable) Country Y. The countries of origin may be listed in any order.

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.

For muscle cut covered commodities derived from animals that are born in Country X or Country Y, raised and slaughtered in the United States, that are commingled during a production day with muscle cut covered commodities that are derived from animals that are imported into the

United States for immediate slaughter as defined in § 65.180, the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y. The countries of origin may be listed in any order.

In all 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. In addition, if animals are raised in another country and the United States, provided the animals are not imported for immediate slaughter as defined in § 65.180, the raising that occurs in the United States takes precedence over the minimal raising that occurred in the animal's country of birth.

With regard to the commingling of meat of different origin categories, the Agency has received comments requesting that the Agency provide additional clarification on how commingled meat products can be labeled. Under this final rule, it is permissible to commingle meat derived from animals imported for immediate slaughter with meat derived from mixed origin animals and label it as Product of U.S., Canada. It is also permissible to commingle meat derived from animals imported for immediate slaughter with meat of mixed origin and label it as category C (product imported for immediate slaughter, i.e., Product of Canada, U.S.). Further, the declaration for meat derived from mixed origin animals may list the countries of origin in any order (e.g., Product of U.S., Canada or Product of Canada, U.S.).

#### Labeling Commingled Covered Commodities

In this final rule, a commingled covered commodity is defined as a single type of covered commodity (e.g., frozen peas, shrimp), 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 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, wild and farm-raised fish and shellfish, 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 commodities having different origins, 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.

In the case of wild and farm-raised fish and shellfish covered commodities, when the retail product contains imported covered commodities that have subsequently undergone substantial transformation in the United States are commingled with other imported covered commodities that have subsequently undergone substantial transformation in the United States (either prior to or following substantial transformation in the United States) and/or U.S. origin covered commodities, the declaration shall indicate the countries of origin contained therein or that may be contained therein.

#### 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 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. If a country of origin is utilized as a raw material source in the production of ground beef, it must be listed on the label. The 60-day in inventory allowance speaks only to when countries may no longer be listed. The 60-day inventory allowance is an allowance for the Agency's enforcement purposes for when the Agency would deem ground meat products as no longer accurately labeled. 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 and method of production information (wild and/or farm-raised), as applicable, either on the sales vehicle or at the time the product is delivered to the consumer.

#### Markings

Under this final rule, the country of origin declaration and method of production (wild and/or farm-raised) designation, as applicable, 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. The country of origin declaration and method of production (wild and/or farm-raised) designation may be combined or made separately.

With respect to the production designation, various forms of the production designation are acceptable, including "wild caught," "wild," "farm-raised," "farmed," or a combination of these terms for products that contain both wild and farm-raised fish or shellfish provided it can be readily understood by the consumer and is in conformance with other Federal labeling laws. Designations such as "ocean caught," "caught at sea", "line caught," "cultivated," or "cultured" do not meet the requirements of this regulation. Alternatively, the method of production (wild and/or farm-raised) designation may also be in the form of a check box.

In general, country 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." or "USA" for the "United States of America" are acceptable. The Agency is aware of a few additional abbreviations allowed by CBP such as "Holland" for The Netherlands and has posted this information on the COOL Web site.

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 "Harvested 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 or method of production (wild and/or farm-raised) designation, as applicable, 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. Such designations must be nationally distinct. For example, Rio Grande Valley would not be an acceptable designation because consumer would not know whether the country of origin was the U.S. or Mexico. Abbreviations may be used for state, regional, or locality label designations for these commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP.

With regard to the use of established State marketing programs such as "California Grown", "Go TEXAN", "Jersey Fresh", etc., these programs may be used for COOL notification purposes provided they meet the requirements to bear a U.S. origin declaration as specified in this final rule.

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 or method of production (wild and/or farm-raised) declaration. However, such declarations must be legible and conspicuous, and allow consumers to find the country(ies) of origin and method of production, as applicable, easily and read them 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 and method of production

(wild and/or farm-raised) designation, as applicable, 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.

With respect to the use of signage for bulk displays for meat covered commodities, the Agency has observed that a vast majority of retailers are utilizing one sign for either the entire meat case or for an entire commodity type (i.e., chicken) to provide the country of origin notification. While the statute and this regulation provide flexibility in how country of origin information can be provided, the Agency believes that the use of such signage could potentially be false or misleading to consumers. For example, frequently display cases also contain noncovered meat commodities for which no origin information has been provided to the retailer. Thus a sign that states, "all of our beef products are of U.S. origin" may not be completely accurate and may be in violation of other Federal laws, regulations, and policies that have truth in labeling provisions such as the Federal Meat Inspection Act, the Federal Trade Commission's "Made in the USA" policies, and the Federal Food, Drug, and Cosmetic Act. The Agency encourages retailers to review signage that they have used in the implementation of the fish and shellfish program for alternative acceptable methods of providing COOL information.

With regard to the provision in both the interim final rule for fish and shellfish and the interim final rule for the remaining covered commodities concerning bulk containers that allows the bulk container to contain a covered commodity from more than one country of origin, under this final rule, it remains permissible provided all possible origins are listed. For example, if a retailer puts apples from the U.S. and New Zealand in a bulk bin, the sign for the bin should list both the U.S. and New Zealand. If the retailer has apples in the store from New Zealand, but has not added these apples to the bulk bin, it would not be permissible to have New Zealand on the sign. Likewise in the case of fish, if a retailer has salmon from both the U.S. and Chile in the back of the store, but has only put out for display salmon from Chile, the country

of origin designation should only list Chile. It would not be permissible to list both the U.S. and Chile at that time because it is not possible that the display contains salmon of U.S. origin.

#### 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 and method of production (wild and/or farm-raised) declarations, as applicable, are necessary in order to provide retailers with credible information on which to base origin and method of production declarations.

Under this 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 and method of production, as applicable, 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 and method of production, as applicable.

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 and, as applicable, method of production declaration, must possess records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. In an effort to reduce the recordkeeping burden associated with COOL, for that purpose, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking indicating the origin as being a country other than the U.S. (i.e., "CAN" or "M") may use that information as a basis for a U.S. origin claim. In addition, packers that slaughter animals that are part of another country's recognized official system (e.g., Canadian official system,

Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. Producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction.

Under this final rule, any intermediary supplier handling a covered commodity that is found to be designated incorrectly as to the country of origin and/or method of production, as applicable, shall not be held liable for a violation of the Act by reason of the conduct of another if the intermediary supplier relied on the designation provided by the initiating supplier or other intermediary supplier, unless the intermediary supplier willfully disregarded information establishing that the country of origin and/or method of production, as applicable, was false.

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 final rule, retailers also have responsibilities. In providing the country of origin notification for a covered commodity, retailers are to convey the origin and, as applicable, method of production information provided by their suppliers. Only if the retailer physically commingles a covered commodity of different origins and/or methods of production, as applicable, in preparation for retail sale, whether in a consumer-ready package or in a bulk display (and not discretely packaged) (i.e., full service meat case), can the retailer initiate a multiple country of origin designation that reflects the actual countries of origin and methods of production, as applicable, for the resulting covered commodity.

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 and method of production, as applicable, must either be maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representatives of USDA within 5 business days of the request. For pre-labeled products, the

label itself is sufficient information on which the retailer may rely to establish the product's origin and method of production, as applicable, and no additional records documenting origin and method of production information are necessary. A pre-labeled covered commodity is a covered commodity that has the commodity's country of origin and method of production, as applicable, and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

Additionally, records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled, the country of origin and method of production information, as applicable, must be maintained for a period of 1 year from the date the origin declaration is made at retail.

Under this final rule, any retailer handling a covered commodity that is found to be designated incorrectly as to the country of origin and/or method of production, as applicable, shall not be held liable for a violation of the Act by reason of the conduct of another if the retailer relied on the designation provided by the supplier, unless the retailer willfully disregarded information establishing that the declaration of country of origin and/or method of production, as applicable, was false.

#### 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 and method of production, as applicable, 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 840 tags on which to base origin claims, 9 CFR 71.22 prohibits the removal of official identification devices except at the time of slaughter. The importation of animals and animal health are regulated by the Animal and Plant Health Inspection Service (APHIS). This regulation does not alter any APHIS requirements.

#### 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.

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.

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. AMS received approximately 800 comments on the interim final rule, the majority of which were form letters from consumers expressing their support for country of origin labeling and requesting that the definition of a processed food item be narrowed to require labeling of canned, breaded, and cooked products.

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. On August 1, 2008, AMS published an interim final rule with a 60-day comment period for the covered commodities other than fish and shellfish. The Agency received 275 comments representing the opinions of 11,798 consumers, retailers, foreign governments, producers, wholesalers, manufacturers, distributors, members of Congress, trade associations and other interested parties. The majority of comments received were on the definition of a processed food item, labeling muscle cuts of multiple countries of origin, and the recordkeeping provisions for both retailers and suppliers.

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 the August 1, 2008, interim final rule, the regulatory provisions for the covered commodities other than fish and shellfish appeared at 7 CFR part 65. For the ease of the reader, the discussion of the comments has been broken down by issue. To the extent that a comment or issue pertains only to fish and shellfish covered commodities, it is noted in the explanation.

#### *Definitions*

##### *Covered Commodity*

*Summary of Comments:* Several commenters requested that the Agency add products to the list of commodities covered by COOL. One commenter suggested that almonds should be included in mandatory COOL and another commenter requested that fresh chestnuts be added. A final commenter suggested that meat commodities derived from beefalo be included as covered commodities. Another commenter asked that the Agency better clarify what is a "muscle cut."

*Agency Response:* The statute specifically defines the commodities covered by the mandatory COOL program. As such, the Agency does not have the authority to include additional classes of covered commodities. Accordingly, recommendations regarding covering additional classes of commodities cannot be adopted. With regard to clarifying what the Agency defined to be a muscle cut of beef, pork,

lamb, chicken, or goat, the Agency has provided information on its Web site and in written form pertaining to specific items and will continue to do so as questions arise. In general, the Agency views those cuts of meat (with or without bone) derived from a carcass (e.g., beef steaks, pork chops, chicken breasts, etc.) to be covered items. However, cuts of meat that are removed during the conversion of an animal to a carcass (e.g., variety meats such as pork hearts, beef tongues, etc.) are not viewed to be muscle cuts nor are items sold as bones practically free of meat (e.g., lamb neck bones, beef femur bones, etc.) or fat practically free of meat (e.g., pork clear plate, chicken skin, etc.) removed from a carcass.

##### *Ground Beef*

*Summary of Comments:* One commenter noted that fabricated steak is not specifically listed as a covered commodity in the law and expressed their belief that AMS could proactively cover a closely related commodity rather than limit COOL to only statutorily listed commodities. The commenter urged the Agency to broaden rather than narrow its scope of covered commodities to include fabricated steak in the definition of ground beef.

Another commenter noted the rule exempts ground beef, hamburger and beef patties that have been seasoned (unless that seasoning is salt or sugar), but does not exempt ground beef, hamburger and beef patties that have not been seasoned. The commenter requested that the definition for ground beef be reconsidered and clarified so that ground beef, hamburger and beef patties where salt or sugar is added are recognized as a processed food item and therefore exempt under this rule.

Several commenters did not agree that the Agency's expansion of the definition of ground beef to include hamburger and beef patties was justified. The commenters pointed out that the covered product specified by the 2008 Farm Bill is "ground beef," which has its own regulatory standard of identity separate from hamburger and beef patties. One commenter also noted that the interim final rule's definitions of "ground lamb" and other ground meats do not similarly specify that patties made from such ground meats are covered items and suggested that this disparity appears to "favor" non-beef patties with possible exemption from the rule, to the disadvantage of beef patties. Another commenter stated that had Congress intended a more expansive range of processed food products to be subject to COOL, it would have specifically included them,

particularly where all other processed foods are categorically exempt from COOL requirements. The commenter urged the Agency to follow the intent of Congress and promulgate a rule that encompasses products captured in the regulatory standard of identity for "ground beef" and not extend the scope to items meeting other definitions.

*Agency Response:* The Agency does not agree that commodities covered by the statute can be construed to cover fabricated steaks. Fabricated steaks are produced to appear like a whole muscle cut of meat but are in fact constructed from many different cuts of meat. Therefore, they are clearly not a "muscle cut" and, because the product is not ground nor is it sold as ground, it is not ground beef either.

The Agency agrees that a regulatory standard of identity for the term "ground beef" exists, but does not agree that it was the intent of Congress to limit the mandatory COOL program to only those products marketed under that standard of identity. Further, the Agency believes it is not reasonable that consumers would understand why beef that is ground and marketed as "ground beef" would require labeling and beef that is ground and marketed as "hamburger" would not. The regulatory standard of identities for "ground beef" and "hamburger" are virtually identical with the minor exception of "added fat" being allowed in beef that is ground and marketed as "hamburger". Both are often marketed in bulk form or in patty form and can sit side by side in the fresh or frozen meat case with only the name capable of distinguishing them apart. Therefore, ground beef and hamburger sold in bulk or patty form are covered commodities under this final rule.

However, in its analysis of the issue and the points raised by the commenters, the Agency does concur with several of the commenters that beef that is ground and marketed as "imitation ground beef", "imitation hamburger", and "beef patty mix" should be exempt in this final rule. Products marketed under these standards of identities typically contain a number of binders and extenders that are not covered commodities and are not assumed by the consumer to be interchangeable with beef that is ground and marketed as "ground beef" or "hamburger". Because the Agency does not view such variety meat items as beef heart meat and tongue meat (which are not allowed in "ground beef" or "hamburger") as covered commodities, requiring such products as "beef patty mix" to carry COOL information would also require the beef processing industry to identify the country of origin for such

beef variety meat items in the event they would be used as extenders in commodities like "beef patty mix", which does allow their inclusion. The Agency believes that the costs associated with this segregation and identification of beef variety meats would be overly burdensome and that these items were not intended to be included as covered commodities under the statute. Accordingly, these recommendations are adopted in part.

#### *Farm-Raised*

*Summary of Comments:* Some commenters expressed concerns regarding the definition of farm-raised in the fish and shellfish interim final rule. The commenters recommended that the Agency exempt molluscan shellfish from the COOL requirements.

*Agency Response:* As the statute defines the term covered commodity to expressly include shellfish, the Agency does not have the authority to provide an exemption for molluscan shellfish. In addition, in the Agency's experience in three years of enforcement of the COOL program for fish and shellfish, it has found good compliance with the labeling of this commodity. Accordingly, this recommendation is not adopted in this final rule.

#### *Lamb*

*Summary of Comments:* Several commenters requested that the regulation be revised to clarify the definition of lamb includes mutton. One of these commenters stated that because there are no common terminology differences describing the meat from different age groups of species such as cattle, swine, goat or chicken, the Agency was in error to exclude mutton in the definition of lamb in the interim final rule. The commenter further stated while specific definitional differences between lamb and mutton exist for other regulatory purposes, it is appropriate to cover meat from all ages of sheep in the rule as is done for the other livestock species.

*Agency Response:* The Agency agrees that it is appropriate to include mutton under the definition of lamb as no distinctions describing meat from the different age groups of other livestock species were made. Accordingly, this recommendation has been adopted in this final rule.

#### *NAIS-Compliant System*

*Summary of Comments:* Two commenters recommended that the Agency eliminate the definition of a "NAIS-compliant system" and replace it with the existing regulatory definition of "Official identification device or

method" that is contained in 9 CFR § 93.400. The commenters contend that this modification is necessary so as to not mislead the public into believing that they must comply with all of the requirements of USDA's NAIS (e.g., premises registration) in addition to maintaining current compliance with existing official identification systems. The commenters stated this change would be consistent with USDA's assurance that the NAIS "does not alter any regulation in the Code of Federal Regulations or any regulations that exist at the State level."

*Agency Response:* The Agency continues to believe that voluntary use of the National Animal Identification System is an acceptable and easy option packers may utilize to obtain origin information on livestock. However, the Agency believes that the definition of NAIS-compliant should be deleted as it is not necessary. However, with regard to the commenter's suggestion to replace this definition with the definition of "Official identification device or method", because they may be applied to imported animals, other identification devices or methods alone cannot be used to establish the U.S.-origin of livestock. Producers' management records will need to be used in conjunction with these other identification devices and methods to establish U.S. origin. Additional discussion on the NAIS provision is included later in the Comments and Responses section.

#### *Processed Food Item*

*Summary of Comments:* Numerous commenters suggested that the Agency should narrow its definition of a processed food item so that more food items sold at retail are covered commodities subject to COOL requirements. The commenters recommended that roasting, curing, smoking and other steps that make raw commodities more suitable for consumer use should not be the criteria for categorizing these commodities under the statutory exemption of an ingredient in a processed food item and therefore exempt from labeling. Many commenters stated that USDA's overly expansive definition of a processed food item, which comes from the 2004 interim final rule for fish and shellfish, should not be used for the other covered commodities. The commenters stated that although the definition was possibly appropriate for fish and shellfish, it resulted in a much more substantial percentage of meat and nut covered commodities sold at retail being exempt. The commenters urged USDA to develop different definitions of a

processed food item for each specific category of covered commodity so that as many items as possible would be covered by the mandatory COOL program.

One commenter noted that relying on a change in character for the definition of processed food is fine as long as the Agency makes it clear that the change in character is such that a consumer would not use the items in the same manner as they would the original commodity. Thus, as spelled out in the 2003 proposed rule, not all forms of cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), as well as canning would constitute a change in character. This commenter added that for muscle cuts of beef, lamb, pork, chicken and goat, chilling, freezing, cooking, seasoning or breading should not render those products as being processed food items as defined in the interim final rule and therefore exempt from mandatory COOL. The commenter expressed their support for the alternative proposal in the 2003 proposed rule in which a covered commodity that is further processed (i.e., cured, restructured, etc.) should not be excluded unless the covered commodity is mixed with other commodities such as a pizza or TV dinner. The commenter noted that by exempting restructured and cured products from COOL, the rule excludes bacon, hams and corned beef briskets from labeling. The commenter further stated that Congress clearly stated that pork was included in COOL, but exempting bacon and hams would exclude a significant portion of the pork market. This commenter also recommended that orange juice be included as a covered commodity since orange juice represents a major component of orange consumption in the U.S. Finally, the commenter noted that in a series of decisions, CBP determined that roasting of pistachios, pecan nuts and coffee beans did not constitute substantial transformation.

Several commenters urged AMS to revise the provision in the processed food item definition that states that combining different covered commodities renders those products being exempt from mandatory COOL. The commenters recommended that if covered commodities are combined, yet are still recognizable, they should be required to be labeled. The commenters suggested that broadly exempting all mixed vegetables as a processed food item is an excessive exclusion because most consumers would expect to have frozen mixed vegetables labeled.

Several commenters agreed with the Agency's definition of a processed food

item. The commenters noted that the processed food definition that the Agency adopted in the interim final rule for fish and shellfish is simple, straightforward and provides a bright line test retailers and others can use to understand which covered commodities are subject to mandatory COOL and which are not.

One commenter recommended that the Agency designate that items with distinct varietal names within a generic category of products be deemed different products and excluded when two or more are combined. Several commenters recommended that any fresh-cut produce item, even those not combined with another substantive food item or other covered commodity, be included in the definition of a processed food item. By taking a raw agricultural commodity, washing it, then cutting it, the commenters contend that a company does change the product from a raw agricultural commodity to a ready-to-eat food item—similar to the way cooking changes a raw meat product to a ready-to-eat food, and that cutting fruit for a value-added package alters the commodity at retail.

One commenter noted that the interim rule provides that “the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption would not in itself result in a processed food item.” The commenter stated that as water, salt and sugar are used only as examples, it is apparent that the Agency assumes other ingredients, too, may merely enhance or further prepare the product for consumption such that they would be insufficient to render a product a processed food item.

Several commenters expressed that they were unclear when water, salt or sugar can be added to a product and still be covered and questioned why a marinated steak is exempt even though “marinated” is not defined. These commenters urged the Agency to clarify what is meant by enhancement steps that do not result in a processed food item. Some of these commenters further urged that the clarification encompass a much broader scope of flavorings, seasonings, etc., beyond water, salt or sugar.

One commenter expressed support for the fact that the addition of a component (such as water, salt, or sugar) does not represent a processing step that changes the character of a covered commodity. The commenter recommended that USDA also expressly state that the addition of water-based or other types of flavoring—such as a solution containing water, sodium

phosphate, salt, and natural flavoring purportedly injected into meat muscle-cut commodities by some retailers—does not represent a processing step that changes the character or identity of a covered commodity. Another commenter agreed with the provision in the 2003 proposed rule in which oil, salt and other flavorings were considered non-substantive ingredients. In addition, the commenter also expressed support for the position laid out in the 2003 proposed rule that “needle-tenderized steaks; fully-cooked entrees containing beef pot roast with gravy; seasoned, vacuum-packaged pork loins; and water-enhanced case ready steaks, chops, and roasts \* \* \* would not be considered processed food items”.

One commenter discussed products made up of a variety of fresh pork and beef muscle cuts that have been injected with a patented solution which, beyond simple water, salt, or sugar, also includes sodium phosphates, potassium lactate and sodium diacetate. The commenter stated that these products should be considered to be “covered commodities” and, therefore, subject to mandatory COOL requirements on the grounds that these products have not undergone a change in character and that because consumers cannot ascertain any difference between such enhanced products and those covered commodities that do not contain such additional ingredients, such an exemption would only confuse consumers.

Several commenters asked that the list of examples of processed food items be expanded. One commenter strongly supported inclusion of the following examples for the types of meat and other covered commodities that should be exempt as a processed food item as defined under the definition and recommended to be included in the final rule: flank steak with portabella stuffing, steakhouse sirloin kabobs with vegetables, meatloaf, meatballs with penne pasta, pot roast with roasted vegetables, cooked and smoked meats, blue cheese angus burgers, cured hams, bacon, sugar cured bacon, dry cured meats, corned beef briskets, marinated pork loin, marinated pork chops, marinated London broil, prosciutto rolled in mozzarella cheese, fruit salad, cooked and canned fruits and vegetables, orange juice, fresh apple sauce, peanut butter, candy coated peanuts, peanut brittle, etc.

*Agency Response:* The Agency believes that the two-part definition of a processed food item defined in the final rule is an appropriate interpretation of the intent of Congress excluding covered commodities that are

an ingredient in a processed food item and provides a bright line differentiating the steps that do and do not result in a commodity being covered by mandatory COOL.

Furthermore, the Agency does not agree that such processing steps as cutting or enhancing render a covered commodity a processed food item. The definition of a processed food item uses examples of the addition of components "such as water, salt, or sugar"; however, such further preparation steps would also be meant to include other examples of enhancements that do not fundamentally alter the character of the product. For example, dextrose is a sugar, phosphate is a salt, and beef stock and yeast are flavor "enhancers". In addition, the Agency believes that enhancement with enzymatic tenderizers, such as ficin and bromelain, do not by themselves change the character of the covered commodity and therefore do not result in a processed food item.

The Agency does agree that specific examples of products that are and are not covered can help the trade and consumers understand which products are covered by mandatory COOL. Therefore, the Agency will work to provide interpretive documents on its Web site and in print materials developed that will provide as many examples as necessary.

#### *Produced*

*Summary of Comments:* One commenter noted that the interim final rule defines the term "produced" in the case of a perishable agricultural commodity, peanuts, ginseng, pecans, and macadamia nuts as grown. The commenter recommended that since some plants may be transplanted across national borders, the Agency should define the term produced as harvested.

*Agency Response:* The Agency agrees with the commenter that the term "harvested" more accurately defines the term "produced" in the case of a perishable agricultural commodity, peanuts, ginseng, pecans, and macadamia nuts and has adopted this change in this final rule.

#### *Country of Origin Notification*

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

*Summary of Comments:* Several commenters disagreed with the exemption for food service establishments from the COOL requirements. These commenters contend that since items sold in these types of establishments represent a major segment of the food industry,

these establishments should not be exempt from labeling.

*Agency Response:* The statute contains an express exemption for food service establishments. Therefore, this exemption is retained in this final rule.

#### *Method of Production*

*Summary of Comments:* Two commenters focused on details for the designation of method of production for fish and shellfish (wild-caught or farm-raised). One commenter sought a more thorough definition and suggested the inclusion of the following additional information: for wild fish, the method of harvest (i.e., long-line, gillnet, trawl, purse seine, line and hook); and for farm-raised fish (1) whether it is a genetically engineered, and (2) the feed conversion ratio (quantity of fish feed required for producing the end-commodity). Another commenter expressed concern about fraudulent labeling of method of production for fish and shellfish. The commenter noted that there may be an economic incentive to mislabel farm-raised fish as wild caught fish, and the commenter provided evidence from a small sample they had investigated in November and December 2005 during the off-season for wild-caught salmon. They purchased 17 salmon products labeled as wild-caught, tested them for the presence of a synthetic coloring agent fed to farmed salmon to turn their flesh pink-orange and found that 7 of the 17 salmon products labeled as wild-caught were determined through this analysis to be actually farm-raised. The commenter noted that supermarkets were more likely to label wild-caught salmon correctly than fish markets.

*Agency Response:* The statute only provides the Agency with the authority to require that fish and shellfish carry notification for country of origin and that the covered commodity distinguish between wild fish and farm-raised fish. Therefore, the additional labeling information cannot be required. With regards to the mislabeling of method of production identified by the commenter, in addition to conducting retail surveillance enforcement activities, the Agency also conducts supplier audits that are intended to prevent such mislabeling.

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

*Summary of Comments:* Two commenters requested that the Agency revisit the regulatory requirements for labeling products as U.S. origin when they have been further processed or handled in a foreign country. One commenter recommended that USDA

delete entirely § 65.300(d)(2), and include language instead that expressly prohibits the retention of a United States origin label for any commodity that undergoes additional processing or handling in a foreign country. Another commenter asked that the Agency clarify what it means by the terms "handled" and "processed" in the context of this provision. The commenter asked USDA to clarify if it intends to include meat products in this section of the interim final rule, and noted that the statute indicates that meat product processed in another country would need to list that particular country on the label. They pointed out that the interim final rule appears to have no discussion or rationale explaining why a U.S. product processed in another country would be eligible to maintain a U.S. origin label.

Another commenter requested that a fourth option for labeling imported products be considered in the final rule. This commenter pointed out that there are no provisions for labeling product that is caught or harvested in the U.S. and substantially transformed in another country. For example, wild fish that is caught in the U.S. and then subsequently filleted in "Country X" must be marked as a product of "Country X" with no allowable reference to the original U.S. source. The commenter suggested an alternative would be to label covered commodities harvested in the U.S. but substantially transformed in another country as "Harvested in U.S., processed in Country X." The commenter concluded that such a label would provide complete information for the consumer while maintaining the original U.S. source of the product.

*Agency Response:* With regards to the origin determination of United States country of origin products that are exported to a foreign country for processing prior to reimportation back into the United States, the Agency has deleted the express provision in the final rule as the Agency believes that the provision may have caused confusion. However, to the extent that existing regulations, including those of CBP and FSIS allow for products that have been minimally processed in a foreign country to reenter the United States as Product of the U.S., nothing in this final rule precludes this practice. In addition, to the extent that additional information about the production steps that occurred in the U.S. is permitted under existing Federal regulations (e.g., CBP, FSIS), nothing in this final rule precludes such information from being included.

### *Labeling Imported Products That Have Not Undergone Substantial Transformation in the United States*

**Summary of Comments:** Four commenters offered suggestions relating to labeling imported products that have not undergone substantial transformation in the United States. One commenter contended that COOL was illogical, unworkable and misleading. Another commenter elaborated on the labeling for transshipped fish and shellfish. The commenter pointed out that many fish and shellfish products are imported into the U.S. from countries that are not necessarily the country where the fish or shellfish were harvested. The commenter recommended that the final rule for fish and shellfish require labeling to identify the location where the seafood was harvested or raised. Another commenter noted that frozen products of "foreign origin," as determined by tariff laws, already are subject to country of origin labeling under a comprehensive set of regulations administered by CBP.

**Agency Response:** With regard to the origin of imported covered commodities, the Agency follows existing regulations, including those of CBP, regarding the origin of such products and requires that such origin be retained for retail labeling.

### *Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin That Include the United States*

**Summary of Comments:** Numerous commenters stated that commodities derived from animals born, raised, and slaughtered in the U.S. should be labeled as "Product of the U.S." and not be diluted or commingled with a multiple country of origin label such as, "Product of the U.S., Canada, and Mexico". These commenters stated that the provision allowing this in the interim final rule directly contradicts the statute and diminished consumer choice and producer benefits that could have resulted from this program.

These commenters stated that the statute established four major categories for meat labeling to enable consumers to have the right to know specifically where their food originates. Other commenters stated that the regulation does not contain specific provisions allowing packers to label meat from livestock exclusively born, raised, and processed in the U.S. as mixed origin and that packers doing so were acting in violation of the regulation. Several members of Congress also commented that it was not the intent of Congress that all U.S. products or such product from large segments of the industry be

combined with the multiple countries of origin category nor was it provided for by the statute. The members of Congress stated that the purpose of COOL is to clearly identify the origin of meat products, providing consumers the most precise information available.

One commenter stated that while processors claim that segregating U.S. meat from foreign meat would be burdensome, processors already easily segregate meat by grade (e.g. USDA Choice vs. USDA Prime) and by source (e.g., USDA Certified Organic vs. nonorganic) and that segregating the origin of U.S. and foreign meat is no more complicated or burdensome.

In contrast, several other commenters expressed support for a more flexible approach to labeling notifications for meat products sourced from multiple countries of origin. One commenter indicated that retailers desperately need the flexibility to commingle product in the display, especially in a full-service display case. The commenter stated that disallowing the commingling of meat from multiple origins including the U.S. is a logistical nightmare for retailers. Another commenter stated that the interim final rule affords critically important flexibility to retailers and the entities that provide covered commodities to retailers with respect to the labeling of covered commodities derived from animals of U.S. origin, as well as animals with multiple countries of origin. Another commenter urged the Agency to apply flexibility consistently for all sectors of the chain including retailers.

Several commenters stated their belief that Congress intended to provide flexibility between categories A and B afforded in the rule based on the permissive language of the statute for those two categories, which is supported by the absence of that very flexibility in subsections 282(a)(2)(C) and (D). The commenters noted that in subsections 282(a)(2)(C) and (D) of the statute, Congress used the word "shall" with respect to types of covered commodities identified in those categories, imported for immediate slaughter and foreign country of origin, and arguably limited the Agency's discretion to interpret how those categories of product should be labeled.

Another commenter recommended the same flexibility given to processors to label meat from animals of U.S. origin with a mixed origin label should be given to the labeling of meat from animals imported directly for slaughter. The commenter recommended that the final rule give processors the flexibility to make use of the order of countries mandated under this category (Product

of Country X and the U.S.) when processing a production run including animals of U.S., mixed origin, or imported for immediate slaughter.

Another commenter noted that little attention seems to have been paid to the amount of exported meat this rule is putting at risk, which is now sold to Mexico, compared to the small amount of cattle born in Mexico and exported to the United States. Another commenter added that producers on the border States rely on Mexican cattle imports. The commenter warned that by establishing these categories, the value of finished Mexican cattle will be discounted at the packing plant because they will have to be sorted on the line in the plant, which costs the packer money. Another commenter stated that COOL has effectively cut off U.S.-Mexican cattle trade and that because of COOL the packers have advised producers that they will not buy Mexican cattle.

One commenter indicated that the multiple country label prescribed in the rule for product derived from U.S.-raised pigs, regardless of their birth country, provides packers, processors and retailers with flexibility in labeling pork products. The commenter further stated that this labeling flexibility, in turn, gives flexibility to U.S. pork producers handling those pigs, which will reduce costs associated with label changes, product segregation, and duplicate stock keeping units at all levels of the pork marketing system.

Several commenters noted that the "Product of the U.S." label allows for the labeling of pork products exclusively from pigs born, raised and slaughtered in the U.S. These commenters stated it will be effectively used for pork products offered to buyers who find value in that label. The commenters fully support the approach taken in the interim final rule. The commenters also expressed that including U.S.-raised pigs in the mixed origin labeling category also meets the "common sense" test as well as the economic reality of today's U.S. pork industry since more than 95 percent of the total end weight of a Canadian-born weaned pig is actually produced in the U.S. using U.S. feed, labor and buildings.

A final commenter wrote that the Agency should harmonize the final rule with the NAFTA Marking Rule. This commenter specifically encouraged the Agency to adopt a final rule that uses the tariff-shift method to determine the country of origin of covered commodities that are produced in the United States using ingredients or raw

materials imported from Canada or Mexico.

*Agency Response:* The Agency recognizes that the multitude of different production practices and possible sales transactions can influence the value determinations made throughout the supply chain resulting in instances of commingling of animals or covered commodities, which will have an impact when mixing occurs. However, the Agency feels it is necessary to ensure information accurately reflects the origin of any group, lot, box, or package in accordance with the intent of the statute while recognizing that regulated entities must still be allowed to operate in a manner that does not disrupt the normal conduct of business more than is necessary. Thus, allowing the marketplace to establish the demand of categories within the bounds of the regulations will provide the needed flexibility while maintaining the structure needed to enforce these clearly defined categories. If an initiator of the claim chooses to mix commodities of different origins within the parameters of a production day, or if the retailer mixes product from different categories willingly, the resulting classification must reflect the broadest possible terms of inclusion and be labeled appropriately. The initiator may elect to segregate and specifically classify each different category within a production day or mix different sources and provide a mixed label as long as accurate records are kept. Likewise, if a retailer wants to mix product from multiple categories, it can only be done in multi-product packages and then only when product from the different categories is represented in each package in order to correctly label the product. With regard to producer benefits, while some U.S. producers may hope to receive benefits from the COOL program for products of U.S. origin, the purpose of the COOL program is to provide consumers with origin information.

With regard to the commenter's recommendation that the same flexibility given to processors to label meat from animals of U.S. origin with a mixed origin label should be given to the labeling of meat from animals imported directly for slaughter, this final rule allows muscle cut covered commodities derived from animals that are born in Country X or Country Y, raised and slaughtered in the United States, that are commingled during a production day with muscle cut covered commodities that are derived from animals that are imported into the United States for immediate slaughter as

defined in § 65.180, the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y.

With regard to using the tariff-shift method to determine the country of origin of covered commodities that are produced in the United States using ingredients or raw materials imported from Canada or Mexico, the Act specifically defines the criteria for covered commodities to be labeled with a U.S. origin declaration. Accordingly, this recommendation is not adopted.

#### *Labeling Commingled Covered Commodities*

*Summary of Comments:* Several commenters expressed concerns about the notification requirements for commingled covered commodities. One produce supplier was concerned about their liability in the event ready-to-eat produce they supplied was commingled with other product from multiple vendors at retail stores. Another commenter voiced opposition to an alphabetical listing on a product sourced and commingled from multiple countries of origin. The commenter expressed support for the provision in the voluntary COOL guidelines published in 2002 (67 FR 63367) that would have required country of origin for each raw material source of the mixed or blended retail item by order of predominance by weight.

Another commenter expressed support for the current provision. The commenter noted that the current interim final rule states that for these products, the country of origin must be designated in accordance with CBP marking regulations, promulgated pursuant to the Tariff Act. To the extent that this will prevent a conflict between the two laws, this commenter supports the Agency's recent approach.

One commenter asked for clarification about the use of the word "or," the phrase "and/or," commas, slashes or spaces to separate the country names in a label listing multiple countries of origin for commingled commodities. The commenter pointed out that a comma would be equivalent to "and," which might not be appropriate for labeling a single produce item that could not physically have been produced in two countries.

*Agency Response:* As noted in both the interim final rule for fish and shellfish and the interim final rule for the other covered commodities, the Agency determined that requiring origin notification either by alphabetical listings or by listing the countries of origin by order of predominance by

weight was overly burdensome to the regulated industries.

As commingling of the same type of products at retail containing different origin is permissible under this final rule, the Agency cannot prohibit the commingling of like products from multiple vendors at retail. The COOL program is not a food safety program. Commingling like products is a commercially viable practice that has been historically utilized by retailers and any decision to continue this practice has to be determined by the retailer.

The Agency does not agree that the statute allows for the use of terms and phrases such as "or, may contain, and/or" that only convey a list of possible origins. The intent of the statute is to require retailers to provide specific origin information to consumers. In addition, such disjunctive labeling schemes are not allowed under CBP regulations except under special circumstances.

For commingled covered commodities, each country must be listed. The Agency does not agree that the regulations should mandate how this list of countries be punctuated with commas, slashes or spaces. The Agency believes that it is best left to individual businesses to decide how to convey the information in a way that is neither confusing nor misleading.

#### *Labeling Ground Meat Covered Commodities*

*Summary of Comments:* Several commenters expressed the opinion that the provision in the interim final rule that states, "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" is too long. The commenters stated that in practical terms, this provision appears to allow a processor to have 60 days to correct the label of a product to delete specific country(s), even though that country's product may no longer exist in its inventory. The commenters provided the example that a processor on day one could have product from the U.S. and Canada, and then on day 7 run out of product from the U.S., and yet could continue using the "Product of U.S. and Canada" label for another 53 days. Commenters feared this provision could be easily abused by meat processors. Several commenters requested that the Agency reconfirm the appropriateness of this time-frame and explain the rationale and justification for this duration. Another commenter urged AMS to clarify this issue for the public record because in the opinion of the

commenter, the wording in this section of the rule is confusing and potentially misleading.

Another commenter pointed out this provision was intended to reflect the sourcing processes of commercial grinders and not to require them to change their labels simply because the market had changed and source product was more expensive from one country than another. As the statutory language that is interpreted here is directed to retailers, this commenter understood this provision to apply to retailers as well, and respectfully requested that the Agency confirm the applicable standard in the final regulation.

One commenter was concerned about the impact that mandatory country of origin labeling will have on imported beef, particularly ground beef at retail. The commenter stated that mandatory origin labeling will add significantly to meat production costs at a time of rapidly increasing food costs, and consumers will have to bear the additional expense resulting from the labeling regime. The commenter was concerned, therefore, that retailers will be induced to simplify their labeling obligations by excluding imported and certain domestic beef from ground beef in order to minimize the resulting increase in the costs that will be associated with compliance.

*Agency Response:* As already stated, the intent of the authorizing statute was for consumers to have available to them for the purposes of making purchasing decisions accurate information pertaining to the country of origin of certain covered commodities sold at retailers as defined. That said, the Agency believes this program should be implemented in as least burdensome a manner possible while still achieving this objective.

In developing the interim final rule, the Agency spent considerable time analyzing the current production systems of the ground meat supply chain and retail industry so that this program could be implemented in a manner that was least burdensome as possible while still providing consumers with accurate information to base their purchasing decisions on. It also must be stressed that if a country of origin is utilized as a raw material source in the production of ground beef, it must be listed on the label. The 60-day in inventory allowance speaks only to when countries may no longer be listed. The 60-day inventory allowance is an allowance for the Agency's enforcement purposes for when the Agency would deem ground meat products as no longer accurately labeled.

The Agency arrived at the 60-day allowance during its analysis of the ground meat industry. In this analysis, the Agency determined that in the ground beef industry a common practice is to purchase lean beef trimmings from foreign countries and mix those with domestic beef trimmings before grinding into a final product. Often those imported beef trimmings are not purchased with any particular regard to the foreign country, but the cost of the trimmings due to currency exchange rates or availability due to production output capacity of that foreign market at any particular time. Because of that, over a period of time, the imported beef trimmings being utilized in the manufacture of ground beef can and does change between various foreign countries.

As large scale beef grinders can have in inventory at any one time, several days worth of beef trimmings (materials to be processed into ground beef) from several different countries and have orders from yet other foreign markets, or from domestic importers, trimmings from several foreign countries that will fulfill several weeks worth of ground beef production, the Agency determined that it was reasonable to allow the industry to utilize labels representing that mix of countries that were commonly coming through their inventory during what was determined to be a 60-day product inventory and on order supply. To require beef grinders to completely change their production system into grinding beef based on specific batches was determined to be overly burdensome and not conducive to normal business practices, which the Agency believes was not the intent of the statute. Further, because beef grinders often purchase their labeling material in bulk, if a given foreign market that a beef grinder is sourcing from is no longer capable of supplying product, the interim final rule allowed that grinder a period of time to obtain new labels with that given country of origin removed from the label.

With regard to the commenters' concerns with the potential of "abuse" of this allowance by processors, the Agency does not believe widespread abuses of this provision will occur and will address any issues with this provision during routine compliance reviews. As such and for all the reasons stated above, the Agency continues to believe that the 60-day inventory allowance is appropriate and was retained in this final rule.

With regard to if this 60-day inventory allowance is made for retailers or for suppliers of covered commodities, the Agency has made no distinction in this

final rule and, as such, the same requirements would apply. Other concerns raised, including the impact of this regulation on the utilization of imported meat and consumer food costs are addressed in the economic impact analysis contained in this action.

#### *Remotely Purchased Products*

*Summary of Comments:* Two commenters expressed the opinion that the provision on remotely purchased products is too weak because it allows country of origin information to be disclosed either on the sales vehicle or at the time the product is delivered to the consumer. The commenters stated that for origin information to be of use to consumers, it must be disclosed at the time that purchasing decisions are made. The commenters recommended that the country of origin or the possible country(ies) of origin could be listed on the sales vehicle (i.e. Internet site, home delivery catalog, etc.) as part of the information describing the covered commodity for sale. Another commenter encouraged the Agency to maintain the provision for remotely purchased products with the additional flexibility of permitting the declaration either on the sales vehicle or on the product at the time of delivery.

*Agency Response:* The Agency believes that the provision contained in the interim final rules, which allows the information to be provided either on the sales vehicle or on the product itself, provides flexibility to suppliers and also provides useful information to consumers. If a consumer desires to purchase a covered commodity of a certain origin, they can so specify to the retailer.

#### *Marking*

##### *General*

*Summary of Comments:* Several commenters addressed the question of preponderance of stickering and sticker efficacy. The commenters recommended that the Agency define "majority" as it applies to bulk display stickering for perishable agricultural commodities. The commenters noted that the Agency has recognized that when fresh produce is stickered with origin information, every product may not bear a sticker for a variety of reasons, and that a majority of the product should have stickers. Two commenters recommended that the Agency define "majority" as it applies to bulk display stickering for perishable agricultural commodities as "50% plus one" so that the industry has a specific understanding for compliance. Another commenter agreed with this definition, citing that the FDA found 50% product

labeling sufficient even in a case of human health. The commenter argued that such a standard would therefore be more than sufficient for adequate disclosure of country of origin. Another commenter recommended that the Agency not require more than a majority of produce items in any given bin to carry a PLU sticker. The commenter added that price look up (PLU) stickers, which include information on the supplier that initiates the country of origin claim, should not only satisfy a retailer's obligation to inform consumers of the country of origin of the item, it should satisfy the retailer's country of origin recordkeeping obligation as well.

Another commenter expressed concern that the lack of a specific minimum labeling requirement could ultimately require suppliers to have multiple containers and packaging inventories available. The commenter stated that a producer supplying fruit for bulk sale that is not currently stickered fruit may now be required by retailers to sticker individual pieces of fruit because the rule only "encourages" retailers to use placards or other methods. The commenter recommended that the rule establish a specific minimum standard to ensure greater consistency in compliance.

As it pertains to fish and shellfish, another commenter suggested that the Agency allow the use of statements such as "wild and/or farm-raised" or "may contain" in addition to allowing the use of "check box" labeling options to minimize the cost of labeling while still providing the required information for the consumer.

*Agency Response:* As stated in the preamble of the August 1, 2008, interim final rule, the Agency understands that stickering efficacy is not 100%. Further, the Agency believes that under normal conditions of purchase, consumers would likely be able to discern the country of origin if the majority of items were labeled regardless if additional placards or other signage was present. Accordingly, the Agency does not believe it is necessary to modify the language with respect to 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.

With regard to this use of "may contain" and "and/or" statements, as previously stated, the Agency does not agree that the statute allows for the use of terms and phrases such as "or, may contain, and/or" that only convey a list of possible origins. Rather the Agency believes that the intent of the statute is

to require retailers to provide specific origin information to consumers. In addition, such disjunctive labeling schemes are not allowed under CBP regulations except under special circumstances.

#### *Signage Over Bulk Display Cases*

*Summary of Comments:* Several commenters expressed concern that the language authorizing a list of "all possible origins" on a bulk container (such as a meat display case that may contain commodities from different origins) would inadvertently allow a retailer to hang a sign over the entire meat display case that stated that the entire display contains products from the U.S. and one or more countries, even if the display case contains only commodities from the U.S. The commenters contend that nothing in the law expressly permits such labels on displays, holding units, or bins to merely provide information regarding "all possible origins" of the commodities contained therein and recommended that the Agency add language to require that if a meat display case contains commodities from more than one country, the commodities must be physically separated according to their origins within the meat display case and a separate origin declaration must be associated with each section.

Another commenter stated that they understood that the Agency is concerned that a sign such as "All beef is Product of the US" might be interpreted by consumers to encompass beef products that are not covered by the statute because they are processed. In order to provide clarity, the commenter urged the Agency to provide "safe harbor" standards for language and placement in order to ensure that retailers are properly meeting their obligations.

One commenter noted that retailers have the discretion to use signs, placards or other communications to convey origin information. Another commenter noted that the interim final rule allows for a bulk container at retail level that contains commingled products to be labeled with the country or countries of origin. However, the commenter also pointed out that the rule is silent on whether the individual pieces contained in bins must also be labeled, which would be difficult for certain species (e.g., broccoli, lettuce). This commenter requested confirmation that, for commingled produce sold in bins or trays, individual pieces of produce do not need to be labeled provided their origins are displayed on appropriate signage by the retailer.

*Agency Response:* With regard to the provision in both interim final rules concerning bulk containers that allows the bulk container to contain a covered commodity from more than one country of origin, as previously stated, under this final rule it remains permissible provided that the notification representing a container, display case, bin or other form of presentation includes all possible country designations available for purchase.

With respect to the use of signage for bulk displays for meat covered commodities, as previously discussed, the Agency has observed that a vast majority of retailers are utilizing one sign for either the entire meat case or for an entire commodity type (i.e., chicken) to provide the country of origin notification. While the statute and this regulation provide flexibility in how the country of origin information can be provided, the Agency believes that the use of such signage could be false or misleading to consumers. The Agency encourages retailers to review signage that they have used in the implementation of the fish and shellfish program for alternative methods of providing COOL information.

With regard to comment concerning the labeling of individual pieces of produce, the rule provides flexibility in how the country of origin information may be conveyed. Thus, this final rule does not contain a requirement that individual pieces of product must be labeled with country of origin information. However, retailers may request that suppliers use specific methods of conveying origin information through contractual arrangements with their suppliers.

#### *Abbreviations*

*Summary of Comments:* Several commenters requested additional guidance on acceptable abbreviations, and they provided a variety of recommendations to the Agency about specifying approved abbreviations. These commenters all favored the use of country abbreviations when marking country of origin declarations. One commenter requested that a select group of countries be permitted for abbreviation to include New Zealand, Guatemala, South Africa, Argentina and Australia. Another commenter said that abbreviations would serve a useful purpose on product labels and recommended that a list of reasonable abbreviations be developed that could be used by processors and retailers (e.g., CAN for Canada).

Other commenters appreciated the Agency's recognition of the need to abbreviate the names of some countries



using abbreviations from CBP. The commenters recommended that the language in section (e) be reworded to remove the first sentence ("In general, abbreviations are not acceptable."). The commenters reasoned that the available space on product labels (e.g., price look-up [PLU] sticker) or bills of lading is scarce. The commenters further stated that it is important for the industry to be able to convey origin information on both of those vehicles for several reasons. Information on the product itself (through a PLU sticker, rubber band, twist tie, tag, etc.) is particularly important because it informs the consumer at point of purchase and moves with the product to the home. When industry can include the information on a bill of lading, it allows companies to use existing records as the statute requires. The commenters suggested that the Agency remove the requirement that a key to abbreviations be included with documents (each time or even once), because the industry is well aware of the abbreviations used and their meanings.

Several commenters suggested that the Agency rely on the ISO 3166 country codes maintained by the International Standardization Organization. One commenter disagreed with the Agency's determination that such abbreviations may not be readily understood by the majority of consumers. One commenter added that in addition to the ISO country codes, CBP recognizes country codes as do other federal agencies such as the Bureau of the Census. The commenter pointed out that the United Nations also recognizes both the two letter and three letter ISO country codes. Another commenter requested that a list of 3-digit country abbreviations be developed and allowed to identify the countries of origin. The commenter noted that these 3-digit codes would not be confused with 2-digit codes used in the U.S. to identify individual States.

One commenter indicated that in the event the Agency retains its current prohibition on abbreviations for consumer information, the Agency must be clear that origin information in records and paperwork can be maintained with any acceptable abbreviations. The commenter added that they strongly support the ability to utilize labeling of a U.S. State, region or locality in which a product is produced to meet label standards as product of United States. In addition, the commenter stated that they support the ability to use State abbreviations, which is standard practice in many current State labeling programs and is readily accepted identification by consumers.

One commenter described a customer who had a requirement to list the State name in addition to the U.S. This commenter asked if it would be permissible to abbreviate State names when more than one needs to be listed (e.g., WA, CA, AZ). The commenter suggested putting the State abbreviations in brackets after USA (e.g., USA (CA, AZ)).

*Agency Response:* As previously stated, the Agency believes that the limited application of abbreviations that unmistakably indicate the country of origin is appropriate. CBP has a long history of administering the Tariff Act and has issued a number of policy rulings with respect to the use of abbreviations. Because many of the covered commodities subject to the COOL regulation are also subject to country of origin marking under the Tariff Act, it would be inconsistent with CBP regulations to allow for the use of additional country abbreviations under the COOL program. With regard to the use of ISO codes that many commenters made reference to, CBP does allow for the use of such codes for statistical and other purposes with respect to e-commerce; however, CBP does not allow for the use of ISO codes for marking purposes. The Agency has obtained a more complete list of abbreviations from CBP and has posted this information to the COOL Web site.

With regard to State labeling for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng, the Agency does believe that the majority of consumers are familiar with the standard State abbreviations used by the U.S. Postal Service and because the purpose of the COOL program is to provide consumers with origin information, it is reasonable to allow such abbreviations. Allowing this flexibility will address industry's concerns about the limited space on PLU stickers, twist ties, rubber bands and other package labels typically used for produce. Under this final rule, abbreviations may be used for state, regional, or locality label designations for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng covered commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP. With regard to the use of abbreviations by suppliers or retailers in conveying origin information in records or documentary systems, there are no restrictions on the use of abbreviations as long as the information can be understood by the recipient.

Accordingly, these recommendations are adopted in part.

#### *State, Regional, and Locality Labeling*

*Summary of Comments:* Several commenters raised issues related to the provision for state, regional, and locality labeling of covered commodities. Three commenters requested that state, regional, and locality labeling be acceptable for covered meat commodities. One commenter sought confirmation that the provisions on State markings in the interim final rule apply also to States, regional and local labels of importing countries. This commenter understood that identification by region and locality is acceptable provided it is nationally distinct, but requested that this provision be clarified in the final rule.

Another commenter noted that USDA is silent on the use of locality labeling, and requested that the final rule recognize that locality labeling is likewise permitted by the statute. The commenter stated that many retailers source products locally and choose to provide this information to consumers because it is meaningful to these customers.

*Agency Response:* With regard to the commenters' recommendation to allow State, regional, and locality labeling for meat covered commodities, the statute contains an express provision for this type of labeling for perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng. As such, the Agency does not have the authority to extend this provision to any other covered commodities. With regard to the commenter's request that the Agency clarify that this provision applies to imported perishable agricultural commodities, nuts, and ginseng and that locality labeling is also permitted, clarifying language has been added to section 65.400(f). Accordingly, these recommendations have been adopted in part.

#### *Supplier Responsibilities*

*Summary of Comments:* Several commenters expressed concerns with the Agency's assertion in the interim final rule that "the supplier of a covered commodity that is responsible for initiating a country of origin claim \* \* \* must possess or have legal access to records that are necessary to substantiate that claim." The commenters maintained that the Agency's jurisdiction stops with the initiator of the origin claim of a covered commodity, which in the case of meat products is the slaughter facility. The commenters further stated that the COOL law authorizes only the Secretary

of Agriculture to conduct an audit for verification purposes, not the packer, and that furthermore, 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 a covered commodity other than those maintained in the course of the normal conduct of the business of such person. The commenters argued that the 2008 Farm Bill language states that producer affidavits are sufficient in making a country of origin claim; therefore, packers or processors should not be given legal access to producers' records. The commenters recommended that the Agency eliminate language referencing "legal access" from the final regulation as they contend it is not authorized by the law.

Two commenters suggested that the Agency should require the original suppliers of covered products to substantiate the chain of custody and the accuracy of country of origin information. One commenter expressed the opinion that it is unreasonable that the liability ultimately is placed on the meat processor to provide country of origin information when they are relying on the word of livestock producers, who may or may not be providing accurate information.

Another commenter pointed out the importance of maintaining origin information by all segments of the industry to verify origin claims and to ensure the integrity of the labeling program. This commenter also stated that it is important that producers not be asked for unreasonable information that goes beyond what would be considered acceptable or the lack of which is a pretext for penalties against a producer or producers. The commenter recommended that the Agency provide a safe harbor of reasonable or acceptable information that can be asked of a producer to help avoid the possibility of unreasonable requests for information that would be considered unfair or an effort to single out a particular producer.

One commenter suggested removing the provision in the rule regarding supply chain traceability in the recordkeeping requirement. The commenter stated that the purpose of COOL is to inform consumers about the origin of the covered commodities and that the added recordkeeping requirement of traceability is not necessary and is an added regulatory burden.

One commenter noted that while producers are not directly affected by the COOL law, Section 282(3) of the statute expressly requires that "anyone engaged in the business of supplying a

covered commodity provide country of origin information." The commenter further stated that in the case of animals imported from Canada, this necessarily implicates Canadian producers who must present health papers to APHIS at the border. The commenter suggested further clarification is needed about the manner in which that origin will be tracked and conveyed to AMS should proof of origin be required further down the supply chain.

One commenter noted that Agency representatives have repeatedly advised the industry of the need for significantly more extensive records than are currently maintained in order to verify COOL. The commenter strongly urged the Agency to clarify in the final rule that the statutory prohibition of any new record requirement is recognized and accepted. This commenter also encouraged the Agency to provide a definitive declaration that suppliers may convey COOL information to retailers through any method of their choosing in order to comply with the regulation. The commenter stated that in current trade practice, some have been confused as to whether supplier labeling of COOL on the actual produce item is required, or whether multiple documents such as invoices or bills of lading must contain COOL information. The commenter suggested that USDA should make clear that COOL information may be provided to the retailer in any form. The commenter further suggested that relationships in the marketplace—not the statute—will determine in what form that communication will take place, including whether individual product eventually is labeled by a supplier.

One commenter stated that the most practical approach to meeting the COOL requirements for most covered commodities is for those producers to print the country of origin on all retail packaging for case and consumer ready, and on all case end labels for all products destined to be store processed or packaged by the retailer. The commenter suggested that producers will not need to continuously transmit country of origin information to the retailer on an order by order basis. Instead, package and case labeling in conjunction with the USDA establishment number (used to identify producer) and the lot or batch number (used to identify the specific lot of live animals from which products are derived) will already be on pre-packaged labels and case end codes. The commenter further stated that retailers already retain invoices to meet other reporting requirements, which identify the producers of the product, and can be

used to satisfy the COOL recordkeeping obligation. The commenter also stated that there will be no required change in business processes for retailers but producers will be required to add accurate origin information to the retail packaging and/or case end labels.

One commenter identified a business process flow they hoped could be simplified with the intervention of the Agency. In import situations where a consolidated shipment could have multiple origins covered by one Bill of Lading (for example, a combined load of Navel Oranges from Australia and South Africa, and Clementines and Lemons from Chile) the commenter currently notes each line item on the documentation, which is an added step in the paperwork process. The commenter requested that the Agency provide suggestions in the rule about alternative means to comply with COOL on Bills of Lading, invoices, or packing slips.

One commenter suggested that the Agency consider a longer period, such as 10 business days, to provide records upon request to any duly authorized representatives of USDA for COOL compliance purposes. Two commenters referenced the statutory prohibition against the Agency requiring records that are not maintained in the normal conduct of business. These commenters noted that such records are deemed sufficient to satisfy the Bioterrorism Act's mandate to be able to identify immediate previous source and immediate subsequent recipient of foods. The commenters recommended that the Agency likewise accept multiple sourcing records for purposes of the mandatory country of origin labeling requirement for intermediary suppliers to identify their immediate previous source and immediate subsequent recipient.

*Agency Response:* It is correct to say that the Agency's authority to audit ends at the slaughter facility as the slaughter facility is the first handler of the covered commodity and the Agency has deleted the requirement that suppliers have legal access to records from this final rule. However, as initiators of origin claims, packers must have records to substantiate those claims. With regard to records maintained in the course of the normal conduct of the business of such person and producer affidavits, the final rule states that producer affidavits shall be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity

unique to the transaction. With regard to the commenter's assertion that producers not be asked for unreasonable information that goes beyond what would be considered acceptable, the Agency has provided examples of records kept in the normal course of business that may be used to substantiate origin claims. As previously stated, packers can utilize producer affidavits to obtain origin information. This final rule has been drafted to minimize the recordkeeping burden as much as possible while still providing the Agency with the information necessary to verify origin claims.

With regard to how suppliers may provide origin information to retailers, this final rule states that the information can be provided on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale. It is up to the supplier and their retailer customers to decide which method is most appropriate. The Agency agrees that bills of lading, invoices, and packing slips may be used to provide origin information. Ultimately, retailers must ensure that covered commodities displayed for retail sale have country of origin designations.

With regard to the recommendation to allow a 10 day period to supply documentation to USDA officials, the Agency believes that the 5 business days provided in the August 1, 2008, interim final rule provides suppliers and retailers reasonable and appropriate time to provide records to USDA upon request. With regard to the commenters' reference to the statutory prohibition against the Agency requiring records that are not maintained in the normal conduct of business and that such records are deemed sufficient to satisfy the Bioterrorism Act's mandate to be able to identify immediate previous source and immediate subsequent recipient of foods, records maintained in the normal conduct of business can be used to satisfy the COOL recordkeeping requirements. However, the Agency recognizes that suppliers and retailers may need to make modifications to their existing records in order to provide the necessary information to be able to substantiate COOL claims as provided for in the statute.

#### *Visual Inspection*

*Summary of Comments:* Several commenters expressed support for the Agency policy to accept visual inspection as a means to verify the origin of livestock during the period between July 15, 2008 and July 15, 2009.

Specifically, the majority of commenters supported the Agency's decision to authorize sellers of cattle to conduct a visual inspection of their livestock for the presence or absence of foreign marks of origin, and that such visual inspection constitutes firsthand knowledge of the origin of their livestock for use as a basis for verifying origin and to support an affidavit of origin. They noted that visual inspection for verification of origin is particularly important to the trade during the period between July 15, 2008, and whenever the final regulation is published. The commenters stated that producers now have livestock without all of the origin documentation that may be necessary and that it would be very difficult, and in some cases impossible, to recreate the paper trail on many of these animals. Other commenters noted that the visual inspection of animals for import markings is a highly reliable, cost effective method of verification of origin and will significantly reduce compliance costs for livestock producers. The commenters recommend that visual inspection be made a permanent method on which to base origin claims.

*Agency Response:* The Agency initially allowed for a transition period for the period July 16, 2008, through July 15, 2009, during which producers may issue affidavits based upon a visual inspection at or near the time of sale that identifies the origin of livestock for a specific transaction. Affidavits based on visual inspection may only be issued by the producer or owner prior to, and including, the sale of the livestock for slaughter. The Agency agrees with the commenters that affidavits based on visual inspection reduce the burden on producers. Accordingly, the Agency is making the ability to utilize visual inspection as the basis for forming an affidavit permanent.

#### *Producer Affidavits*

*Summary of Comments:* Numerous commenters expressed support for the "Universal Country of Origin Affidavit/Declaration" that was developed by consensus across the livestock and chicken industry to serve as verification from producers to slaughter facilities for the country of origin of livestock. Several commenters requested that these agreed-upon documents be incorporated in the final rule. Several commenters also argued that producers should not be asked for unreasonable information. They urged AMS to consider a standardized producer affidavit that would accompany an

animal from its first sale throughout the chain of custody.

Several commenters expressed support for the Agency's decision to allow composite affidavits where a producer can put together lots of cattle for sale and have one new affidavit for that lot based on the affidavits received for each animal, or lot of animals, that was combined in the new lot. The commenters also expressed support for the ability for producers to file an "evergreen" or "continuous" affidavit with the buyers of their livestock saying that, until otherwise noticed or revoked, all the cattle they will deliver to that buyer will be of a specific origin.

One commenter disagreed that a producer affidavit in conjunction with animal ID records can be deleted after 1 year when a majority of breeding stock lives beyond 5 years and 95% of cattle in the U.S. on July 15, 2008 were not close to slaughter age. The commenter was of the opinion that documentation and retention of affidavits needs to last longer if the Agency has to audit and trace back meats.

*Agency Response:* The Agency believes the Universal Country of Origin Affidavit/Declaration that was developed by consensus across the livestock and chicken industry will assist the industry in implementing the rule in as least burdensome manner as possible. While the statute and this final rule allow for the use of producer affidavits, because the statute does not provide the Agency with authority to regulate producers, the Agency cannot mandate the use of such affidavits.

The Agency recognizes that animal production cycles vary greatly and depending upon which records are used for origin verification, retention of documents should be commensurate with the claim being affirmed through an affidavit or other means of declaration. However, the Agency only has the authority to require record retention for covered commodities. As the initiator of origin claims for meat, packers may specify the length of time records need to be maintained by entities outside the packer's system.

#### *National Animal Identification System (NAIS)*

*Summary of Comments:* Commenters had mixed opinions about relying on NAIS as a safe-harbor for COOL compliance. Numerous commenters supported the provision in the interim final rule stating that voluntary participation in NAIS program will comply with COOL verification requirements. The commenters that support the use of NAIS stated that official USDA 840-tags can serve as a

universal passport for an animal during its lifetime indicating the animal is of U.S. origin, no matter how many times ownership of the animal changes during its lifetime. Commenters strongly encouraged the Agency to utilize Radio Frequency Identification (RFID) tags in NAIS to allow verification of country of origin at the speed of commerce and stated that official NAIS USDA 840-RFID tags for livestock represent the simplest way for producers to assist in the marketing of their animals to ensure compliance with COOL.

One commenter recommended that NAIS should be made mandatory. Two commenters suggested that the Agency could alleviate the record keeping burden by simply requiring all foreign cattle to bear a permanent mark that defines their origin. They suggested that this will not only aid commerce by reducing paperwork, but it will also enhance compliance.

Three commenters expressed support for reliance on other existing animal identification systems. One commenter noted that USDA/APHIS currently operates the National Scrapie Eradication Program (NSEP), which includes a regulated animal identification program. By regulation, feeder and slaughter sheep that are imported from Canada must carry official permanent identification. The commenter urged AMS to help processors and others recognize the relatively straight-forward nature of proving animal origin in the sheep industry. Two commenters pointed out that livestock producers who participate in "Age and Source Verified" programs administered by USDA should also be in compliance with COOL for both origin and verification claims.

Another commenter stated that identification of animal origin by ear tag is a cause for concern. This commenter noted that USDA has not provided guidance about what records will suffice for imported animals, stating only that for animals that are part of an official identification system, such as the Canadian cattle identification system, ear tags will suffice for proving origin at the slaughterhouse. The commenter was concerned with having requirements imposed because of a specific animal health concern, such as Canadian ear tags on cattle, ensnared in separate regulations for an entirely different and unrelated purpose. The commenter stated that this could restrict Canada's abilities to adapt its national cattle identification system to changing environments or technologies in the future.

A final commenter warned that the acceptance of an ear tattoo does not

meet the needs of modern industry practices. Due to issues associated with the speed of commerce, recordkeeping, accuracy and overall effectiveness of the program, the commenter stated that the Agency should only allow a hot iron brand on all live foreign cattle.

*Agency Response:* The Agency believes that voluntary use of the National Animal Identification System is an easy option packers may utilize to obtain origin information on livestock. The Agency has also made modifications to this provision for clarity. The Animal Identification Number (AIN) is defined in the Code of Federal Regulations as "A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States." As stated in the interim final rule published on September 18, 2008, (73 FR 54059), the AIN version starting with 840 is prohibited for use on animals born outside the United States. Therefore, under this final rule, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking (i.e., "CAN" or "M") may use that information as a basis for a U.S. origin claim. Packers that slaughter animals that are part of another country's recognized official system (e.g. Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. With regard to the commenter's concern regarding having requirements imposed because of a specific animal health concern, such as Canadian ear tags on cattle, in separate regulations for an entirely different and unrelated purpose, this regulation does not impact regulations pertaining to animal health or importation. In addition, use of official ear tags as the basis of origin claims is just one option that can be utilized to obtain origin information.

The other comments received relevant to making NAIS mandatory and allowing only hot iron brands on live foreign cattle are outside of the scope of this rulemaking. Accordingly, these recommendations have been adopted in part.

### *Retailer Responsibilities*

*Summary of Comments:* Numerous commenters addressed issues relating to the retailer recordkeeping provisions of COOL. One commenter stated that the Agency has offered simple, effective rules for recordkeeping by retailers. One commenter recommended that in § 65.500(c)(1), the Agency put the last sentence of the paragraph first ("For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish the product's origin."). The commenter also requested that the Agency state specifically that retailers need not maintain any new or additional records documenting origin for those products that are pre-labeled on the product itself or on the box/container when the box/container is visible to consumers, such as when it is used as part of a retail display.

One commenter suggested sample and common technological standards such as the portable document format (PDF) or use of a common and interoperable database file system such as Microsoft Excel to enable both industry and the Agency to adopt a common computing platform. Another commenter suggested that the Agency should refer to the two different types of documents required to be maintained by retailers as Verification Records and Supplier records. The commenter suggested that the Agency should clarify in the final regulation that the information to satisfy both requirements may be on the same or different documents, provided all of the requirements are met. Several commenters encouraged the Agency to permit retailers to rely on the records that are currently maintained for Bioterrorism Act purposes.

One commenter strongly supported the specific recognition that retailers may rely upon pre-labeled products as "sufficient evidence" of the country of origin. The commenter stated that this is an important safe harbor for the produce and retail industries as an increasing share of fresh produce now arrives at retail stores pre-labeled with the country of origin. The commenter expressed concern that the IFR and the Agency's Q&A documents are not written in a way that conveys this information accurately, which is creating significant confusion throughout the produce distribution chain. The commenter recommended that the Agency clearly define pre-labeled products to include all produce items that bear a COOL declaration, regardless of any other information that may or may not be affixed directly to the produce item. In turn, the Agency must then specify that additional

recordkeeping at retail is not required for pre-labeled products as the vendor who supplied the pre-labeled produce has the responsibility to verify the claim. One commenter recommended that the Agency only require retailers to maintain the country of origin for covered products in the retail store for as long as the product is on hand.

*Agency Response:* With regard to pre-labeled covered commodities, the Agency has added a definition of pre-labeled in this final rule. In addition, the Agency has clarified that for pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and no additional records documenting origin information are necessary. However, the Agency does not agree with the commenter's recommendation to change the order of the sentences with respect to the provision on pre-labeled products.

With regard to the recommendation that the Agency adopt a common computing platform, the Agency does not have the authority to mandate a specific system. In addition, the Agency believes that retailers and suppliers should have the flexibility to choose whatever system works best in their particular operation. Accordingly, this recommendation is not adopted.

With regard to the suggestion that the Agency should refer to the two different types of documents required to be maintained by retailers as Verification Records and Supplier records and that the Agency should clarify in the final regulation that the information to satisfy both requirements may be on the same or different documents provided all of the requirements are met, the Agency has added language to the preamble to indicate that the supplier and origin information needed to satisfy the COOL recordkeeping requirements can be in the same document or different documents. However, the Agency does not believe that any changes to how the required documents are referenced are necessary. Accordingly, these recommendations have been adopted in part.

The Agency recognizes that several commenters encouraged the Agency to permit retailers to rely on the records that are currently maintained for Bioterrorism Act purposes. To the extent that these records contain the necessary information to meet the COOL recordkeeping requirements, the Agency agrees that records currently maintained to meet the requirements under the Bioterrorism Act can also be used to comply with the COOL recordkeeping requirements.

With regard to the recommendation that the Agency only require retailers to maintain the country of origin for covered products in the retail store for as long as the product is on hand, under this final rule, records and other documentary evidence relied upon at the point of sale to establish a covered commodity's country(ies) of origin must be either maintained at the retail facility for as long as the product is on hand or provided to any duly authorized representative of USDA in accordance with § 65.500(a)(2). For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and no additional records documenting origin information are necessary. Accordingly, this recommendation has been adopted in part.

#### *Enforcement*

#### *Liability Shield*

*Summary of Comments:* Several commenters discussed the concept of a "liability shield" found in the interim final rule for fish and shellfish, but deleted from the interim final rule for the remaining covered commodities. The commenters noted that the Agency had previously contemplated a "shield" from liability for entities subject to the law on the theory that they should be permitted to reasonably rely on information provided by their suppliers. The commenters recommended that the Agency add a clarification to the final rule that will assure retailers that they will not be penalized when a retailers' non-compliance results from the conduct of others. The commenters further stated that the interim final rule holds suppliers responsible for providing retailers with country-of-origin information and that because the statutory liability standard only penalizes retailers for "willful" violations, it follows that a retailer should not be held responsible for its supplier's failure to provide COOL information or its supplier's provision of inaccurate information. The commenters recognized that the Agency deleted the safe harbor language from the interim final rule for remaining covered commodities because that language created a negligence standard of liability instead of the willfulness standard specified in the 2008 Farm Bill. These commenters agreed that a willfulness standard is required by statute. However, they also stated that an explicit safe harbor should be restored to the rule, in addition to the willfulness standard the statute requires. Thus, paralleling the language that had been used in the safe harbor

provision for the fish and shellfish interim rule, a safe harbor provision one commenter suggested new regulatory language, "No retailer shall be held liable for a violation of the Act by reason of the conduct of another unless the retailer acted willfully in the same regard". Another commenter strongly urged the Agency to reinstate the liability shield in the final rule, but given the change in the liability standard as a result of the 2008 Farm Bill, recommended alternative language.

*Agency Response:* As noted by the commenters, the Agency deleted the liability shield language from the interim final rule for the remaining covered commodities because that language created a negligence standard of liability instead of the willfulness standard specified in the 2008 Farm Bill. Because of the willfulness standard contained in the 2008 Farm Bill, the Agency does not agree that the liability shield is necessary. However, to the extent that the liability shield language provides the industry with assurances that they will not be held liable for the conduct of others, the Agency believes that the liability shield is useful. Therefore, the Agency has included the liability shield provision in this final rule and has modified the language to reflect the willfulness standard contained in the 2008 Farm Bill. Accordingly, this recommendation has been adopted.

#### *Assurances Against Meat Recalls for COOL Violations*

*Summary of Comments:* Several commenters expressed concerns about how FSIS or other federal agency may use a country of origin labeling failure as a reason to recall pork and other meat products. These commenters noted that the law does not amend any food safety law and that it is not a food safety program. The commenters further stated since it is a marketing program, failure to properly label the origin of products in the retail meat case should not force a product recall. Many producers reported to be confused and fearful that this law will be used to assert product liability claims. These commenters requested clarification regarding the scope of the COOL law to eliminate this confusion. They asked that USDA clarify that any violation of COOL will not trigger a recall of meat products.

*Agency Response:* As noted by the commenter, the intent of the law and this rule 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 FDA and FSIS and are subject to any recall requirements imposed by those agencies. The Agency does note that FSIS did publish an interim final rule (73 FR 50701) on labeling to address concerns with compliance of their voluntary labeling approval authority and requirements of the COOL program. In addition, FSIS provided guidance that inspection program personnel are not to take any action to enforce the FSIS interim final rule until further notice and that during the next six months, FSIS will defer to the AMS program of outreach and education to ensure that there is compliance.

#### *Timeframe for Implementation*

*Summary of Comments:* Numerous commenters provided suggestions about the Agency's informed compliance period during which the Department will provide education and outreach to aid industry in understanding the requirements of the COOL program.

Three commenters expressed appreciation for the 6-month phase-in period articulated in the rule and stated that the Agency must be prepared to provide producers, suppliers, retailers, and consumers with assistance to understand the regulations through guidance documents, seminars, and other resources that are readily available to the public during this period of informed compliance. One commenter pointed out that it will be critical for the AMS to work with officials with FSIS to ensure that there is common understanding between the two USDA agencies regarding questions that meat processing plant operators and federal meat inspectors may have. One commenter urged the Agency to withhold publishing a final rule until after the conclusion of the 6-month period in order to maximize the lessons learned under the interim final rule. Another commenter encouraged the Agency to provide as much time as possible to acclimate both retailers and those involved within the supply chain to the new requirements of the regulations prior to any enforcement.

Several commenters expressed support that the requirements of the interim final rule do not apply to covered commodities produced or packaged before September 30, 2008. However, these commenters noted that many firms in the industry procure packaging materials for a year's worth (or more) of production. The commenters recommended that given the short amount of time between the release of the Interim Final Rule and the effective date, companies subject to the

rule be given a year from the effective date to use up existing packaging inventories, provided those packaging inventories were acquired prior to the effective date of the rule. One of these commenters expressed concern that a 6-month grace period will prove insufficient to implement a verifiable records system. This commenter stated that an 18-month implementation period will allow current nut products in the marketplace to rotate out and allow those in the field sufficient time to comply with all aspects of COOL. Another commenter was concerned about ensuring a reasonable phase-in period for the rule so that suppliers could use existing inventory to the greatest extent possible. This commenter supported a one-year phase-in as opposed to 6 months because the shipping season for table grapes and tree fruit generally runs from May through October. Therefore, a 6-month phase in from October through March would be of little benefit for this food sector. Another commenter noted that retailers, processors, and producers have expressed their willingness to make a good faith effort to comply with COOL; however, it is not clear that the 6-month industry education and phase-in period is sufficient. They strongly encouraged USDA to extend this period to 12 months in order that issues like recordkeeping and auditing the supply chain can be fully understood.

*Agency Response:* In response to the commenters' request that the Agency not publish the final rule until after the six month period of education and outreach, the Agency is moving forward in an expeditious manner of publishing the final rule in order to provide retailers and suppliers as well as all other interested parties with the requirements for a permanent program. The Agency will allow sufficient time for the regulated industries to adapt to the changes in this final rule and will continue to provide for a period of education and outreach. The Agency believes that the six month period provided for in the interim final rule is adequate time for retailers and suppliers to adapt to the COOL program requirements. In addition, the Agency will continue to ensure that retailers and suppliers are educated on the Agency's compliance and enforcement procedures so that the regulated industries have clear expectations as to how the Agency will enforce this rule. With regard to using up existing packaging inventories, this final rule does not require that covered commodities are individually labeled with COOL information. Retailers can

use placards and other signage to convey origin information.

#### *Miscellaneous*

##### *WTO/NAFTA Trade Agreements*

*Summary of Comments:* Several commenters expressed concern that COOL may violate U.S. trade commitments under the World Trade Organization and the North American Free Trade Agreement, and that provisions of the COOL regulation ignore the reality of an integrated North American meat and livestock industry. Two foreign governments expressed that the amendments passed with the 2008 Farm Bill are still cause for concern, and that as they have consistently expressed in the past, COOL requirements should be consistent with the United States' international trade obligations. One commenter pointed out that the Codex General Standard for the Labeling of Prepackaged Food was considered adequate in the U.S. system for a number of years and will continue to remain the standard for retailers outside of the U.S. The commenter further stated that it remains the most practical, and also the most adaptable, to evolving commercial practice and growing international trade; and yet it is not the standard adopted in the COOL regulations.

One commenter stated that the COOL statute and regulation will likely result in discrimination against imported product, contrary to U.S. obligations under the WTO Agreement on Technical Barriers to Trade. The commenter indicated that despite changes in the law and the IFR that have made it less onerous for regulated firms to comply with the requirements of the regulation, COOL will still discriminate against imported cattle and beef. This commenter warned that the industry practice of importing cattle for feeding and/or slaughter will be discouraged by the increased complexity associated with the identification, segregation, and labeling requirements mandated for the resulting products to be sold at retail. This commenter suggested that the simplest solution would be to allow processors and retailers to label ground product with "May contain U.S. and imported meat" with the option to list the specific countries if the producer or its customers so desired. Another commenter acknowledged that the IFR makes some concessions to earlier complaints by trading partners with concerns regarding the compatibility of COOL with the WTO obligations of the United States.

*Agency Response:* 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. Further, as described more fully in the Summary of Changes section of this rule, the Agency has made a number of modifications in this final rule that provide additional labeling flexibilities. In addition, the Agency has worked closely with USDA's Foreign Agricultural Service to educate U.S. trading partners on the requirements of COOL and to assist them in complying with the regulation.

In regards to a commenter's statement that when a food undergoes processing in a second country that changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling, existing CBP rules and regulations with respect to determining origin of imported products apply to the extent that it is permissible under the statute. However, it is not permitted under the statute to consider imported products that are substantially transformed in the U.S. to be of U.S. origin as they do not meet the definition of U.S. origin provided in the Act.

With regard to the comment to allow a label to state "May contain U.S. and imported meats," the Agency does not believe this type of labeling meets the intent of the statute. Accordingly, this recommendation is not adopted.

#### *COOL as a Food Safety Program*

*Summary of Comments:* Commenters expressed differing opinions regarding whether or not COOL serves as a food safety program. Several commenters expressed the opinion that COOL is a retail labeling program that does not provide a basis for addressing food safety. The commenters argued that the U.S. has a safe food safety system; that all meat sold at retail, whether grown domestically or imported, must be inspected and declared safe for human consumption; and that country of origin labeling is solely a marketing tool. One commenter found it particularly problematic that mandatory COOL has been portrayed by some advocates as contributing to efforts to make America's food safe, yet there is no provision in the COOL statute or the interim final rule that prescribes food safety or inspection standards. Another noted that the food production, supply and retailing industry needs to help consumers understand that geography cannot become shorthand for food safety. Several commenters noted that Congressional intent is clear that COOL

is not intended to be a traceability law, but merely to provide country of origin information to consumers. These commenters urged the Agency to implement COOL in a way that is true to its goal to inform consumers about where produce comes from, not create a new regulatory infrastructure. Other commenters noted their support for the provision of accurate information to consumers as required by the law and agreed with the Agency's statement in the preamble that this law is not a food safety law.

Two commenters wrote that COOL can serve as a risk management measure. One commenter suggested that developing 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. Another commenter referred to a GAO study that reported three elements of food-safety systems that were critical to respond to outbreaks of food borne illness: Traceback procedures that allow industry and government officials to quickly track food products to origin to minimize harm to consumers and the impact on business; cooperative arrangements between veterinarians and public health officials to document the names of suppliers and customers as well as the dates of delivery; and authority to recall a product from the market. The commenter noted that such food-safety systems depend on a verifiable chain of custody for food products that the COOL program can help institute. The commenter further stated that the COOL law provides for traceback provisions and for cooperative partnerships with states.

*Agency Response:* As previously stated, the COOL program is neither a food safety or traceability program, but rather a consumer information program. Food products, both imported and domestic, must meet the food safety standards of the FDA and FSIS. Food safety and traceability are not the stated intent of the rule and the COOL program does not replace any other established regulatory programs that related to food safety or traceability.

#### *USDA COOL Labeling Surveys*

*Summary of Comments:* Two commenters requested that USDA conduct nationwide retail surveys to gather information regarding country of origin labeling. One commenter requested that the Agency conduct a "nationwide retail meat labeling survey" within the year to discern the amount of product, the kind of product and the locations where exclusively

U.S. labeled meat is being sold. The second commenter suggested that the Agency insert additional data entry points in the retail survey instrument used for existing retail reviews. The commenter encouraged the Agency to gather information relative to the availability and price of meat items by origin at the retail stores under review. Furthermore, the commenter requested this information be reported to the House Committee on Agriculture and the House Committee on Appropriations 60 and 90 days after the labeling law takes effect.

*Agency Response:* The Agency is currently reviewing possible methods to collect data relative to the availability and price of meat items by origin at the retail stores under review. The Agency will work with members of Congress to provide any information collected to the appropriate Congressional committees.

#### *Existing State Programs*

*Summary of Comments:* One commenter agreed that the Agency had properly concluded that the COOL law preempts conflicting federal and state laws. This commenter stated it is imperative that companies subject to the federal statute be subject to one uniform set of regulatory requirements. One commenter agreed that it is preferable for producers to have one law to govern compliance, but suggested it is also important that the maximum amount of product information be provided to consumers as intended by the COOL legislation. In the event of conflict, this commenter preferred that the Agency err on the side of more information to the consumer rather than less, and asked the Agency to allow the States maximum flexibility to enforce their own laws, if doing so will provide the most information to the consumer.

*Agency Response:* 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.

#### *Impacts on Livestock Producers and Meat Packers*

*Summary of Comments:* Several commenters felt that a large portion of the implementation costs will be shouldered by the meat production and packing industry because there is little evidence that consumers are willing to pay more for products bearing country of origin information and that these additional costs will not be successfully passed through the supply chain. These commenters concluded that the costs of COOL implementation and compliance will be highly detrimental to the livelihood of numerous small meat processors. One meat packer observed that COOL will require the company to incur additional costs due to the recordkeeping and labeling requirements. Due to the nature of the business, the company relies on livestock producers to provide and verify origin information, yet as the originator of covered commodities derived from those animals, the burden of proof is on the company in the event the source information is ever questioned. Because there is no universal animal identification system in place to provide meat processors with proper background information, meat processors do not have readily available information with which to accurately label covered products. One commenter noted that COOL costs to livestock producers will be \$9 per head. This commenter was concerned that cattle owners will end up paying all costs as other sectors of the supply chain work on margin. This commenter urged USDA to consider costs when implementing this law since extra costs would be detrimental to consumers and producers.

Numerous state and national pork producer organizations submitted comments contending that the majority of program costs would be driven by two factors: Disruption of product flow through packers caused by differentiated labels and record-keeping burdens for producers and packers.

One commenter stated that since the true costs of COOL are as yet vague, and the burden of who is going to pay for the cost of additional recordkeeping requirements and labeling is unknown, the recordkeeping and documentation requirements should be designed so American producers do not end up paying for COOL.

*Agency Response:* The Agency believes that firms and establishments throughout the supply chain for affected

commodities will incur costs associated with the implementation of COOL. This includes producers, intermediaries, and retailers. Increased costs are likely to be absorbed by all firms and establishments throughout the supply chain and some costs may be passed on to consumers.

As previously stated, the Agency believes that voluntary use of the National Animal Identification System is a straightforward option packers may utilize to obtain origin information on livestock. In addition, following the implementation of the August 1, 2008, interim final rule, a coalition of representatives from throughout the livestock and meat industries established a universal affidavit to convey country of origin information. This rule provides flexibility in how the required country of origin information is conveyed along the supply chain, thus enabling firms to implement the requirements with the least possible disruption to cost-efficient production methods and trade flows.

#### *Costs on Affected North American Industries*

*Summary of Comments:* One commenter expressed concern that COOL will impose unnecessary costs on affected North American industries. The commenter stated that the substantial volume of two-way trade between Canada and the United States has been a testament to the integrated and cooperative nature of many of our industries and that trade with Canada supports more than 7.1 million jobs in the United States. The commenter further stated that trade is also vital in the agricultural sector where Canada is the largest single-country export market for the United States with more than US\$15 billion in sales last year.

*Agency Response:* As discussed more fully in the Regulatory Impact Analysis, the results of the Computable General Equilibrium (CGE) model suggest that overall impacts on trade in livestock and meats will be relatively small. The rule allows considerable flexibility, thus enabling firms to implement the requirements with the least possible disruption to cost-efficient production methods and trade flows.

#### *Marketing Exclusion of Imported and Certain Domestically Produced Meat*

*Summary of Comments:* One commenter expressed concern about the impact that mandatory COOL will have on imported beef, particularly ground beef at retail. The commenter stated that mandatory origin labeling will add significantly to meat production costs at a time of rapidly increasing food costs,

and consumers will have to bear the additional expense resulting from the labeling regime. This commenter was therefore concerned that retailers will be induced to simplify their labeling obligations by excluding imported and certain domestic beef from ground beef in order to minimize the resulting increase in the costs that will be associated with compliance. Another commenter reported that over the last several years, the total number of Mexican cattle crossing into the U.S. has ranged from 820,000 head to 1,200,000 per year, and that those numbers per year represent less than a two-week kill volume on a national basis. The commenter concluded that the loss to both the Mexican rancher and the U.S. producer will be considerable. Another commenter indicated that there is no question that while a vast majority of fresh beef in the retail sector is U.S. beef, it remains a huge question as to the benefit of identifying U.S. beef and adding costs to the producers and to consumers.

One commenter provided a more detailed assessment of potential costs associated with this legislation and its regulations. The commenter noted their belief that COOL is already causing economic losses and threatening the survival of the hog industry in Manitoba, Canada. The commenter pointed out that hog producers in Manitoba have developed an integrated supply chain with family hog farms in the mid-West U.S. by supplying over four million weanlings per year, and over one million finished pigs to packing plants in this area. Finally, the commenter stated that if the changes wrought in the marketplace by this legislation continue, Manitoba producers will lose about \$200 million in finished hog sales to U.S. packers. This commenter reported that it is currently preparing an assessment of the immediate financial impact on its members and provided some examples of recent economic setbacks to producers.

*Agency Response:* The Agency believes that there may be some adjustment costs as industry adapts to the requirements of the rule. Over the longer run, however, the Agency believes that uncertainty will lessen and firms will continue to seek sources of livestock and meat products consistent with efficient production and marketing operations. It is believed that the major cost drivers for the rule occur when livestock or other covered commodities are transferred from one firm to another, when livestock or other 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 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 and, if applicable, method of production 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.

#### *Quantifying Benefits of COOL*

*Summary of Comments:* One commenter expressed disappointment that the Department continues to deny any benefits or consumer desire for COOL. This commenter stated that since the COOL debate began, the number of consumers and organizations supporting the mandatory program has only expanded. The commenter further stated that numerous surveys and polls have indicated that consumers overwhelmingly support COOL and are willing to pay a premium for U.S.-origin labeled products and cited a June 2007 Consumer Reports poll, which found 92 percent of consumers think food should be labeled with country of origin information. Several other commenters noted that all consumers will pay to secure these labeling benefits demanded by a small minority.

*Agency Response:* As stated in the Regulatory Impact Analysis, the Agency concludes after reviewing many studies and comments, the economic benefits from COOL will be small and will accrue mainly to those consumers who desire country of origin information. Several analysts concluded that the main benefit is the welfare effect resulting from removing informational distortions associated with not knowing the origin of products. Numerous comments received during the rulemaking process 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 IRIA—namely, consumer surveys and willingness-to-pay studies, including the most recent studies reviewed for this analysis. The Agency does not believe that these types of studies provide a sufficient basis to estimate the quantitative benefits, if any, of COOL.

#### *Improvements That Reduce COOL Costs*

*Summary of Comments:* One commenter noted that USDA has made the definition of a “processed food item” consistent with the definition used in the interim final rule for fish and shellfish, thereby reducing the number of affected establishments significantly. The commenter further noted that the estimated first-year implementation cost per producer operation is an average of \$258, significantly lower than previously stated. This commenter regarded the implementation cost estimate as generally accurate. Another commenter noted that the use of producer affidavits and reliance on visual inspection should satisfactorily reduce costs of program compliance since import brands are highly visible. Another commenter pointed out that Congressional intent regarding the level of burden this law should impose on industry is clear. In the 2008 Farm Bill, Congress included provisions that expressly restrict USDA's ability to impact current business practices under the mandatory country of origin labeling law.

A final commenter added comments related to USDA's administration of the program. This commenter believes the final rule should make it clear that it is essential that all costs to administer this program must be supported by USDA's appropriated budget, and should not be paid by an assessment of user fees or divert USDA staff time and commitment from other AMS programs for which user fees are required.

*Agency Response:* The Agency is implementing COOL in the most cost-effective way available while still meeting Congressional mandates. The Agency currently receives appropriated funds for the administration of the mandatory COOL program for fish and shellfish. As the budget for fiscal year 2009 has not yet been passed, it is unknown at this time whether the COOL program will receive additional appropriated funds to administer the program for all covered commodities.

#### *COOL as an Economic Barrier to Entry*

*Summary of Comments:* One commenter predicted that COOL will provide an economic barrier to entry for smaller companies that may wish to enter the food supply industry. This commenter noted that consumers who wish to avoid products that do not declare the country of origin are already free to do so. As a result, this commenter predicted that COOL will cost all consumers, but particularly those consumers who do not demand country of origin information.

*Agency Response:* The Agency agrees that COOL will benefit those consumers who are seeking and using country-of-origin information in their purchasing decisions. However, the costs will be absorbed by all consumers shopping at covered retailers. The Agency disagrees that COOL will provide a barrier to entry for smaller companies that may wish to enter the food supply industry. These companies may decide to supply products to retailers or food service companies not covered by COOL. There is little evidence to support conclusions that complying with COOL is more costly for small firms as opposed to larger firms. Indeed, the likelihood is that smaller-scale operations would have more flexibility in implementation of COOL requirements compared to larger operations.

#### *Executive Order 12866—Final Regulatory Impact Analysis*

USDA has examined the economic impact of this 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 annual 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 and OMB Circular A-4 requires that a regulatory impact analysis be performed on all economically significant regulatory actions.

This 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; wild and farm-raised fish and shellfish; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans. Thus, this regulatory impact assessment addresses the economic impacts of all covered commodities as defined by law.

This regulatory impact assessment reflects revisions to the Interim Regulatory Impact Assessment (IRIA)

(73 FR 45106). Revisions to the IRIA were made as a result of changes to the rule relative to the August 1, 2008, interim final rule, and the interim final rule for wild and farm-raised fish and shellfish published October 5, 2004, **Federal Register** (69 FR 89708).

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

#### Summary of the Economic Analysis

The estimated economic benefits associated with this final rule are likely to be small. The estimated first-year incremental costs for growers, producers, processors, wholesalers, and retailers are \$2.6 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 start up and maintenance costs versus ongoing maintenance costs for this final rule. Maintenance costs beyond the first year are expected to be lower than the combined start up and maintenance costs required in the first year.

While USDA recognizes that there appears to be consumer interest in knowing the origin of food based on the comments received, USDA finds little evidence that private firms are unable to provide consumers with country of origin labeling (COOL) consistent with this regulation, if consumers are willing to pay a price premium for it. 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 final rule remains unchanged from the IRIA. 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 changed federal labeling requirements for muscle cuts of beef, pork, lamb, goat, and chicken; ground beef, ground pork, ground lamb, ground goat, and ground chicken; wild and farm-raised fish and shellfish; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans (hereafter, covered commodities).

As described in the IRIA, 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 IRIA and previous requests for comments elicited no evidence of significant barriers to the provision of this information other than private costs to firms and low expected returns. Thus, from the point of view of society, such evidence suggests that market mechanisms would ensure that the optimal level of country of origin information would be provided.

#### Alternative Approaches

The IRIA noted that many aspects of the mandatory COOL provisions contained in the Act are prescriptive and provide little regulatory discretion for this rulemaking. As stated previously, this final rule provides flexibility in implementation to the extent allowed by the statute. 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 IRIA and previous requests for comment 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. As stated in this final rule, the Agency is allowing for producers to

issue affidavits based upon a visual inspection at or near the time of sale that identifies the origin of livestock for a specific transaction. Affidavits based on visual inspection may only be issued by the producer or owner prior to, and including, the sale of the livestock for slaughter (i.e., meat packers are not permitted to use visual inspection for origin verification).

A number of commenters suggested that USDA reduce the recordkeeping burden for the rule. 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 and method of production (wild and/or farm-raised), as applicable, to be either maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA, upon request, within 5 business days of the request. For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and method of production, as applicable, and no additional records documenting origin and method of production information are necessary. Under the August 1, 2008, interim final rule, retailers were required to maintain these records for a period of 1 year.

These changes 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.

As noted in the IRIA, the law stated that COOL applies to the retail sale of covered commodities other than fish and shellfish beginning September 30, 2008. The implementation date for fish and shellfish covered commodities was September 30, 2004.

#### III. Analysis of Benefits and Costs

As in the IRIA, the baseline for this analysis is the present state of the affected industries absent mandatory COOL. USDA recognizes that most affected firms have already begun to implement changes in their operations to accommodate the law and the requirements of the August 1, 2008, interim final rule. Therefore, we will also discuss changes in the final rule analysis due to regulatory changes between the IFR and final rule.

Because the Act contains an effective date of September 30, 2004, for wild and farm-raised fish and shellfish 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 benefits and costs of the rule abstracts away from the staggered dates of implementation and treats all commodities as having the same effective date of implementation. Since a two-pronged approach was used to estimate the costs of this rule, direct fish and shellfish costs have been updated using more recent data and included to estimate the overall impacts of this rule on the United States economy even though labeling of fish and shellfish was implemented in 2004. 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 economic 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 IRIA—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 contingent valuation studies that call into question the appropriateness of using this approach to make determinations about the benefits to consumers of this rule. First, respondents in such studies may 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 or full choices they would face at retail outlets, such as all of the labeling options allowed under this final rule. In practice, this may

distort valuations obtained from such studies, leading to both over and underestimation. 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 few commenters suggested that mandatory COOL would provide food safety benefits to consumers. As discussed in the IRIA, 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 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 economic 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 IRIA and the previous PRIA's. This section provides the revised cost estimates and describes revisions made to the IRIA for this final analysis.

First-year incremental costs for directly affected firms are estimated at \$2.6 billion, an increase of \$0.1 billion over the IRIA due to the inclusion of fish and shellfish. Costs per firm are estimated at \$370 for producers, \$48,219 for intermediaries (such as handlers, importers, processors, and wholesalers), and \$254,685 for retailers.

To assess the overall net impacts of the higher costs of production resulting from the rule, a computational general equilibrium (CGE) model of the model of the United States economy developed by USDA's Economic Research Service (ERS) (Ref 4) was used. The model was adjusted by imposing the estimated implementation costs on the directly impacted segments of the economy. That is, the costs of production for directly affected firms increase due to the costs of implementing the COOL program. 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 10-year period 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 is estimated to be lower, and prices are estimated to be higher, compared to the absence of this rulemaking. In addition, United States exports are estimated to decrease for all covered commodities. 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 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 “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 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 and transferred along the entire supply chain.

*Number of firms and number of establishments affected:* This rule is estimated to directly or indirectly affect approximately 1,333,000 establishments owned by approximately 1,299,000 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 Lambs .....	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 & Product Wholesale .....	2,509	2,706
<b>Chicken</b>		
Chicken Producer and Processor .....	38	168
Chicken Wholesaler/Distributor .....	510	564
<b>Fish</b>		
Farm-Raised Fish and Shellfish .....	3,752	3,752
Fishing .....	71,128	71,142
Fresh & Frozen Seafood Processing .....	516	590
Fish & Seafood Wholesale .....	2,254	2,330
<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
Peanut, Pecan, & Macadamia Wholesalers .....	5	5
General line grocery wholesalers .....	3,037	3,436
Retailers .....	4,040	36,392
<b>Totals:</b>		
Producers .....	1,271,906	1,272,050
Handlers, Processors, & Wholesalers .....	23,444	24,963
Retailers .....	4,040	36,392
<b>Grand Total</b> .....	<b>1,299,390</b>	<b>1,333,405</b>

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 likely overstates the number of affected firms and establishments, it is believed that 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 interim final

rule for beef, pork, lamb, chicken, goat meat, perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts 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 and, as applicable, method of production information through other point-of-sale

materials. This may require additional retail labor and personnel training. Modification of existing recordkeeping systems will likely 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), it is assumed 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 and, as applicable, method of production 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 and, as applicable, method of production 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 and, as applicable, method of production (wild and/or farm-raised) of the products that they sell. To do so, their suppliers will need to provide documentation regarding the country of origin and, as applicable, method of production of the products that they sell. 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 and/or methods of production, there may also be a need to separate shifts for processing products from different origins, or to split processing within shifts, or to alter labels to correctly identify the country or countries of origin and method or methods of production, as applicable. However, in the case of meat covered commodities, there is flexibility in labeling covered commodities of multiple origins under this final rule. In the case where products of different origins are segregated, our analysis indicates costs are likely to increase. The rule requires that records be maintained to ensure that accurate country of origin information is retained throughout the process and available to permit compliance and enforcement reviews.

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, although such costs would likely be mitigated in those cases where firms are only using covered commodities which are multiple-origin labeled. Procurement costs also may be unaffected in this case, if the processor

is able to continue sourcing products from the same suppliers. Alternatively it is possible that a processor currently sourcing products from multiple countries may choose to limit its source to fewer countries. In this case, such cost avoidance may be partially offset by additional procurement costs to source supplies from a narrower country of origin. Additional procurement costs of a narrower supply chain 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 and fish and shellfish harvesters need to maintain records to establish country of origin and, as applicable, method of production information for the products they produce and sell. Country of origin and, as applicable, method of production 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. For all covered commodities, producer affidavits shall be considered acceptable records on which suppliers may rely to initiate country of origin and, as applicable, method of production claims. 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).

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

	Beef	Pork	Lamb and goat	Chicken	Fish	Fruit, vegetable, and ginseng	Peanuts, pecans, and macadamia nuts
	Million head			Million pounds			
Producer .....	33.9	104.8	2.9	45,012.9	7,808.0	120,388.5	212.7
	Million pounds						
Intermediary .....	24,890	6,721	354	27,710	3,024	99,449	11
Retailer .....	8,193	2,330	133	17,645	1,104	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, 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.

For fish and chicken producers, production is measured by round weight (live weight) pounds, except mollusks, which excludes the weight of the shell. Wild caught fish and shellfish production is measured by United States domestic landings for fresh and frozen human food. It is assumed that fish harvesters generally know whether their catch is destined for fresh and frozen markets, canning, or industrial use. Fish production also includes farm-raised fish. Fish production has been updated with 2006 data from the regulatory analysis contained in the interim final rule for fish and shellfish.

For fruits and vegetables, it is assumed 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.

As previously discussed, only green and raw peanuts, macadamia nuts, and pecans sold at retail are subject to the requirements of this rule. 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. It is assumed that no more than 5 percent of the sales of peanuts at subject retailers are sold as green or raw peanuts. Macadamia nuts and pecans have been included with peanuts.

It is assumed 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, it is assumed that these intermediaries will seek to keep their marketing options open for possible sales to subject retailers.

Fish production at the intermediary level is increased by 505 million pounds from the RIA estimate of 2004 in the interim final rule for fish and shellfish due to more recently available data.

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. 5). 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, it is believed that Wisconsin represents most of the ginseng production and 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. 6]. 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 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.

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	Fish	Fruit, vegetable, and ginseng	Peanuts, pecans, & macadamia nuts	Total
Producer .....	305	105	10	0	20	30	0	470
Intermediary .....	373	101	5	139	15	497	0	1,130
Retailer .....	574	93	5	44	77	235	0	1,029
Total .....	1,252	299	21	183	112	763	0	2,629

Assumptions and procedures underlying the cost estimates are described fully in the discussion of the estimates presented in the PRIA and the IRIA.

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.

It is expected that intermediaries will face increased costs associated with tracking cattle and the covered beef commodities produced from these animals and then 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 discussed, under this final rule, there is greater flexibility for labeling muscle cut covered commodities. 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. 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.

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.

Total costs for affected entities in the beef sector are thus estimated at \$1,252 million.

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.

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.

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. Total costs for the pork sector are estimated at \$299 million.

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.

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.

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.

Total costs for producers, intermediaries, and retailers in the lamb and goat industries are estimated costs at \$21 million.

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 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, recordkeeping, 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 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 estimated at \$44 million.

Total estimated costs for chicken producers, intermediaries, and retailers are \$183 million.

The estimated costs to fish and seafood producers are \$0.0025 per pound. Total costs for fish and seafood producers are thus estimated at \$20 million, \$1 million more than the RIA in the interim final rule for fish and shellfish.

Costs for intermediaries are estimated at \$0.005 per pound in the fish and seafood sector. Processors need to collect country of origin and method of production information from producers, maintain this information, and supply this information to other intermediaries or directly to retailers. There are also labeling costs associated with providing country of origin and method of production information on consumer-ready packs of frozen and fresh fish that are labeled by processors. Total costs for fish and seafood intermediaries are thus estimated at \$15 million, an increase of \$2 million from the RIA in the interim final rule for fish and shellfish. The increase is attributable to using the most recently available data, which reflects a higher demand for fresh fish and shellfish.

Retailer costs are estimated at \$0.07 per pound for fish and seafood. This estimate results in total costs of \$77 million for retailers of fish and seafood, an increase of \$20 million from the RIA in the interim final rule for fish and shellfish.

Total costs for fish and seafood are estimated at \$112 million, an increase of \$23 million from the RIA in the interim final rule for fish and shellfish.

Although fruit, vegetable, and ginseng producers maintain the types of records that will be required to substantiate 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.

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.

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. 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 retailers of fruits, vegetables, and ginseng are estimated at \$235 million.

Total costs for producers, intermediaries, and retailers of fruit, vegetable, and ginseng products are estimated at \$763 million.

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 incremental costs are estimated for this rule at \$470 million for producers, \$1,130 million for intermediaries and \$1,029 million for retailers for the first year. Total incremental costs for all supply chain participants are estimated at \$2,629 million for the first year, an increase of \$112 million from the IRIA due to the inclusion of and updating of data for the fish and shellfish industries.

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 fishing operations and 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 .....	\$370	\$369
Intermediary .....	48,219	45,285
Retailer .....	254,685	28,273

Average estimated implementation costs per producer are relatively small at \$370 and slightly less than from the IRIA due to the inclusion of fish and shellfish producers. The slight difference between the cost per producers for firms and establishments is due to the inclusion of fish and shellfish and that there are more fishing establishments than firms. Estimated costs for intermediaries are substantially larger, averaging \$48,219 per firm and \$45,285 per establishment. The average cost per firm is \$5,729 less than the IRIA estimated cost, with the lower cost attributable to the inclusion of fish and shellfish. Similarly, the average cost per intermediary establishment is \$5,313 lower than IRIA estimate due to the inclusion of fish and shellfish. At an average of \$254,685 per firm, retailers have the highest average estimated costs

per firm. This is \$19,134 higher than the IRIA estimate. The higher estimated cost per retailer is attributable to the inclusion of fish and shellfish. Retailers' average estimated costs per establishment are \$28,273. This amount is \$2,124 higher than the IRIA 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



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

Producer	Average
Beef .....	\$314
Lamb & Goats .....	128
Pork .....	1,599
Chicken .....	0
Fish .....	261
Fruits, Vegetables, & Ginseng .....	376
Peanuts, Pecans, & Macadamia Nuts .....	258
All .....	369

operations, estimated costs per hog operation are large relative to other producer operations. These costs are unchanged from the IRIA estimates except for fish which used more up-to-date information.

It is believed that the major cost drivers for the rule occur when livestock or other covered commodities are transferred from one firm to another, when livestock or other covered commodities are segregated in the production or marketing process when firms are not using a multiple-origin label, 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 and, if applicable, method of production, 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 \$2.6 billion.

In the IRIA, 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 final 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, 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.

*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 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 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 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 operation 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 may 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 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 to account for the cross-commodity effects between covered commodities. 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 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 impacts on the overall United States economy.

The ERS CGE model traces the impacts from an economic “shock,” in this case an 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 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 cost to the United States economy after all transfers and adjustments in consumption and production patterns have occurred.

As noted above, the 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 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 commodity’s 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.

TABLE 6—ESTIMATED INCREASES IN OPERATING COSTS BY SUPPLY CHAIN SEGMENT AND INDUSTRY

		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 covered 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.

As discussed above, consumption and production patterns will change as the incremental increases in operating costs 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 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 United States 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. The estimated increases in operating costs reflect anticipated adjustments by industry as a result of the rule and provide the basis for the CGE analysis. However, the analysis does not reflect dynamic adjustments that industry will undertake to comply with the requirements of the rule, such as the flexibilities afforded by the use of multiple-origin labels.

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

Commodity	Price	Production	Exports (volume)	Imports (volume)
	Percent change from base year			
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	-0.57	-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 the model assumes United States domestic suppliers of these products 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. 10), 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 beef, chicken, and pork mirrors the decline in the production of beef, broilers, and hogs.

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. Thous .....	191,523	-383
Cattle .....	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

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

Indicator	Units	Base	Change from base
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
U.S. Exports (volume):			
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
U.S. Imports (volume):			
Fruits & Vegetables .....	Mil. Lbs. Thous .....	37,573	15
Beef .....	Hd .....	2,502	-58
Chicken .....	Mil. Hd. Thous .....	0	0
Pork .....	Hd .....	5,741	-49
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 declines 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 covered 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 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, it is examined how much of a shift or increase in demand for commodities of United States origin would need 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 suggests that demand at covered retailers actually would have 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 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 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 possible 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 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 percent (Ref. 11). If applied to the next 10 years this implies an economy approximately 36 percent 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, Brazil, South America (including 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.

#### *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 final regulatory flexibility analysis of the rule's likely economic impact on small businesses pursuant to section 604 of the Regulatory Flexibility Act. Section 604 of the RFA requires the Agency to provide a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis. The Comments and Responses section includes the comments received on the interim final 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 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, goat; ground beef, ground lamb, ground pork, ground goat, and ground chicken; farm-raised fish and shellfish; wild fish and shellfish; chicken; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans. The implementation date for mandatory COOL for the fish and shellfish covered commodities was September 30, 2004. The implementation date for the other covered commodities was September 30, 2008.

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 and, if applicable, method of production (wild and/or farm-raised) 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. A complete discussion of the information collection and recordkeeping requirements and associated burdens appears in the Paperwork Reduction Act section.

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, fishing operations, processors, wholesalers, and retailers. Section 604 of the RFA requires the Agency to provide an estimate of the number of small entities to which the rule will apply. 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 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. By utilizing an existing regulatory definition for a retailer, Congress provided a simple and straightforward approach to determine which retailers are subject to the COOL program. In utilizing this definition, 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 and, if applicable, method of production 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 1,333,000 establishments owned by approximately 1,299,000 firms will be either directly or indirectly affected by this rule. The only change from the Interim Regulatory Impact Analysis contained in the August 1, 2008, interim final rule is the inclusion of affected firms and establishments in the fish and shellfish sector in this final rule. These changes and the use of more up-to-date information resulted in the number of establishments and firms increasing from the IRIA.

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 \$2,629 million as noted in Table 3. The increase in the direct incremental cost in the rule as compared to the IRIA is mainly the result of including fish and shellfish in this final 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 sales and fishing operations with less than \$3.5 million in annual sales. 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. 8). Therefore, the number of these stores provides an indicator of the number of entities *potentially* affected by this rule. The 2002 Economic Census (Ref. 9) shows there were 42,318 food stores, warehouse clubs, 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 that described in section 1(b) of the Perishable Agricultural Commodities Act of 1930 (PACA). Thus, under this 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. 12). 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 store, 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 \$1,029 million. Costs are estimated at \$254,685 per retail firm and \$28,273 per retail establishment.

Retailers will face recordkeeping costs, costs associated with supplying country of origin and, if applicable, method of production 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 and, if applicable, method of production 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 United States Businesses (Ref. 13) 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.

For fish and seafood wholesalers there are a total of 2,254 firms. Of these, 2,199 firms have less than 100 employees. Therefore, approximately 98 percent of the fish and seafood wholesalers could be considered as small firms.

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 United States 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 \$1,130 million. Costs are estimated at \$48,219 per intermediary firm and \$45,285 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 and, if applicable, method of production information to retailers, possibly costs associated with segmenting products by country of origin and, if applicable, method of production and possibly 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 put in place to implement mandatory COOL. Instead, wholesalers will be given flexibility to 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 and, if applicable, method of production 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 United States Businesses (Ref. 13) 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 fresh and frozen seafood processing there is a total of 516 firms. Of these, 492 have less than 500 employees and thus, 95 percent are considered to be small firms.

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 and, if applicable, method of production information to retailers, possibly costs associated with segmenting products by country of origin and, if applicable, method of production and possibly additional handling costs. Some of the comments received on the interim final 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 put in place to implement mandatory COOL. Instead, manufacturers will be given flexibility to 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 fish, 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 create and maintain country of origin and, if applicable, method of production 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 United States Census of Agriculture (Ref. 7) 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 United States 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.

Based on 2005 Census of Aquaculture data (Ref. 14), it is estimated that at least 95 percent of fish and shellfish farming operations are small. Similar information on fishing operations is not

known to exist. However, it is assumed that the majority of these producers would be considered small businesses.

At the production level, agricultural producers will need to maintain records to establish country of origin and, if applicable, method of production information 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 establishing and maintaining a recordkeeping system for the country of origin and, if applicable, method of production information, animal or product identification, and labor and training. Based on our knowledge of the affected industries as well as comments received on the interim final rules, 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 and, if applicable, method of production 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 \$470 million, or an estimated \$370 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 and, if applicable, method of production 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:* Section 604 of the RFA requires the Agency to describe the steps taken to minimize the significant economic impact on small entities including a discussion of 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 and, if applicable, method of production 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 and, if applicable, method of production 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 and, if applicable, method of production claims. In other words, no producer, processor, wholesaler, or other supplier is required to make and substantiate a country of origin and, if applicable, method of production 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 and, if applicable, method of production information nor to make country of origin and, if applicable, method of production 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 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 adopt 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 and, if applicable, method of production 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 and, as applicable, method of production 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 and method of production 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.

*Paperwork Reduction Act*

Pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C 3501–3520) the information collection provisions contained in this rule have been approved by OMB and have been assigned OMB Control Number 0581–0250. This revision reflects a 155,464 increase in the number of annual responses and an 861,282 increase in the number of annual burden hours from the August 1, 2008, interim final rule due to the inclusion of fish and shellfish data. The Comments and Responses section includes the relevant comments received 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:* Mandatory Country of Origin Labeling of Covered Commodities.

*OMB Number:* 0581–0250.

*Type of Request:* Revision of a previously approved collection.

*Expiration Date:* November 30, 2011.

*Abstract:* The COOL provision in the 2002 and 2008 Farm Bills requires that specified retailers inform consumers as to the country of origin and, if applicable, method of production (wild and/or farm-raised) of covered commodities. Covered commodities included in this rulemaking are: Muscle cuts of beef, lamb, goat, pork, and chicken; ground beef, ground lamb, ground pork, ground goat, and ground chicken; wild and farm-raised fish and shellfish; perishable agricultural commodities; ginseng; peanuts; macadamia nuts; and pecans. Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available 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 growers, distributors, handlers, packers, and processors), whether directly or indirectly, must make country of origin and, if applicable, method of production 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 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 records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. In the case of all covered commodities, producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity 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 United States Customs and Border Protection 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.

*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 and, if applicable, method of production 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 1,333,000 establishments owned by approximately 1,299,000 firms are estimated to be either directly or indirectly affected by this rule. The only changes from the IRIA are increases in the numbers of affected firms and establishments due to including and updating fish and shellfish information.

In general, the supply chain for each of the covered commodities includes agricultural producers or fish harvesters, 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	712,745	9,146	1,371,381	2,084,126
Chicken Producer and Processor .....	38	2,961	168	25,190	28,151
Farm-Raised Fish & Shellfish .....	3,752	292,386	3,752	562,575	854,961
Fishing .....	71,128	5,542,863	71,142	3,555,677	9,098,540
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	3,582,387	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

TABLE 9—COSTS ASSOCIATED WITH PAPERWORK BURDEN—Continued

Type	Firms	Initial costs	Establishments	Maintenance costs	Total costs
Chicken Processor and Wholesaler .....	510	667,590	564	545,941	1,213,531
Fresh & Frozen Seafood Processing .....	516	675,444	590	571,108	1,246,552
Fish & Seafood Wholesale .....	2,254	2,950,486	2,330	2,255,393	5,205,879
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
Totals					
Producers .....	1,271,906	99,117,097	1,262,050	175,237,476	274,354,573
Handlers, Processors, & Wholesalers .....	23,444	30,688,196	24,963	83,145,610	113,833,806
Retailers .....	4,040	5,288,360	36,392	247,264,534	252,552,894
Grand Total .....	1,299,390	135,093,653	1,333,405	505,647,620	640,741,274

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.

With respect to initial recordkeeping costs, it is believed that most producers currently maintain many of the types of records that would be needed to substantiate country of origin and, if applicable, method of production claims. However, producers do not typically record or pass along country of origin and, if applicable, method of production information to subsequent purchasers. Therefore, producers will incur some additional incremental costs to record, maintain, and transfer country of origin and, if applicable, method of production information to substantiate required claims made at retail. Because much of the necessary recordkeeping has already been developed during typical farm, ranch, and fishing operations, it is estimated that the incremental costs for producers to supplement existing records with country of origin and, if applicable, method of production 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 and, if applicable, method of production 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 establish 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 establishing 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, 2006 wage rates and benefits published by the Bureau of Labor statistics from the National Compensation Survey are used.

For producers, it is assumed that the added work needed to initially adapt an existing recordkeeping system for country of origin and, if applicable, method of production 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 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 \$135.1 million to modify existing recordkeeping systems in order to substantiate country of origin and, if applicable, method of production 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 and, if applicable, methods of production 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 many of the types of necessary records in their existing systems. Thus, it is assumed that country of origin and, if applicable, method of production information will require only modification of existing recordkeeping systems rather than development of entirely 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 and, if applicable, method of production 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 \$31 million, and initial recordkeeping costs at retail will be approximately \$5 million. The recordkeeping cost to producers increases due to the inclusion of fish and shellfish.

The total initial recordkeeping costs for all firms are thus estimated at approximately \$135 million. This increase in the recordkeeping cost as compared to the recordkeeping costs in the interim final rule is due to the inclusion of fish and shellfish.

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 and, if applicable, method of production claims is expected to be relatively small.

For wild fish harvesters, fruit, vegetable, and ginseng producers, and peanut, macadamia nut, and pecan producers, country of origin and, if applicable, method of production generally is established at the time that the product is harvested, and thus there is no need to track country of origin and, if applicable, method of production 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 and, if applicable, method of production information.

Compared to wild fish harvesters, chicken, fruit, vegetable, ginseng, peanut, macadamia nut, and pecan producers, it is expected that fish farmers and livestock producers will incur higher costs to maintain country of origin and, if applicable, method of production information. Wild fish, chicken, fruits, vegetables, ginseng, peanuts, and macadamia nuts are generally harvested once and then shipped by the producer to the first handler. In contrast, farm-raised fish and 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. Fish and livestock may be acquired from other countries by United States producers, which may complicate the task of tracking country of origin and, if applicable, method of production 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 fish farmers and 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 and, if applicable, method of production 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, this results in an hourly rate of \$12.50 for livestock workers and \$11.87 for other crops workers. Wage rates for fish workers were unavailable, so the average wage rate for livestock workers is used. Assuming 12 hours of labor per year for livestock and farmed fish operations and 4 hours per year for all other operations, the estimated total annual maintenance costs to producers is \$175 million which is higher than the initial maintenance costs in the interim final rule. The increase in the estimated maintenance cost is due to the inclusion of fish and shellfish in this final rule.

It is expected that intermediaries such as handlers, processors, and wholesalers will face higher costs per enterprise to maintain country of origin and, if applicable, method of production 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 and, if applicable, method of production recordkeeping is estimated to be 52 hours per year per establishment. For this part of the supply chain, the recordkeeping activities are ongoing 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, each of which must maintain its country of origin identity. In addition, businesses that produce ground beef, lamb, goat, and pork products 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 and, if applicable, method of production 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 benefit 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 \$83 million.

Retailers will need to supply country of origin and, if applicable, method of production 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 and, if applicable, method of production 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 benefit costs for a total of \$18.62 per hour) results in total estimated annual maintenance costs to retailers of \$247 million.

The total maintenance recordkeeping costs for all enterprises are thus estimated at approximately \$506 million. The increase in the total maintenance cost over the maintenance cost estimate in the interim final rule is due to the inclusion of fish and shellfish in this final rule.

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 \$274 million; for handlers, processors, and wholesalers at approximately \$114 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 \$641 million for the first year, with subsequent maintenance costs of \$506 million per year.

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

*Estimated Number of Firms*

*Recordkeepers:* 1,299,390.

*Estimated Total Annual Burden:*

5,884,661 hours.

*Annual Reporting and Recordkeeping*

*Burden (Maintenance):* Public reporting burden for recordkeeping storage and maintenance is estimated to average 23.8 hours per year per individual recordkeeper.

*Estimated Number of Establishments*

*Recordkeepers:* 1,333,405.

*Estimated Total Annual Burden:*

31,790,642 hours.

To the extent possible, the Agency complies with the e-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. This information collection has no forms and is only for recordkeeping purposes. Therefore, the provisions of an electronic submission alternative are not required.

*References*

1. Dinopoulos, Elias, Grigorios Livanis, and Carol West. "How Cool is C.O.O.L.?" Working Paper WPTC 05-11, University of Florida, International Agricultural Trade and Policy Center, 2005.
2. Plastina, Alejandro and Konstantinos Giannakas. "Market and Welfare Effects of Mandatory Country-of-Origin Labeling in the US Specialty Crops Sector." Selected Paper American Agricultural Economics Association Annual Meeting, Portland, Oregon, July 2007.
3. Mabiso, Athur, James Sterns, Lisa House, and Allen Wysocki. "Estimating Consumers' Willingness-To-Pay for Country-Of-Origin Labels in Fresh Apples and Tomatoes: A Double-Hurdle Probit Analysis of American Data Using Factor Scores." American Agricultural Economics Association Annual Meeting, Providence, Rhode Island, July 2005.
4. Krissoff, Barry, Fred Kuchler, Kenneth Nelson, Janet Perry, and Agapi Somwaru. "Country of Origin Labeling: Theory and Observation. USDA, ERS, WRS-04-02, January 2004.
5. NASS, USDA, Wisconsin Department of Agriculture. Wisconsin 2007 Agricultural Statistics. [http://www.nass.usda.gov/Statistics\\_by\\_State/Wisconsin/](http://www.nass.usda.gov/Statistics_by_State/Wisconsin/)
6. NASS, USDA, Hawaii Department of Agriculture. Hawaii 2007 Agricultural Statistics. [http://www.nass.usda.gov/hi/stats/t\\_of\\_c.htm](http://www.nass.usda.gov/hi/stats/t_of_c.htm)
7. NASS, USDA. 2002 Census of Agriculture.
8. ERS, USDA. Food CPI, Prices and Expenditures: Sales of Food at Home by Type of Outlet. <http://www.ers.usda.gov/Briefing/CPI/FoodAndExpenditures/Data/table16.htm>
9. U.S. Census Bureau. 2002 Economic Census. Retail Trade Subject Series. Establishment and Firm Size. EC97R44S-SZ. Issued September 2004.
10. Office of the Chief Economist, USDA. USDA Agricultural Baseline Projections

to 2016, Staff Report WAOB-2007-1. February 2007.

11. Bureau of Economic Analysis. <http://www.bea.gov/national/index.htm#gdp>.
12. AMS, USDA. Perishable Agricultural Commodities Act database.
13. U.S. Census Bureau. 2004 Statistics of U.S. Businesses.
14. NASS, USDA. 2005 Census of Aquaculture.
15. Bureau of Labor Statistics, Department of Labor, National Compensation Survey, May 2006, Employer Cost for Employee Compensation.
16. Food and Drug Administration. "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," proposed rule. May 9, 2003.
17. RTI, International 2000. FDA Labeling Cost Model: Final Report. Revised April 2002.
18. NASS, USDA. Farm Labor, August 17, 2007.

*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 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 Executive Order 13132, AMS has consulted with

the States that have country of origin labeling programs.

The effective date of this regulation is March 16, 2009. In the August 1, 2008, interim final rule for the remaining covered commodities, the Agency indicated that during the six month period following the effective date of that regulation, AMS would conduct an industry education and outreach program concerning the provisions and requirements of that rule. AMS will continue this period of informed compliance for this regulation through March 2009.

#### List of Subjects

##### 7 CFR Part 60

Agricultural commodities, Fish, Food labeling, Reporting and recordkeeping requirements.

##### 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 as follows:

■ 1. Part 60 is revised to read as follows:

## PART 60—COUNTRY OF ORIGIN LABELING FOR FISH AND SHELLFISH

### Subpart A—General Provisions

#### Definitions

Sec.	
60.101	Act.
60.102	AMS.
60.103	Commingled covered commodities.
60.104	Consumer package.
60.105	Covered commodity.
60.106	Farm-raised fish.
60.107	Food service establishment.
60.108–60.110	[Reserved]
60.111	Hatched.
60.112	Ingredient.
60.113	[Reserved]
60.114	Legibly.
60.115	[Reserved]
60.116	Person.
60.117	[Reserved]
60.118	Pre-labeled.
60.119	Processed food item.
60.120	[Reserved]
60.121	[Reserved]
60.122	Production step.
60.123	Raised.
60.124	Retailer.
60.125	Secretary.
60.126	[Reserved]
60.127	United States.
60.128	United States country of origin.
60.129	USDA.
60.130	U.S. flagged vessel.
60.131	Vessel flag.
60.132	Waters of the United States.
60.133	Wild fish and shellfish.

#### Country of Origin Notification

60.200 Country of origin notification.  
60.300 Labeling.

#### Recordkeeping

60.400 Recordkeeping requirements. Appendix A to Subpart A—Exclusive Economic Zone and Maritime Boundaries; Notice of Limits

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

### Subpart A—General Provisions

#### Definitions

##### § 60.101 Act.

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

##### § 60.102 AMS.

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

##### § 60.103 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.

##### § 60.104 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.

##### § 60.105 Covered commodity.

(a) *Covered commodity* means:

- (1) [Reserved]
- (2) [Reserved]
- (3) Farm-raised fish and shellfish (including fillets, steaks, nuggets, and any other flesh);
- (4) Wild fish and shellfish (including fillets, steaks, nuggets, and any other flesh);
- (5) [Reserved]
- (6) [Reserved]

(b) Covered commodities are excluded from this part if the commodity is an ingredient in a processed food item as defined in § 60.119.

##### § 60.106 Farm-raised fish.

*Farm-raised fish* means fish or shellfish that have been harvested in controlled environments, including ocean-ranched (e.g., penned) fish and including shellfish harvested from leased beds that have been subjected to production enhancements such as providing protection from predators, the addition of artificial structures, or providing nutrients; and fillets, steaks, nuggets, and any other flesh from a farm-raised fish or shellfish.

**§ 60.107 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.

**§ 60.108–60.110 [Reserved]****§ 60.111 Hatched.**

*Hatched* means emerged from the egg.

**§ 60.112 Ingredient.**

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

**§ 60.113 [Reserved]****§ 60.114 Legible.**

*Legible* means text that can be easily read.

**§ 60.115 [Reserved]****§ 60.116 Person.**

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

**§ 60.117 [Reserved]****§ 60.118 Pre-labeled.**

*Pre-labeled* means a covered commodity that has the commodity's country of origin and method of production and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

**§ 60.119 Processed food item.**

*Processed food item* means a retail item derived from fish or shellfish 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., breeding, 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, compressing into blocks and cutting into portions). Examples of items excluded include fish sticks, surimi, mussels in tomato sauce, seafood medley, coconut shrimp, soups, stews, and chowders, sauces, pates, smoked salmon, marinated fish fillets, canned tuna, canned sardines, canned salmon, crab salad, shrimp cocktail, gefilte fish, sushi, and breaded shrimp.

**§ 60.120 [Reserved]****§ 60.121 [Reserved]****§ 60.122 Production step.**

*Production step* means in the case of:

- (a) [Reserved]
- (b) Farm-raised Fish and Shellfish: Hatched, raised, harvested, and processed.
- (c) Wild Fish and Shellfish: Harvested and processed.

**§ 60.123 Raised.**

*Raised* means in the case of:

- (a) [Reserved]
- (b) Farm-raised fish and shellfish as it relates to the production steps defined in § 60.122: The period of time from hatched to harvested.

**§ 60.124 Retailer.**

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

**§ 60.125 Secretary.**

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

**§ 60.126 [Reserved]****§ 60.127 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, and the waters of the United States as defined in § 60.132.

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

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

- (a) [Reserved]
- (b) [Reserved]
- (c) Farm-raised Fish and Shellfish: From fish or shellfish hatched, raised, harvested, and processed in the United States, and that has not undergone a

substantial transformation (as established by U.S. Customs and Border Protection) outside of the United States.

(d) Wild-fish and Shellfish: From fish or shellfish harvested in the waters of the United States or by a U.S. flagged vessel and processed in the United States or aboard a U.S. flagged vessel, and that has not undergone a substantial transformation (as established by U.S. Customs and Border Protection) outside of the United States.

(e) [Reserved]

(f) [Reserved]

**§ 60.129 USDA.**

*USDA* means the United States Department of Agriculture.

**§ 60.130 U.S. flagged vessel.**

*U.S. flagged vessel* means:

- (a) Any vessel documented under chapter 121 of title 46, United States Code; or
- (b) Any vessel numbered in accordance with chapter 123 of title 46, United States Code.

**§ 60.131 Vessel flag.**

*Vessel flag* means the country of registry for a vessel, ship, or boat.

**§ 60.132 Waters of the United States.**

*Waters of the United States* means those fresh and ocean waters contained within the outer limit of the Exclusive Economic Zone (EEZ) of the United States as described by the Department of State Public Notice 2237 published in the **Federal Register** volume 60, No. 163, August 23, 1995, pages 43825–43829. The Department of State notice is republished in Appendix A to this subpart.

**§ 60.133 Wild fish and shellfish.**

*Wild fish and shellfish* means naturally-born or hatchery-originated fish or shellfish released in the wild, and caught, taken, or harvested from non-controlled waters or beds; and fillets, steaks, nuggets, and any other flesh from a wild fish or shellfish.

**Country of Origin Notification****§ 60.200 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, display case, carton, crate, barrel, cluster, or consumer package must contain country of origin and method of production information (wild and/or farm-raised) as set forth in this regulation.

(b) *Exemptions*. Food service establishments as defined in § 60.107

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 § 60.119.

(d) *Designation of Method of Production (Wild and/or Farm-Raised).* Fish and shellfish covered commodities shall also be labeled to indicate whether they are wild and/or farm-raised as those terms are defined in this regulation.

(e) *Labeling Covered Commodities of United States Origin.* A covered commodity may only bear the declaration of "Product of the U.S." at retail if it meets the definition of United States Country of Origin as defined in § 60.128.

(f) *Labeling Imported Products That Have Not Undergone Substantial Transformation in the United States.* An imported covered commodity shall retain its origin as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale, provided that it has not undergone a substantial transformation (as established by U.S. Customs and Border Protection) in the United States.

(g) *Labeling Imported Products That Have Subsequently Been Substantially Transformed in the United States.*

(1) [Reserved]

(2) *Wild and Farm-Raised Fish and Shellfish:* If a covered commodity was imported from country X and subsequently substantially transformed (as established by U.S. Customs and Border Protection) in the United States or aboard a U.S. flagged vessel, such product shall be labeled at retail as "From country X, processed in the United States." Alternatively, the product may be labeled as "Product of country X and the United States".

(h) *Labeling Commingled Covered Commodities.* (1) For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with other imported covered commodities that have not been substantially transformed in the United States, and/or covered commodities of U.S. origin and/or covered commodities as described in § 60.200(g), the declaration shall indicate the countries of origin for covered commodities in accordance with existing Federal legal requirements.

(2) For imported covered commodities that have subsequently undergone substantial transformation in the United States that are commingled with other imported covered commodities that have subsequently undergone

substantial transformation in the United States (either prior to or following substantial transformation in the United States) and/or U.S. origin covered commodities, the declaration shall indicate the countries of origin contained therein or that may be contained therein.

(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 and method of production (wild and/or farm-raised) designation either on the sales vehicle or at the time the product is delivered to the consumer.

#### § 60.300 Labeling.

(a) Country of origin declarations and method of production (wild and/or farm-raised) designations can either be in the form of a placard, sign, label, sticker, band, twist tie, pin tag, or other format that provides country of origin and method of production information. The country of origin declaration and method of production (wild and/or farm-raised) designation may be combined or made separately. Except as provided in § 60.200(g) and 60.200(h) of this regulation, the declaration of the country(ies) of origin of a product shall be listed according to applicable Federal legal requirements. Country of origin declarations may be in the form of a check box provided it is in conformance with other Federal legal requirements. Various forms of the production designation are acceptable, including "wild caught", "wild", "farm-raised", "farmed", or a combination of these terms for blended products that contain both wild and farm-raised fish or shellfish, provided it can be readily understood by the consumer and is in conformance with other Federal labeling laws. Designations such as "ocean caught", "caught at sea", "line caught", "cultivated", or "cultured" are not acceptable substitutes. Alternatively, method of production (wild and/or farm-raised) designations may be in the form of a check box.

(b) The declaration of the country(ies) of origin and method(s) of production (wild and/or farm-raised) (e.g., placard, sign, label, sticker, band, twist tie, pin tag, or other display) must be 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 the country(ies) of origin and the method(s) of production (wild and/or farm-raised)

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 and/or more than one method of production (wild and farm-raised) provided all possible origins and/or methods of production are listed.

(e) In general, country 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. or USA" for the "United States" are acceptable. The adjectival form of the name of a country may be used as proper notification of the country(ies) 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) State or regional label designations are not acceptable in lieu of country of origin labeling.

#### Recordkeeping

##### § 60.400 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 and method of production (wild and/or farm-raised). 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 and method(s) of production (wild and/or farm-raised), 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 that it identifies the product and its country(ies) of origin and method(s) of production. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin and method(s) of production (wild and/or farm-raised) claim must possess records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. Producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction.

(2) Any intermediary supplier handling a covered commodity that is found to be designated incorrectly as to the country of origin and/or method of production (wild and/or farm-raised) shall not be held liable for a violation of the Act by reason of the conduct of another if the intermediary supplier relied on the designation provided by the initiating supplier or other intermediary supplier, unless the intermediary supplier willfully disregarded information establishing that the country of origin and/or method of production (wild and/or farm-raised) declaration was false.

(3) 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 harvesters, producers, distributors, handlers, 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.

(4) For an imported covered commodity (as defined in § 60.200(f)), the importer of record as determined by U.S. Customs and Border Protection, 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 and method of production (wild and/or farm-raised) 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) In providing the country of origin and method of production (wild and/or farm-raised) notification for a covered commodity, in general, retailers are to convey the origin and method of production information provided to them by their suppliers. Only if the

retailer physically commingles a covered commodity of different origins and/or methods of production in preparation for retail sale, whether in a consumer-ready package or in a bulk display (and not discretely packaged) (i.e., full service fish case), can the retailer initiate a multiple country of origin and/or method of production designation that reflects the actual countries of origin and method of production for the resulting covered commodity.

(2) Records and other documentary evidence relied upon at the point of sale to establish a covered commodity's country(ies) of origin and designation of wild and/or farm-raised must either be maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA in accordance with § 60.400(a)(2). For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and method(s) of production (wild and/or farm-raised) and no additional records documenting origin and method of production information are necessary.

(3) Records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled, the country of origin information and the method(s) of production (wild and/or farm-raised) must be maintained for a period of 1 year from the date the declaration is made at retail.

(4) Any retailer handling a covered commodity that is found to be designated incorrectly as to the country of origin and/or the method of production (wild and/or farm-raised) shall not be held liable for a violation of the Act by reason of the conduct of another if the retailer relied on the designation provided by the supplier, unless the retailer willfully disregarded information establishing that the country of origin and/or method of production declaration was false.

#### Subpart B—[Reserved]

■ 2. Part 65 is revised to read as follows:

### PART 65—COUNTRY OF ORIGIN LABELING OF BEEF, PORK, LAMB, CHICKEN, GOAT MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADAMIA NUTS, PECANS, PEANUTS, AND GINSENG

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#### Country of Origin Notification

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#### Recordkeeping

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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.



**§ 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 term "hamburger" in 9 CFR 319.15(b).

**§ 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 produced from sheep.

**§ 65.195 Legible.**

*Legible* means text that can be easily read.

**§ 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.

**§ 65.218 Pre-labeled.**

*Pre-labeled* means a covered commodity that has the commodity's country of origin and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

**§ 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 harvested.

**§ 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.* 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.

(e) *Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin that include the United States.*

(1) For muscle cut covered commodities derived from animals that were born in Country X or (as applicable) Country Y,

raised and slaughtered in the United States, and were not derived from animals imported for immediate slaughter as defined in § 65.180, the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y.

(2) For muscle cut covered commodities derived from animals born, raised, and slaughtered in the U.S. that are commingled during a production day with muscle cut covered commodities described in § 65.300(e)(1), the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y.

(3) 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.

(4) For muscle cut covered commodities derived from animals that are born in Country X or Country Y, raised and slaughtered in the United States, that are commingled during a production day with muscle cut covered commodities that are derived from animals that are imported into the United States for immediate slaughter as defined in § 65.180, the origin may be designated as Product of the United States, Country X, and (as applicable) Country Y. In each case of paragraphs (e)(1), (e)(2), and (e)(4) of this section, the countries may be listed in any order. 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.

(f) *Labeling Imported Covered Commodities.* Imported covered commodities for which origin has already been established as defined by this law (e.g., born, raised, and slaughtered or produced) 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 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 Labeling.**

(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, country abbreviations are not acceptable. Only those

abbreviations approved for use under Customs and Border Protection rules, regulations, and policies, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland", "Luxemb" for Luxembourg, and "U.S. or USA" for the "United States of America" 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) Domestic and imported perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng may use State, regional, or locality label designations in lieu of country of origin labeling. Abbreviations may be used for state, regional, or locality label designations for these commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP.

### 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 records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. For that purpose, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking (i.e., "CAN" or "M") may use that information as a basis for a U.S. origin claim. Packers that slaughter animals that are part of another country's recognized official system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. Producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction. In the case of cattle, producer affidavits may be based on a visual inspection of the animal to verify its origin. If no markings are found that would indicate that the animal is of foreign origin (i.e., "CAN" or "M"), the animal may be considered to be of U.S. origin.

(2) Any intermediary supplier handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the intermediary supplier relied on the designation provided by the initiating supplier or other intermediary supplier, unless the intermediary supplier willfully disregarded information establishing that the country of origin declaration was false.

(3) 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.

(4) 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) In providing the country of origin notification for a covered commodity, in general, retailers are to convey the origin information provided by their suppliers. Only if the retailer physically commingles a covered commodity of different origins in preparation for retail sale, whether in a consumer-ready package or in a bulk display (and not discretely packaged) (i.e., full service meat case), can the retailer initiate a multiple country of origin designation that reflects the actual countries of origin for the resulting covered commodity.

(2) Records and other documentary evidence relied upon at the point of sale to establish a covered commodity's country(ies) of origin must either be maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA in accordance with § 65.500(a)(2). For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and no additional records documenting origin information are necessary.

(3) Any retailer handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the retailer relied on the designation provided by the supplier, unless the retailer willfully disregarded information establishing that the country of origin declaration was false.

(4) 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]

Dated: January 9, 2009.

**James E. Link,**

*Administrator, Agricultural Marketing Service.*

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