

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 60

[No. LS-03-04]

RIN 0581-AC26

Mandatory Country of Origin Labeling of Fish and Shellfish

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: The Farm Security and Rural Investment Act of 2002 (Farm Bill)(Pub. L. 107-171) and the 2002 Supplemental Appropriations Act (2002 Appropriations)(Pub. L. 107-206) amended the Agricultural Marketing Act of 1946 (Act)(7 U.S.C. 1621 et seq.) to direct the Secretary of Agriculture to promulgate regulations by September 30, 2004, requiring retailers to notify their customers of the country of origin of covered commodities. Covered commodities include muscle cuts of beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities; and peanuts. The FY 2004 Consolidated Appropriations Act (2004 Appropriations)(Public Law 108-199) delayed the applicability of mandatory country of origin labeling (COOL) for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006. After issuance of a proposed rule, the

Department has decided to provide further opportunity to comment due to the changes made as a result of comments received and the costs associated with this rule. This interim final rule contains definitions, the requirements for consumer notification and product marking, and the recordkeeping responsibilities of both retailers and suppliers for fish and shellfish covered commodities. Regulatory provisions for the other covered commodities will be provided in a separate regulatory action as appropriate.

DATES: This interim final rule is effective [Insert date 180 days after date of publication in the Federal Register]. The requirements of this rule do not apply to frozen fish or shellfish caught or harvested before [Insert date 60 days after date of publication in the Federal Register]. Comments must be submitted on or before [Insert date 90 days after date of publication in the Federal Register] to be assured of consideration.

ADDRESSES: Send written comments to: Country of Origin Labeling Program, Room 2092-S; Agricultural Marketing Service (AMS), USDA; STOP 0249; 1400 Independence Avenue, SW.; Washington, D.C. 20250-0249, or by facsimile to 202/720-3499, or by e-mail to cool@usda.gov. State that your comments refer to Docket No. LS-03-04. Comments may also be submitted electronically through www.regulations.gov. All comments

received will be posted to the AMS website at:

<http://www.ams.usda.gov/cool/>. Comments may also be inspected at the above location between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. Comments sent to the above location that specifically pertain to the information collection and recordkeeping requirements of this action should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street, NW., Room 725, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: William Sessions, Associate Deputy Administrator, Livestock and Seed Program, AMS, USDA, by telephone on 202/720-5705, or via e-mail at: william.sessions@usda.gov.

SUPPLEMENTARY INFORMATION: The information that follows has been divided into three sections. The first section provides background information including questions and answers about this interim final rule, a summary of the history of this rulemaking, and a general overview of the law. The second section provides a discussion of the rule's requirements, including a summary of the comments received in response to the proposed rule published in the October 30, 2003, Federal Register (68 FR 61944) and the Agency's responses to these comments. The last section provides for the required impact

analyses including the Regulatory Flexibility Act, the Paperwork Reduction Act, Civil Rights Analysis, and the relevant Executive Orders.

I. Background

Questions and Answers Concerning This Interim Final Rule

What are the general requirements of Country of Origin Labeling?

The Farm Bill amended the Act to direct the Secretary of Agriculture to issue regulations by September 30, 2004, to require retailers to notify their customers of the country of origin of beef (including veal), lamb, pork, fish, shellfish, perishable agricultural commodities, and peanuts beginning September 30, 2004. The 2004 Appropriations Act delayed the applicability of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006. The law defines the terms "retailer" and "perishable agricultural commodity" as having the meanings given those terms in section 1(b) of the Perishable Agricultural Commodities Act of 1930 (PACA)(7 U.S.C. 499 et seq.). Food service establishments are specifically excluded as are covered commodities that are ingredients in a processed food item. In addition, the law specifically outlines the criteria a covered commodity must meet to bear a "United States country of origin" label.

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

Questions regarding whether a product is considered a covered commodity or is labeled accurately under this regulation may be e-mailed to cool@usda.gov.

What is the definition of a processed food item and what types of products are considered processed food items?

Fish and shellfish covered commodities are exempt from COOL under this rule if they are an ingredient in a processed food item. An ingredient is a component either in part or in full of a finished retail food product. A processed food item is 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 components (e.g., 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, compressing into blocks and cutting into portions).

Examples of fish and shellfish combined with different covered commodities or other substantive food components include scallops and shrimp in a seafood medley, breaded shrimp, breaded fish fillets, coated shrimp, and marinated fish fillets.

What requirements must be met for a retailer to label a covered commodity as being of U.S. origin?

The law prescribes specific criteria that must be met for a covered commodity to bear a "United States country of origin" declaration. The specific requirements for fish and shellfish covered commodities are as follows: 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 U.S. Customs and Border Protection) outside of the United States; 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 U.S. Customs and Border Protection) outside of the United States.

How should I label a retail product that contains a covered commodity (such as a bag of shrimp) commingled from more than one country of origin?

For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with other imported and/or U.S. origin commodities, the declaration shall indicate the countries of origin for all covered commodities in accordance with existing Federal legal requirements. 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.

What are the requirements for maintaining country of origin information for blended covered commodities that contain products from more than one country of origin?

The labeling requirements are consistent with other Federal legal requirements under which facilities are not required to separately track throughout the process, and ultimately into each individual retail package, the country source of the commodities that are found within each individual retail package. Rather, the declaration of the retail product can indicate the several countries of origin that are represented in the overall blending process, without being required to verify

which specific countries of origin are found within each individual retail package.

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

The COOL provision of the Farm Bill applies to all covered commodities. Moreover, the law specifically identifies the criteria that products of U.S. origin must meet. The law further states that "Any person engaged in the business of supplying a covered commodity to a retailer shall provide information to the retailer indicating the country of origin of the covered commodity." And, the law does not provide authority to control the movement of product. In fact, the use of a mandatory identification system that would be required to track controlled product through the entire chain of commerce is specifically prohibited.

When will the requirements of this regulation be enforced?

The effective date of this regulation is six months following the date of publication of this interim final rule. The requirements of this rule do not apply to frozen fish or shellfish caught or harvested before [insert 60 days after date of publication in the Federal Register]. The country of origin statute provides that "not later than September 30, 2004, the Secretary shall promulgate such regulations as are necessary to implement this subtitle." Many of the covered commodities sold

at retail are in a frozen or otherwise preserved state (i.e., not sold as "fresh"). Thus, many of these products would already be in the chain of commerce prior to September 30, 2004, and the origin/production information may not be known. Therefore, it is reasonable to delay the effective date of this interim final rule for six months to allow existing inventories to clear through the channels of commerce and to allow affected industry members to conform their operations to the requirements of this rule. During this time period, AMS will conduct an industry education and outreach program concerning the provisions and requirements of this rule. AMS also will focus its resources for the six months immediately following the effective date of this interim final rule on industry education and outreach. After a careful review of all its implications, AMS has determined that its allocation of enforcement resources will ensure that the rule is effectively and rationally implemented. This AMS plan of outreach and education, conducted over a period of one year, should significantly aid the industry in achieving compliance with the requirements of this rule.

How will the requirements of this regulation be enforced?

USDA will seek to enter into partnerships with States having existing enforcement infrastructure to assist in the administration of this law. USDA will determine the scheduling and procedures for the 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. In addition, the Agency plans to publish a compliance guide that will provide the industry with information on compliance and the phasing in of active enforcement.

What are the recordkeeping requirements of this regulation?

Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, for a period of 1 year from the date of the transaction. For retailers, records and other documentary evidence relied upon at the point of sale by the retailer to establish a product's country(ies) of origin and

method(s) of production (wild and/or farm-raised) must be available during normal business hours to any duly authorized representatives of USDA for as long as the product is on hand. For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish a product's origin and method(s) of production (wild and/or farm-raised). Records that identify the supplier, the product unique to that transaction by means of a lot number or other unique identifier, and for products that are not pre-labeled, the country of origin and method of production (wild and/or farm-raised) information must be maintained for a period of 1 year from the date the origin and production designations are made at retail.

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

To the extent that State country of origin labeling programs encompass commodities which 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.

Can food products that are not covered by this regulation be voluntarily labeled with COOL information?

Yes. Such voluntary claims must be truthful and accurate and adhere to existing Federal labeling regulations.

Prior Documents in this Proceeding

This interim final rule is issued pursuant to the Farm Bill, the 2002 Appropriations, and the 2004 Appropriations, which amended the Act.

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.

Overview of the Law

Section 10816 of Public Law 107-171 (7 U.S.C. 1638-1638d) amended the Act (7 U.S.C. 1621 et seq.) to require retailers to

inform consumers of the country of origin of covered commodities beginning September 30, 2004.

The intent of this law is to provide consumers with additional information on which to base their purchasing decisions. COOL is a retail labeling program and as such does not provide a basis for addressing food safety. Seafood products, both imported and domestic, must meet the food safety standards of the Food and Drug Administration (FDA). The law defines the term "covered commodity" as muscle cuts of beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities; and peanuts. The law excludes items from needing to bear a country of origin declaration when a covered commodity is an "ingredient in a processed food item." The law defines the terms "retailer" and "perishable agricultural commodity" as having the meanings given those terms in PACA. The law defines the term "wild fish" as naturally-born or hatchery-raised fish and shellfish harvested in the wild and excludes net-pen aquacultural or other farm-raised fish.

The law specifically outlines the criteria a covered commodity must meet in order to bear a "United States country of origin" declaration. In the case of farm-raised fish and shellfish, the covered commodity must be derived from fish or

shellfish hatched, raised, harvested, and processed in the United States. In the case of wild fish and shellfish, the covered commodity must be derived 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. In addition, the law also requires that fish and shellfish covered commodities be labeled to indicate whether they are wild or farm-raised.

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

The law makes reference to the definition of "retailer" in section 1(b) of PACA as the meaning of "retailer" for the application of the labeling requirements under the COOL law. Under this interim final rule, a retailer is any person engaged in the business of selling any perishable agricultural commodity at retail. Retailers are required to be licensed when the invoice cost of all purchases of produce exceeds \$230,000 during a calendar year. Since fish markets and similar specialty shops

do not generally sell fruits and vegetables, they do not meet the PACA definition of a retailer and therefore are not covered by this rule.

The law requires any person engaged in the business of supplying a covered commodity to a retailer to provide the retailer with the product's country of origin information. In addition, the law states the Secretary of Agriculture may require that any person that prepares, stores, handles, or distributes a covered commodity for retail sale maintain a verifiable recordkeeping audit trail. The law prohibits the Secretary from using a mandatory identification system to verify the country of origin of a covered commodity and provides examples of existing certification programs that may be used to certify the country of origin of a covered commodity. The law contains enforcement provisions for both retailers and suppliers that include civil penalties of up to \$10,000 for each violation. The law also encourages the Secretary to enter into partnerships with States with enforcement infrastructure to the extent possible to assist in the program's administration.

II. Highlights of this Interim Final Rule

Covered Commodities

The term "covered commodity" includes: farm-raised fish and shellfish (including fillets, steaks, nuggets, and any other

flesh) and wild fish and shellfish (including fillets, steaks, nuggets, and any other flesh).

Exclusion for Ingredient in a Processed Food Item

Items are excluded from labeling under this regulation when a covered commodity is an ingredient in a processed food item. Under this interim final rule, a "processed food item" is defined as: a retail item derived from 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 (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, 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, salmon that has been smoked, marinated fish fillets, canned tuna, canned sardines,

canned salmon, crab salad, shrimp cocktail, gefilte fish, sushi, and breaded shrimp.

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. The specific requirements for each commodity are as follows:

(a) 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 U.S. Customs and Border Protection) outside of the United States.

(b) 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 U.S. Customs and Border Protection) outside of the United States..

Labeling Country of Origin for Imported Products That Have Not Been Substantially Transformed in the United States

Under this interim final rule, an imported covered commodity shall retain its origin as declared to U.S. Customs

and Border Protection at the time the product enters the United States, through retail sale, provided it has not undergone a substantial transformation (as established by U.S. Customs and Border Protection) in the United States.

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

Labeling Imported Products That Have Been Substantially Transformed in the United States

Under this interim 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 U.S. Customs and Border Protection guidelines and policies) 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." 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 U.S. Customs and Border Protection guidelines and policies) in the United States, the product shall be labeled at retail as "From [country X],

processed in the United States.” The covered commodity shall also be labeled to indicate that it was derived from farm-raised fish or shellfish.

Defining Country of Origin for Blended Products

Under this interim final rule, the country of origin declaration of blended or commingled retail food items comprised of the same covered commodity (e.g., bag of shrimp) having different origins, shall indicate the countries of origin for covered commodities in accordance with existing Federal legal requirements when the commingled product contains imported covered commodities that have not subsequently been substantially transformed in the United States. When the retail product contains imported covered commodities that have subsequently undergone substantial transformation in the United States 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.

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), either on the sales vehicle or at the time the product is delivered to the consumer.

Markings

Under this interim final rule, the country of origin declaration and method of production (wild and/or farm-raised) designation may be provided to consumers by means of a label, stamp, mark, placard, 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. Except as provided in §60.200(g) and §60.200 (h)(2) of this regulation, the declaration of the country(ies) of origin of a product shall be listed according to existing Federal legal requirements. Abbreviations and variant spellings that unmistakably indicate the country of origin, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland" 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.

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 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" 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. However, the labeling requirements under this rule do not supersede any existing Federal legal requirements, unless otherwise specified, and any such country of origin and method of production (wild and/or farm-raised) notification must not obscure or intervene with other labeling information required by existing regulatory requirements.

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 conspicuous and allow

consumers to determine the country(ies) of origin and method(s) of production (wild and/or farm-raised) when making their purchases and provided that existing Federal labeling requirements must be followed. For example, under FDA labeling regulations (21 CFR 101.2) it is not permissible to include the method of production (wild and/or farm-raised) designation in either the ingredient statement or as part of the common or usual name of a product.

Recordkeeping Requirements and Responsibilities

The law states that the Secretary may require any person that prepares, stores, handles, or distributes a covered commodity for retail sale to maintain a verifiable recordkeeping audit trail that will permit the Secretary to verify compliance. As such, records and other documentary evidence to substantiate origin declarations and designations of wild and/or farm-raised are necessary in order to provide retailers with credible information on which to base origin declarations.

Under this interim final rule, any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly (i.e., harvesters, producers, distributors, handlers, etc.), must make available information to the subsequent purchaser 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 it identifies the product and its country(ies) of origin and method(s) of production, unique to that transaction by means of a lot number or other unique identifier. If after [Insert date 365 days after date of publication in the Federal Register] a frozen fish or shellfish covered commodity caught or harvested before [Insert date 60 days after date of publication in the Federal Register] is offered for retail sale and for which origin and/or method of production information is not known, the supplier must possess records to substantiate the date of harvest or capture of the fish or shellfish.

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, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, for a period of 1 year from the date of the transaction.

In addition, the supplier of a covered commodity that is responsible for initiating a country of origin declaration and method of production (wild and/or farm-raised) designation must possess records necessary to substantiate the claim.

For an imported covered commodity, the importer of record as determined by CBP, must ensure that records: provide clear product tracking from the U.S. port of entry to the immediate subsequent recipient and accurately reflect the country(ies) of origin and method(s) of production (wild and/or farm-raised) 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.

Any intermediary supplier (i.e. not the supplier responsible for initiating a country of origin declaration and method of production (wild and/or farm-raised) designation) handling a covered commodity that is found to be designated incorrectly for 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 could not have been reasonably expected to have had knowledge of the violation.

Under this interim final rule, retailers also have recordkeeping responsibilities. Records and other documentary evidence relied upon at the point of sale by the retailer to establish a product's country(ies) of origin and method(s) of production (wild and/or farm-raised), or , if applicable, date of harvest or capture designation, must be available during normal business hours to any duly authorized representatives of

USDA for as long as the product is on hand. For pre-labeled products (i.e., labeled by the manufacturer/first handler) the label itself is sufficient evidence on which the retailer may rely to establish a product's origin and method(s) of production (wild and/or farm-raised). Records that identify the retail supplier, the product unique to that transaction by means of a lot number or other unique identifier, and for products that are not pre-labeled, the country of origin and method of production (wild and/or farm-raised) information must be maintained for a period of 1 year from the date the origin declaration is made at retail. Such records may be located at the retailer's point of distribution, warehouse, central offices, or other off-site location.

Any retailer handling a covered commodity that is found to be designated incorrectly as to country of origin and/or the method of production (wild and/or farm-raised) shall not be held liable by reason of the conduct of another if the retailer could not have been reasonably expected to have had knowledge of the violation.

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 will seek to

enter 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 in a timely manner during normal hours of business 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 \$10,000 for each violation. For retailers, the law states that if the Secretary determines that a retailer is in violation of the Act, the Secretary must notify the retailer of the determination and provide the retailer with a 30-day period during which the

retailer may take necessary steps to comply. If upon completion of the 30-day period the Secretary determines the retailer has willfully violated the Act, after providing notice and an opportunity for a hearing, the retailer may be fined not more than \$10,000 for each violation.

For suppliers, the law states that section 253 of the Act shall apply to a violation of this subpart. This section states in part that in determining the amount of a civil penalty to be assessed for violations of this subpart, the Secretary must consider the gravity of the offense, the size of the business involved, and the effect of the penalty on the ability of the person that has committed the violation to continue in business. The Act also states that the Secretary shall consider whether there has been a pattern of errors in the violation of this subtitle in determining whether to assess a civil penalty. This section also provides that in addition to or in lieu of a civil penalty, the Secretary may issue a cease and desist order from continuing any violation. In addition, section 253 also contains the administrative process that must be followed in assessing a civil penalty or cease and desist order. As with retailers, if the Secretary determines that a supplier is in violation of the Act, the Secretary will notify the supplier of the determination and provide the supplier with a 30-day period during which the supplier may take necessary steps to comply.

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

In order to provide regulated parties with additional information relative to the enforcement of this program, AMS will issue a compliance guide. This compliance guide will contain additional information about the audit process, the types of records that may be useful in verifying compliance with this regulation, examples of instances that would be considered violations, as well as other information that may be useful in complying with this regulation.

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 which generally reflected the substance of the timely comments received. Specific comments are discussed in detail below. As this interim final rule contains the requirements for labeling fish and shellfish covered commodities, to the extent practicable, only those comments that pertain to fish and shellfish covered commodities and to the general requirements of this regulation are discussed herein. In some cases, the summary of comments and Agency response encompass both fish and shellfish covered commodities and other covered commodities. These comments and the Agency response are included in this interim final rule in cases where their inclusion facilitates the reader's understanding of the changes that were made in this rule based on the commenters' recommendations.

Definitions

Covered Commodity

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

Agency Response: Section 281(2)(A) of the Act defines the term "covered commodity" as "muscle cuts of beef, lamb, and pork; ground beef, ground lamb, ground pork; farm-raised fish; wild fish; a perishable agricultural commodity; and peanuts." Accordingly, this recommendation is not adopted.

Processed (for fish and shellfish)

Summary of Comments: One commenter recommended that USDA adopt a clearer definition of determining a country of origin's location of processing if USDA is unable to clearly articulate what substantial transformation means in this rule. Other commenters recommended that the definition of processed be modified so that imported products subjected to processing beyond repackaging but less than substantial transformation should be eligible to voluntarily be labeled as processed in the United States.

Agency Response: Because of changes made by the Agency in the regulatory text in §60.200(g) to simplify the labeling of imported products that have been substantially transformed in the United States, the Agency no longer believes that a separate

definition of processed is necessary. With respect to allowing imported products that have been subjected to processing beyond repackaging but less than substantial transformation to voluntarily be labeled as processed in the United States, such labeling would not conform to U.S. Customs and Border Protection requirements. Accordingly, because the definition of processed has been deleted no changes have been made as a result of these comments.

Processed food item

Summary of Comments: AMS received numerous comments on the definition of a processed food item. Some commenters offered specific recommendations as to what should be considered a processed food item such as canned fish, breaded products, all products that have been substantially transformed, and all seafood products made from block derivatives. Other commenters offered specific recommendations as to what products should not be considered a processed food item such as smoked fish, cured products, and simple mixtures of covered commodities. Several commenters recommended that the first alternative definition provided in the proposed rule should be utilized which would exclude any product that bears an ingredient statement. Several other commenters recommended that the second alternative definition provided in the proposed rule should be utilized which would exclude any covered commodity that has undergone

processing as defined by other existing Federal regulations. Other commenters recommended that the third alternative definition provided in the proposed rule should be utilized which would only exclude a covered commodity if it is mixed with other commodities to create a distinct food item such as a pizza or TV dinner. Another commenter recommended that a processed food item be defined as "transformation of a covered commodity that results in a finished product that has a distinct character from the covered commodity so that consumers do not use the item in the same fashion as they would use the covered commodity itself." Another commenter stated his belief that Congress intended for COOL to cover only those products not currently covered under existing tariff laws. Other commenters expressed general concern about the proposed definition, but did not offer any alternatives. Some commenters stated that the definition as proposed will result in USDA deciding on a case by case basis which food products must be labeled. Other commenters expressed concern that the concept of substantial transformation which is the basis for determining origin under both CBP regulations and the World Trade Organization's Rules of Origin is being overwritten.

Agency Response: In an effort to make the definition of a processed food item clearer, the Agency has modified the language in the proposed rule to provide specific examples of

the types of processing that would result in a product being considered a processed food item. In addition, the Agency has determined that the application of the definition and thus the scope of covered commodities should be modified. Accordingly, under this interim final rule, all cooked (e.g., canned fish, cooked shrimp) and breaded products, which in the case of shrimp can account for up to 50 percent of the finished product, are considered processed food items and are excluded from labeling under this regulation. In addition, retail items that have been given a distinct flavor (e.g., Cajun marinated catfish) are also considered processed food items. Further, to provide additional guidance to the industry, the Agency has added additional examples of the types of products that would be excluded in the Questions and Answers section of this rule. With respect to the issue of substantial transformation, the law specifically defines the criteria for a covered commodity to be labeled as having a United States country of origin. Thus, under this regulation, imported products that have been subsequently substantially transformed in the United States are not eligible to bear a "product of the U.S." declaration.

Raised

Summary of comments: One commenter recommended that the definition of raised for farm-raised fish and shellfish be

modified to include farm-raised fish and shellfish originally obtained from the wild.

Agency Response: The Agency defined "raised" in the case of farm-raised fish and shellfish in the context of defining the production steps contemplated by the law for this commodity (hatched, raised, harvested, and processed). The Agency separately defined the term "farm-raised fish" to include farm-raised fish and shellfish originally obtained from the wild. However, the Agency has modified the definition of "raised" to clarify that it is defined in context of the production steps defined by the law (hatched, raised, harvested, and processed).

Retailer

Summary of comments: Numerous commenters recommended that the definition of retailer be modified to include specialty shops such as fish markets.

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

United States country of origin

Summary of comments: One commenter expressed concern that the definition of United States country of origin departs from the relevant international standard in which the country of origin is defined as the country where substantial transformation occurred.

Agency Response: The law specifically defines the criteria a covered commodity must meet to bear a United States country of origin declaration. As such, the Agency is unable to modify this definition in the manner recommended by the commenter. However, the Agency has modified the definition to clarify that products otherwise meeting the definition of U.S. origin that are subsequently substantially transformed outside of the United States are not eligible to bear a U.S. origin declaration.

Country of Origin Notification

General

Summary of comments: One commenter recommended that §60.200(a) of the proposed rule should be deleted as it could be construed as requiring each individual commodity to bear a label indicating its country of origin.

Agency Response: The Agency agrees with the commenter that the language could be interpreted as requiring each individual covered commodity to bear a label. However, the Agency does not agree that this section should be deleted. The

Agency has modified the language in this section to clarify that the regulation does not require each covered commodity to be individually labeled.

Designation of Wild Fish and Farm-Raised Fish

Summary of Comments: Several commenters recommended the Agency clarify that the designation of the method of production for fish and shellfish as either wild or farm-raised is a separate requirement from the requirement to provide notice of a covered commodity's country of origin.

Agency Response: The Agency agrees with the commenters' recommendation and has modified §60.200(d) accordingly.

Labeling Covered Commodities When the Product Has Entered the United States During the Production Process

Summary of Comments: Several commenters recommended alternative methods of labeling products that have entered the United States during the production process. Several commenters recommended that mixed origin products should be labeled to reflect each country involved in the production process (e.g., capture/farming country, processing country). Other commenters recommended that the Agency should delete any requirement to display the origin where processing occurred for any of the covered commodities. Several other commenters expressed support for the provisions contained in the proposed rule. Another commenter recommended that all countries involved in the

production of a covered commodity be listed alphabetically. In addition, one commenter recommended that the words "by a vessel other than a U.S. flagged vessel" be inserted after the phrase "was harvested in country X" in §60.200(2)(ii).

Agency Response: The Agency has made modifications to §60.200(g) in order to harmonize the requirements of this regulation with current Federal legal requirements. No additional changes have been made as a result of these comments.

Blended Products

Summary of Comments: Numerous commenters recommended alternative methods for labeling products comprised of the same commodity that are prepared from raw material sources having different origins. Several commenters recommended that companies should be allowed to list the countries either alphabetically or by weight. Numerous other commenters recommended that companies be allowed to use labels that indicate what countries may be contained within the package. Several commenters recommended that AMS consider using general rather than specific labels for products involving more than one country such as "mixed origin." Another commenter recommended that labels should list all of the countries but in no particular order. Another commenter recommended that the label should indicate the percentage of each country contained within the package (e.g., 65% country Y, 35% country X). Finally, one commenter expressed concern as to whether listing the countries alphabetically is acceptable under FDA and CBP regulations.

Agency Response: The law requires all covered commodities to be labeled with country of origin information. As such, the use of "mixed origin" labels does not provide consumers with the required information and are therefore unacceptable. However, USDA is concerned about the burden imposed by the rule on facilities that produce a blended retail product. The proposed

rule would have required such facilities to document that the origin of a product was separately tracked, while in their control, during production and packaging. The proposed rule also would have required that the labeling of all blended products specify precisely the countries of origin represented within each individually-packaged retail product. In this interim final rule, the provision to separately track the product has been removed, and the labeling requirements have been made consistent with other Federal legal requirements. Therefore, this interim final rule does not impose any additional burden with respect to the labeling of blended products for which labeling is also required under U.S. Customs and Border Protection legal requirements. For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with other imported or U.S. origin covered commodities, the declaration shall indicate the countries of origin for all covered commodities in accordance with existing Federal legal requirements. 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.

Remotely Purchased Products

Summary of comments: Some commenters recommended that consumers be notified of a product's country of origin prior to the purchase being made. Other commenters recommended that the country of origin notification should be allowed to be made either on the sales vehicle or at the time the product is delivered to the consumer.

Agency Response: The Agency believes that companies should be allowed flexibility in providing the notice of country of origin and method of production (wild and/or farm-raised). As such, under this interim final rule, companies can provide the required notification either on the sales vehicle or at the time the product is delivered to the consumer.

Markings

Section 60.300(a)

Summary of Comments: Several commenters recommended that the method of production (wild and/or farm-raised) designation should be allowed to be made separately from the country of origin declaration. Another commenter requested flexibility in labeling commingled similar wild and farm-raised products. Several other commenters recommended that the Agency

specifically allow the use of check boxes to convey both the country of origin and method of production (wild and/or farm-raised) information.

Agency Response: The Agency believes that the law provides the same flexibility in providing the method of production (wild and/or farm-raised) designation as it does the country of origin notification. As such, §60.300(a) has been modified to clarify that various forms of the method of production (wild and/or farm-raised) designation are permissible and that the country of origin declaration and method of production (wild and/or farm-raised) designation can be combined or made separately. In addition, §60.300(d) has been modified to clarify that a bulk container used at the retail level to present product to consumers may contain products comprised of both wild and farm-raised fish or shellfish provided all possible origins and/or method(s) of production are listed. In addition, §60.300(a) has been modified to clarify that products may contain both wild and farm-fish provided the label identifies both methods of production. With respect to check boxes, the Agency has added language in §60.300(a) to specifically authorize the use of check boxes as an acceptable method of notification.

Section 60.300(b)

Summary of Comments: Several commenters recommended that the conspicuous location requirement should include any place on the package or product. Another commenter recommended that the preamble recognize that conspicuous may be provided in a broad number of ways, including signs adjacent to a bulk display, pin tags for seafood, etc.

Agency Response: The Agency believes the current explanation of a conspicuous location as being likely to be read and understood by a customer under normal conditions of purchase is sufficient. In addition, the proposed rule adequately clarified that the country of origin and method of production (wild and/or farm-raised) declarations can be made in a multitude of ways (e.g., placard, sign, label, sticker, band, twist tie, etc.). However, the Agency will add pin tags as a specific example. Accordingly, these recommendations have been adopted in part.

Section 60.300(d)

Summary of Comments: One commenter recommended that bulk commodities should be allowed to be commingled in bins as long as the signage indicates the countries of origin of the contents of the bin. Another commenter requested that the words "that a substantial amount of" be inserted after the word provided. Another commenter expressed concern that requiring individual

stickering may result in the elimination of bulk displays and in packaged products displacing fresh displays.

Agency Response: The Agency has modified §60.300(d) such that a bulk container used at the retail level may contain a covered commodity from more than one origin and/or method of production provided that all possible origins and/or methods of production are listed. No additional changes have been made as a result of these comments.

Section 60.300(e)

Summary of Comments: Several commenters recommended that the Agency define acceptable standard country abbreviations. One commenter recommended that the three letter format accepted by the International Olympic Committee be used while the other commenter expressed concern that if the International Organization for Standardization country codes were utilized, abbreviations for many of the countries exporting to the United States will not be recognized by consumers. Another commenter requested clarification on whether "Brazilian product" would be accepted as proper country of origin notification. Another commenter recommended that the language allowing the use of the adjectival form of the name of a country be modified to delete the reference to "region/city" since the Agency expressly prohibited the use of State or regional label designations in lieu of country of origin notification.

Agency Response: The Agency believes that the language regarding abbreviations as proposed that allows abbreviations and variant spellings that unmistakably indicate the country of origin is appropriate. This is the same language contained in U.S. Customs and Border Protection laws and regulations, which will minimize the burden on the industry by allowing them to continue to follow existing regulations. With respect to the clarification on the use of "Brazilian product" as country of origin notification, the adjectival form of the name of a country is specifically authorized as long as it does not refer to a kind or species of product (e.g., Brazil nuts). With respect to the commenter's recommendation to delete the reference to "region/city," the Agency agrees with the commenter's recommendation and has deleted the reference to "region/city." Accordingly, these recommendations have been adopted in part.

Section 60.300(f)

Summary of Comments: Numerous commenters recommended that the Agency accept State and regional label designations in lieu of country of origin labeling.

Agency Response: The Act specifically requires that all covered commodities be labeled with country of origin information. Thus, allowing State and regional label designations in lieu of country designations would not meet the

requirements of the statute. Accordingly, this recommendation is not adopted.

Recordkeeping

General

Summary of Comments: Several commenters recommended that the Agency list the specific records that it will use to determine the validity of origin claims. Other commenters recommended that the Agency cite the examples of records that can be used to substantiate origin and method of production (wild and/or farm-raised) claims that the Agency has posted on its website in the preamble of the final rule. Other commenters recommended that the Agency require no additional records beyond those mandated by the Tariff Act, PACA, and FDA. Several other commenters requested that the Agency provide guidance on what records could be used to substantiate method of production (wild and/or farm-raised) claims for imported products and asked what AMS would require of foreign suppliers. Another commenter expressed concern that the preamble provides no explanation of the records that would be necessary to establish the chain of custody of a product. The commenter further contends that this requirement is higher than the standard set forth in FDA's recordkeeping authority under the Bioterrorism Act and suggested that it be deleted.

Agency Response: With regard to identifying records that may be useful in verifying origin and method of production (wild and/or farm-raised) claims, the Agency has included some examples of records in the regulation and additional examples will be included in the compliance guide. In addition §60.400 (b)(4) has been modified to clarify the responsibilities of importers. With respect to using existing records mandated by the Tariff Act, PACA, and FDA to verify compliance with this regulation, it is not necessary that additional records be created to comply with this regulation to the extent that existing records contain the necessary information. With respect to establishing the chain of custody of a product, the Agency has deleted this language from this rule. The requirement in the interim final rule that retail suppliers maintain records to establish and identify the immediate previous source and immediate subsequent recipient of a covered commodity, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, is sufficient documentation to allow the Agency to track a product back through the marketing chain in order to verify compliance with this regulation.

Recordkeeping Retention

Summary of Comments: The Agency received numerous comments regarding the recordkeeping retention requirement. The

majority of commenters recommended a shorter record retention time for both retailers and suppliers. Specifically, most commenters recommended that a one-year record retention requirement for suppliers and for the centrally-located retail records. Several other commenters recommended alternate retention times including, for the reasonable life of the product (and that for most perishable items 30 days would be sufficient), six months for perishable items, and 90 days for both retailers and slaughter facilities. Other commenters suggested various recordkeeping retention requirements at the store level including, limiting it to the time that the products are located at the store, lengthening it to 30 days, reducing it to 2 days or eliminating it all together. Another commenter requested that the preamble include language specifying that the "date the origin declaration was made at retail" with respect to retaining the centrally located retail records that identify the retail supplier is the date that the product is received at the retail store. Another commenter expressed concern that it may be impossible for retailers to determine when the proposed recordkeeping retention requirement of 7 days after retail sale has elapsed. One commenter recommended that the regulations should expressly recognize that a document that identifies the country of origin and method of production (wild and/or farm-raised) of a covered commodity provided by the supplier that

accompanies the product from the supplier all the way to the retail store would serve as an adequate record upon which the retailer could justifiably rely at the point of retail sale to establish a covered commodity's origin and method of production (wild and/or farm-raised). The commenter also recommended that pre-labeled products should not require additional documentation at the retail level as the label itself is the documentary evidence on which the retailer is relying.

Agency Response: The Agency believes that a 1-year record retention requirement for suppliers and centrally located retail records as recommended by many of the commenters is appropriate. This requirement would be consistent with the recordkeeping retention time proposed by FDA under the Bioterrorism Act and would allow the Agency ample time to conduct enforcement reviews to verify compliance with this regulation. With respect to the recordkeeping retention requirement for store-level records, the Agency agrees with the commenters' recommendation that records only need to be available while the product is on hand. As one commenter pointed out, it would be difficult for the retail facility to determine when the 7 day time period after retail sale had elapsed. In addition, generally retail enforcement activities would not encompass products that have already been sold. With respect to a commenter's request to clarify that the date the origin declaration is made at retail is the date the

product is received at the retail store, the Agency does not believe such a clarification is appropriate. In the case of nonperishable products, the retailer may receive products at the store that are not actually displayed for sale for some time. Accordingly, this recommendation is not adopted. With respect to the commenter's recommendation that pre-labeled products should not require any additional documentation at the retail level and that a document containing country of origin and method of production (wild and/or farm-raised) information that accompanies the product through retail sale should be adequate documentation on which a retailer can rely, the Agency agrees and has modified §60.400(b)(1) and §60.400(c)(1) accordingly.

Responsibilities of Suppliers and Retailers

Summary of Comments: One commenter recommended that the final rule should clarify that only USDA has the authority to verify, audit, and administer the labeling program. Another commenter recommended that the Agency clarify that suppliers of covered seafood products must also separately track and document the method of production (wild and/or farm-raised). The commenter also recommended that the preamble should expressly state that suppliers such as wholesalers who simply distribute pre-packaged product are not required to document that the product was separately tracked. Another commenter recommended that importers be required to maintain adequate records to

reconcile purchase, inventories, and sales of imported and domestic commodities. One commenter stated their belief that the safe harbor provision for retailers and intermediary suppliers does not have a specific statutory basis in the Act and expressed an interest in understanding the application of the PACA standard to claims required under the Act. The commenter also recommended that the safe harbor provision for retailers should also extend to misstatements of the method of production (wild and/or farm-raised). The commenter also requested that the preamble should articulate that retailers can accept information provided by suppliers without liability and without obligations to investigate the declarations or systems put in place to ensure the accuracy of declarations. Several commenters requested that the "reasonable knowledge" language contained in the safe harbor provision be deleted as the commenters contend it is difficult to determine what someone should have been reasonably expected to be known.

Agency Response: With respect to clarifying that only USDA has the authority to verify, audit, and administer the labeling program, the Enforcement section of the preamble states that only USDA may initiate enforcement actions against a person found to be in violation of the law. Thus, the Agency believes no further clarification is necessary. With respect to clarifying that suppliers of covered seafood products must also

separately track and document the method of production (wild and/or farm-raised), the Agency has deleted §60.400(b)(5) as it is duplicative and unnecessary given the requirement in the regulation that suppliers provide country of origin and method of production information for all covered commodities. No additional changes as a result of these comments have been made. With respect to the recommendation to require importers to maintain adequate records to reconcile purchases, inventories, and sales of imported and domestic commodities, the law does not provide the Agency with the authority to require such detailed information nor is such information necessary to substantiate origin and method of production claims. Accordingly, this recommendation is not adopted. With respect to the safe harbor provision, the Agency agrees with the commenters' recommendations to extend the safe harbor to misstatements of the method of production (wild and/or farm-raised) and has modified §60.400(b)(2) accordingly. With respect to the statutory basis for the "safe harbor" provision, the basis for providing regulatory protection for retailers in instances where they receive inaccurate COOL information and/or method of production (wild and/or farm-raised) information is based on the language contained in sections 253 and 283 of the Act. Section 283 speaks of specific enforcement procedures and penalties for retailers, while enforcement procedures and penalties as to

other persons are found in section 253. Because the penalty as to retailers requires a willful violation, where a retailer acting in good faith relies on statements or records given by others, we do not believe it was Congress' intent to hold retailers responsible for violations when they relied upon false and/or inaccurate information provided by a supplier. However, the Agency believes the "reasonable knowledge" language is necessary as there are instances in which a retailer would likely have had knowledge that the country of origin information provided to them by the supplier was not correct and should be held accountable. For example, a retailer that receives fresh wild salmon from Alaska in January labeled as product of the U.S. should have known that such a declaration was inaccurate. With respect to the issue of retailers accepting information provided by suppliers without liability and without requiring third-party verification of the information, the Agency believes that because the penalty as to retailers specifically requires a willful violation and the final regulation contains a safe harbor provision, there is no additional language needed.

Use of Affidavits and Self-Certification

Summary of Comments: In the proposed rule, the Agency invited comment on the practicality of requiring suppliers to provide an affidavit for each transaction to the immediate subsequent recipient certifying that the country of origin

claims and, if applicable, designations of wild or farm-raised, being made are truthful and that the required records are being maintained. Numerous commenters recommended that such affidavits not be required as they believe it would be expensive, onerous, unnecessary, and does nothing to alleviate knowing violations of the law. Another commenter supported the use of affidavits as they believe it would provide a level of insurance that the retailer can rely on the information provided by the supplier. One commenter suggested that providing an affidavit with each transaction would be helpful, but legal requirements for such a legally binding document may vary by State. Numerous other commenters interpreted allowing the use of affidavits as allowing self-certification. These commenters recommended that suppliers should be allowed to self-certify the origin of their product.

Agency Response: Self-certification documents or affidavits may play a role in assuring that auditable records are available throughout the marketing chain, but the auditable records must themselves also be available to ensure credibility of country of origin labeling claims. However, in view of the marketing practices of the fish and shellfish industries and the probable cost impacts, the Agency has concluded that requiring affidavits is not practicable or necessary.

Enforcement

Summary of Comments: The Agency received numerous comments on the issue of enforcement. Several commenters recommended that the Agency incorporate a grace period in which enforcement of this regulation would be delayed and implement a program emphasizing compliance rather than enforcement for the first year. Numerous other commenters requested that the Agency clearly define the process of enforcement including recognizing the circumstances under which retailers will be considered to have willfully violated the statute. Several commenters suggested that retailers should not be found in willful violation of the statute unless the retailer intentionally removed or changed the information provided by the supplier. Another commenter recommended that willful be defined as any act resulting in misinformation that was a deliberate and intentional act for the purpose of misstating the COOL label. Several other commenters recommended that the Agency should expressly recognize that if the majority of covered commodity items bear a label, the retailer has met their obligation. Several commenters requested additional information on the process the Agency will employ to fulfill the mandate to partner with States. Other commenters recommended that the Agency expressly prohibit third-party audits from being required of any party subject to this regulation. Another commenter expressed

concern that the Agency does not define what type of information will be sufficient to withstand third-party audits which the commenter believes will lead to a lack of uniformity exposing all participants to unnecessary legal liability. Another commenter recommended that the final regulation clearly describe or at least reiterate the statutory standards for non-retailers. Another commenter recommended that AMS establish a sliding scale for penalties.

Agency Response: Many of the covered commodities sold at retail are in a frozen or otherwise preserved state (i.e. not sold as "fresh"). Thus, many of these products would already be in the chain of commerce prior to September 30, 2004, and the origin/production information may not be known. Accordingly, the effective date of this regulation is six months following the date of publication of this interim final rule. The requirements of this rule do not apply to frozen fish or shellfish caught or harvested before [Insert date 60 days after date of publication in the Federal Register]. Further, AMS will focus its activities on industry education and outreach for an additional six months from the effective date of this interim final rule. This will allow a total of 12 months for AMS to conduct an industry education and outreach program concerning the provisions contained within this rulemaking. With respect to the issue of acts that will constitute "willful" violations

of this subpart, determinations will be made on a case by case basis. However, the Agency will take into consideration the facts and circumstances regarding the situation before initiating an enforcement action. In addition, the Agency will issue a compliance guide similar to the guide published by FDA in promulgating regulations under the Bioterrorism Act of 2002 to provide the industry with further information on compliance and enforcement. With respect to partnerships with States, following publication of the interim final rule, USDA will seek to enter into cooperative agreements with States that have existing infrastructure to conduct audits at the retail level. USDA will provide States with a schedule identifying the stores that should be audited and with what frequency, identify the products to be audited, and outline the audit procedures that will be followed. If a noncompliance is identified by the State, the State will notify USDA. USDA will then proceed with the appropriate enforcement action. With regard to third-party audits, the law does not require third-party audits of any party subject to these regulations. However, the law does not prohibit any party subject to this regulation from requiring a third-party audit of another party as part of their contractual arrangement if they so choose. With respect to penalties for non-retailers, the Farm Bill incorporates by reference section 253 of the Act as applying to violations of this subpart by non-

retailers. This section details the penalties that may be assessed as well as other enforcement mechanisms (e.g., cease and desist orders) and the administrative process that must be followed. Therefore, it is not necessary to fully restate the penalties for non-retailers. However, the Agency has added additional information regarding enforcement of non-retailers to the provisions regarding enforcement in the Highlights of the Interim Final Rule section. With respect to establishing a sliding scale for penalties, the Agency will determine the appropriate penalty on a case by case basis depending on the circumstances surrounding the violation.

Existing State Programs

Summary of Comments: The Agency invited comment on the proposed rule as it relates to existing State programs. One commenter recommended that the Agency reiterate the conclusion that this regulation preempts State law. No comments from States were received on this issue.

Agency Response: In the discussion on Executive Order 13132, Federalism, the Agency has added additional language clarifying that State programs that encompass commodities that are subject to this regulation are preempted.

Miscellaneous

Summary of Comments: Numerous commenters recommended that mandatory COOL be repealed and replaced with a voluntary program

and recommended that USDA seek administrative relief from Congress. Another commenter requested that USDA promulgate an interim final regulation instead of a final rule. Other commenters stated their belief that COOL is a nontariff trade barrier intended to discriminate against imported products and questioned whether this regulation is in conformance with various WTO agreements.

Agency Response: The Agency could not implement a voluntary program without legislative changes. With respect to promulgating an interim final regulation, the Agency believes that because of the changes made as a result of comments received and the costs associated with this rule, additional public input should be obtained and is issuing this regulation as an interim final rule. However, the Agency is not making final provisions that concern other covered commodities at this time. With respect to the commenters' concern regarding WTO agreements, the Agency has considered these obligations throughout the rulemaking process and concludes that this regulation is consistent with these international obligations.

Preliminary Economic Impact Analysis (Executive Order 12866)

Summary of Comments: A commenter stated that USDA did not consider any of its alternative approaches viable and that AMS failed to consider an array of obvious alternatives. The commenter suggested that AMS could reduce the recordkeeping

requirement for retailers from 7 days to 2 days at the point of sale and reduce the overall recordkeeping requirement from 2 years to 1 year. The commenter also suggested that AMS could consider using general rather than specific labels for products involving more than one country (e.g., "mixed origin").

Agency Response: The proposed rule identified limited discretionary authority for alternative regulatory approaches, but alternative approaches were considered. The preliminary economic impact assessment considered alternative definitions of the term "processed food item," which change the scope of commodities required to be labeled with country of origin and method of production (wild and/or farm-raised) information. This interim final rule includes a revised definition of a processed food item that leads to lower costs of implementation for the affected industries. The Agency also considered the impacts of the use of affidavits to transmit country of origin information along the food production and marketing chain.

The interim final rule reduces the recordkeeping burden at the retailer's point of sale from 7 days following retail sale of the product to the length of time the product is on hand. The interim final rule also reduces the recordkeeping burden for suppliers and retailers of covered commodities from 2 years to 1 year.

The Agency disagrees that the law provides discretionary authority to use general rather than specific labels for products involving more than one country. The law requires a retailer of a covered commodity to inform consumers of the country of origin of a covered commodity. A label such as "mixed origin" does not fulfill this requirement because it provides no information regarding the country of origin of the commodity, other than the fact that the origin involves more than one country.

Summary of Comments: A commenter observed that AMS argued in the proposed rule that if COOL was really desirable to consumers, the marketplace would provide the information on a voluntary basis. The commenter further noted that some retailers do label seafood as to its source. In addition, the commenter noted that such labeling is erratic and can be inconsistent, and said that seafood is far less likely to be labeled for foreign than domestic origin. On this basis, the commenter concluded that mandatory COOL requirements are essential.

Agency Response: The Agency concluded in its preliminary economic impact assessment that there was no compelling market failure argument regarding the provision of country of origin information. This conclusion stemmed from a lack of evidence of barriers to private provision of voluntary COOL should consumer

demand support the increased costs of such labeling. The fact that some retailers already label seafood as to its source indicates that market participants will provide country of origin information in response to market demand.

Summary of Comments: A commenter stated that the preliminary economic impact analysis depended heavily on a study, Umberger, et al., concerning beef labeling. The commenter said that Umberger et al.'s and other analyses may not apply to seafood, which the commenter noted is far more likely than beef to be imported from other countries -and, unlike beef, comes from two distinct types of production systems (wild capture and fish farming).

Agency Response: The Umberger, et al. study was referenced as one of the available studies on consumer response to country of origin labeling. The Agency agrees that there are differences in terms of consumer demand characteristics for beef versus seafood products. Therefore, the transfer of estimates from Umberger, et al. may be a source of uncertainty. Based on the numerous comments received on the issue, the Agency also concludes that wild capture versus farm-raised is an important distinction for many seafood consumers.

Summary of Comments: A commenter said that when determining the actual value of COOL regulations, USDA needs to consider the importance of consumer education, small U.S. based

producers and their inability to mount extensive lobbying campaigns, the importance of progressive regulations, and discouraging fraudulent information in the marketplace.

Agency Response: The Agency agrees that consumer education will be vital to firms' abilities to derive benefits from mandatory COOL. While the Agency will make available to the public information about the requirements of this rule, industry will need to undertake any initiatives to educate consumers with an eye toward using COOL as a promotional tool. The Agency also recognizes the importance of discouraging fraudulent information in the marketplace, which underlies the rationale for much of this rule. That is, this rule is designed to ensure that mandatory country of origin claims made at retail are credible and verifiable back through the supply chain.

Summary of Comments: A number of commenters expressed concern about USDA's preliminary analysis of benefits for the proposed rule, and many claimed that USDA failed to identify or acknowledge any benefits of the COOL law. One commenter noted results of a poll of 900 people conducted in January 2004 – 82 percent of respondents said that food should be labeled with country of origin information, 85 percent would be more inclined to buy food produced in U.S., and 81 percent said they would be willing to pay a few cents more for food products of U.S. origin. Another commenter reported results of a survey

conducted by Fresh Trends in 2002, in which 86 percent of respondents favored the concept of COOL. This commenter also cited a study by North Carolina State University, in which 68 percent of respondents indicated willingness to pay more for U.S. food products. Another commenter said that there is little factual support for USDA's finding that there is "little evidence that consumers are willing to pay a price premium for country of origin labeling."

Agency Response: In the preliminary economic impact analysis, the Agency did identify and acknowledge benefits from the proposed rule. The Agency noted that surveys show that a majority of consumers state at least some interest in knowing where their food was produced, and a smaller but significant number indicate a strong desire to know where their food was produced. The Agency also cited results of studies that found substantial degrees of willingness-to-pay for country of origin information by consumers. The comment period did not elicit additional evidence sufficient to change the Agency's conclusion that such professed interest in country of origin labels would result in increased demands or higher prices for U.S.-origin covered commodities.

The January 2004 poll commissioned by the National Farmers Union reconfirms that consumers, when prompted, indicate an interest in country of origin information for food. The poll

also indicates that respondents would be "willing to pay a few cents more" for food products grown and/or raised in the U.S. This poll does not overcome limitations of previous surveys and willingness-to-pay studies, namely, that there is little basis to support the notion that these prompted responses will carry over into actual purchasing behavior. No comments brought forth evidence that there are barriers to the voluntary provision of country of origin information by firms that produce and market the covered commodities. In addition, the Agency did not receive any information that indicated an increased demand for U.S.-origin products in States that currently require country of origin labeling for some of the covered commodities. Therefore, the Agency continues to conclude that in the presence of demand for U.S.-origin products, food companies would respond by sourcing such products and providing consumers with the information.

Summary of Comments: One commenter believes there are a number of scenarios where consumer preference would shift to U.S. products, creating a one to five percent shift in consumer demand, thus recovering implementation costs of the proposed rule.

Agency Response: This commenter did not specify the scenarios under which consumer preference would shift to U.S. products. Neither this commenter nor other commenters provided

evidence sufficient to conclude that there would be a shift in consumer demand for U.S.-origin products of one to five percent.

Summary of Comments: One commenter stated that USDA needs to address the direct cost of administering this program and where the funds would come from (not from user fees).

Agency Response: The Agency intends to use funds that may be appropriated for administration of this program. The Agency estimates the costs for a minimal level of enforcement to be \$2.8 million per year. About five percent of covered retailers would be audited each year under this scenario.

Summary of Comments: A commenter stated that the preliminary economic impact assessment is inadequate due to the broad range of implementation costs presented.

Agency Response: In its preliminary economic impact assessment, the Agency estimated a range of direct, incremental costs to reflect uncertainty about steps that affected entities would need to take to implement the proposed rule. Comments on the voluntary country of origin labeling guidelines (67 FR 63367) and feedback that the Agency received through its outreach efforts during development of the proposed rule painted two very different pictures of the costs and difficulty of implementing mandatory COOL. One viewpoint suggested that implementation and operational costs would be relatively low and would consist of primarily additional recordkeeping costs. The

other viewpoint suggested that implementation and operational costs would be relatively high and would consist of not only additional recordkeeping, but would entail substantial changes to operations, systems development, and capital expenditures. Thus, the Agency's estimated range of direct costs reflected the different viewpoints expressed about costs of implementing mandatory COOL.

Taking into account comments received on the proposed rule, the Agency concludes in its interim final economic impact assessment that implementation costs will exceed the lower range estimates presented in the preliminary economic impact assessment published with the proposed rule. Affected firms and trade associations noted that implementation costs will involve costs and operational changes beyond recordkeeping practices alone. Therefore, in its interim final economic impact assessment, the Agency no longer presents a range of costs.

Summary of Comments: A commenter said that the preliminary economic impact assessment is incomplete because it fails to explain in detail the components underlying each of the cost estimates. The commenter said that the analysis should have included cost estimate subcategories for each type of covered commodity.

Agency Response: As described in the preliminary economic impact assessment, the Agency derived its direct, incremental

cost estimates from publicly available sources of data and studies. These sources are fully referenced in the proposed rule. The Agency presented details about cost components to the extent that such information was provided in the available studies. Lack of available information precludes further sub-categorization of costs.

Summary of Comments: One commenter stated that USDA's preliminary cost estimates do not take into account industry infrastructure and current labeling practices and do not consider existing regulations such as PACA. Similarly, another commenter stated that the preliminary regulatory impact assessment fails to net out the cost of complying with existing regulations such as the Tariff Act and PACA and does not take into account existing signage.

Agency Response: The Agency's preliminary cost estimates did take into account existing industry infrastructure, labeling practices, and statutes such as PACA. The Agency sought to estimate the incremental cost of implementing the proposed rule. The Agency assumed that incremental changes would be made to affected firms' operations and recordkeeping systems to implement the requirements of the rule. The Agency's assumptions recognized the existence of existing Federal regulations such as those promulgated under PACA. PACA does not require that retailers provide country of origin information to

consumers, or that producers, processors, dealers, and other industry participants provide country of origin information to their customers. Instead, PACA would require records to substantiate any transaction or product claim made by entities subject to PACA, such as a claim that a perishable agricultural commodity had a certain country of origin.

PACA requires maintenance of records and firms subject to PACA have developed recordkeeping systems to comply with the requirements of PACA. The existence of such infrastructure and recordkeeping systems reduces the incremental costs of additional informational requirements, including mandatory COOL. The Agency's preliminary cost estimates reflected these existing conditions, which is one reason that per-unit costs were estimated generally to be less for perishable agricultural commodities than for other covered commodities not covered by PACA, its regulations, and recordkeeping requirements.

Summary of Comments: A commenter noted that the preliminary economic impact assessment does not consider or discuss similar voluntary State labeling programs, such as the "Buy California" or "Go Texan" programs.

Agency Response: Voluntary State labeling programs have limited application to the analysis of the impacts of the rule. First and foremost, State labeling programs are voluntary, while this rule is mandatory. Under these types of voluntary State

programs, there is no requirement for any firms to participate, and firms will not choose to participate unless it is in their economic interest to do so. Even when firms do participate in these types of voluntary State programs, they are not required to label everything that they sell. Conversely, this rule is mandatory, and retailers and their suppliers must adhere to the requirements of the rule for 100 percent of the sales of the covered commodities that must be labeled at retail. Second, these voluntary State programs do not have the same types of requirements for recordkeeping and tracking as contained in this mandatory rule. Third, State labeling programs such as "Buy California" and "Go Texan" generally involve a more comprehensive program of marketing and promotional tools beyond just labeling, while this mandatory rule addresses labeling but does not address marketing and promotional activities. For example, some State programs require certain minimum quality standards for participation in the program. Most State programs also include promotional and marketing activities by the State. Such voluntary quality standards and promotional activities imply different market effects compared to this rule, which addresses only labeling requirements.

Summary of Comments: A commenter said that seafood labeling should not be costly because the National Oceanic and

Atmospheric Administration (NOAA) already has recordkeeping requirements for fishing vessels that are pertinent to COOL.

Agency Response: The Agency believes that costs for seafood producers (wild fish harvesters and fish farmers) will be relatively low. The Agency's interim final regulatory impact analysis estimates first-year implementation costs for fish producers at \$241 per producer. The difficulty, however, lies in passing the relevant information along through the food production and marketing chain so that credible and verifiable information is made available to consumers at retail. The additional costs throughout the production and marketing chain are not embodied in current NOAA recordkeeping requirements for fishing vessels.

Summary of Comments: A commenter noted that potential costs include additional equipment for printing codes, significant computer programming, and complete label review and redesign.

Agency Response: The Agency believes that these types of costs will be incurred to implement the rule. Both the preliminary upper-range cost estimates published with the proposed rule and the interim final economic impact assessment reflect these added costs.

Summary of Comments: A commenter said that USDA's cost estimates are substantially understated because they fail to

recognize complexity of the industry, and that USDA's upper-range cost estimates are too low.

Agency Response: The Agency disagrees with this comment. The upper-range estimates presented in the preliminary economic impact assessment sought to reflect the full range of direct, incremental costs that affected entities would incur during the first year of implementation. Likewise in this interim final rule, the Agency's cost estimates seek to reflect the full implementation costs that will be faced by industry.

Summary of Comments: One commenter observed that the proposed rule will impact the canned seafood production process by requiring the segregation of both raw materials and frozen stock, requiring multiple lids, and requiring the processing line to be shut down to switch to another origin.

Agency Response: Although canned seafood is exempt from the interim final rule, the Agency believes that these types of adjustments to operational procedures will be incurred by affected firms to comply with the rule. The estimated implementation costs presented in the interim final economic impact assessment reflect these types of costs.

Summary of Comments: A commenter noted that about three-fourths of fish and shellfish consumed in the U.S. is imported and about one-fourth is farmed-raised.

Agency Response: The greater the potential number of countries of origin from which to source a given product, the more complicated will be the task of making, maintaining, and transferring country of origin claims as the product moves through the production and marketing chain. For example, a product that is sourced from only one country would require only one production line along with a sufficient recordkeeping trail. A product that is sourced from more than one country likely would require some type of segregation plan, additional storage, and perhaps additional production lines along with the requisite recordkeeping requirements. The fact that fish must also be labeled as wild caught or farm-raised represents another piece of information that must be maintained and transferred throughout the system.

Summary of Comments: Several commenters noted the anticipated costs of the proposed rule for their businesses. For example, one grower-cooperative estimated that costs for its growers alone would exceed \$3.5 million. A grocery store chain noted that the proposed rule would cost its company \$3.5 million per year.

Agency Response: These comments confirm the Agency's conclusion that implementation of this regulation is a complex matter for the affected industries and that costs will be substantial for many affected entities. In these examples, the

retailer estimate appears to be consistent with the upper range cost estimates presented in the preliminary economic impact assessment. The grower-cooperative estimate appears to be lower than the Agency's upper range cost estimate per pound, although the comment does not provide much detail about how the total was computed and whether the total includes both grower costs and intermediary costs.

Summary of Comments: A seafood processor noted that it already includes country of origin information on all imported canned crabmeat as required by U.S. Customs and Border Protection, and said that to indicate whether it is wild or farm-raised will impose huge financial and administrative burden. This commenter stated that it already has a substantial amount of inventory of cans that will be unusable and to make design changes to the packaging will take about 1 year, and that it will not have time to implement by September 30, 2004.

Agency Response: Canned seafood products are exempt from the interim final rule. Nevertheless, the Agency recognizes that labeling of wild versus farm-raised fish and fish products will entail additional costs, even in cases in which country of origin information is already maintained. In addition, many of the covered commodities sold at retail are in a frozen or otherwise preserved state (i.e., not sold as "fresh"). Thus, many of these products would already be in the chain of commerce

prior to September 30, 2004, and the origin/production information may not be known. Accordingly, the effective date of this regulation is six months following the date of publication of this interim final rule. Further, AMS will focus its activities for the six months immediately following the effective date of this interim final rule on industry education and outreach. This will allow a total of 12 months for existing product to clear through the channels of commerce and for AMS to conduct an industry education and outreach program concerning the provisions contained within this rulemaking. Additionally, this will permit existing inventories of labels and packaging materials to be exhausted.

Summary of Comments: A commenter observed that the preliminary economic impact analysis of costs on the fish and seafood sector derive from the findings of one study, namely Sparks/CBW. This commenter stated that in the proposed rule, USDA argues that the Sparks/CBW estimates are too low without providing detailed rationale.

Agency Response: For fish and seafood producers, the Agency estimates costs per pound of \$0.0025 per pound for a total of \$19 million, compared to the Sparks/CBW total estimate of \$1 million. Fish harvesters and farmers already maintain many of the types of records sufficient to substantiate country of origin and wild caught versus farm-raised claims. For

example, it is USDA's expectation that the information contained in records typically kept by fish and shellfish harvesters and farmers will provide the necessary information to substantiate these claims. These records include but are not limited to hatching records, site maps, feeding records, vessel records, a U.S. vessel identification number, spawning records, and import permits. Additional examples of the types of records that may be used to substantiate origin and method of production claims will appear in the compliance guide. However, the basis for arguing higher costs is that systems need to be implemented to ensure that this information is transferred from producers to the next buyers of their products, and that the information is maintained for the required amount of time. Currently, this type of information exchange does not necessarily take place. The Agency believes that its estimated first-year implementation costs of \$241 per producer are within reason.

In the case of fish and seafood intermediaries and retailers, the Agency adopted the upper range of the Sparks/CBW estimated costs per pound. However, the Agency estimated that greater total units of fish and seafood production would be affected by mandatory COOL. In the case of both intermediaries and retailers, the Agency's preliminary estimates for fish and seafood intermediaries included canned product, while the Sparks/CBW estimates included only fresh and frozen product.

The Agency's revised estimates exclude canned product, as well as fish sticks, fish portions, and breaded shrimp, due to the change in the definition of a processed food item. In addition, Sparks/CBW estimated that one-third of fish and seafood products would move through retail, compared to the Agency's estimate that 41.4 percent of the domestic disappearance of the covered commodities would be sold through retailers covered by this rule. The Agency received no comments to refute its initial estimated share of production that would be sold through retailers covered by this rule, but the share estimates are revised to reflect the lower proportion of fish and shellfish consumed at home relative to other food products.

Summary of Comments: A commenter observed that USDA did not provide a cost comparison for development of a compliance system with the new FDA recordkeeping requirement under the Bioterrorism Act.

Agency Response: There are several reasons that the Agency did not take into consideration the requirements of the FDA rules being promulgated under the Bioterrorism Act. Of the rules proposed by FDA, only the rule relating to the establishment and maintenance of records likely would have much, if any, impact on firms' initiatives to comply with mandatory COOL. FDA's proposed rule on records maintenance is not yet final, and the Agency cannot anticipate how the final rule may

differ from the proposed rule. Also, the covered commodities beef, pork, and lamb are exempt from the FDA rulemaking as the FDA rules do not cover food regulated exclusively by USDA. Finally, as with PACA's regulations and similar existing Federal rules, the FDA rules would not require that country of origin information be provided to consumers by retailers, or that firms' in the supply chain provide country of origin information.

Summary of Comments: A commenter said that U.S. farmers will be required to absorb a majority of the costs, marginalizing any profits attributed to increased demand for U.S. commodities.

Agency Response: The Agency assumes that in the longer run, higher costs will be passed onto consumers in the form of higher prices for the covered commodities. In the short run, however, increased costs incurred by intermediaries and retailers may lead to lower demand at the farm level. Lower market demand may in turn translate into lower farm-level prices for producers.

Summary of Comments: Several commenters pointed out potential trade-restricting impacts of the proposed rule, especially for ground beef processing. One commenter noted that a meat grinder looking for product of least cost would tend to seek domestic U.S. product at the disadvantage of imported

product. Another commenter stated that the increased cost of mandatory COOL will cause suppliers to cease selling to customers in the U.S, as the cost associated with multiple sources will force distributors to source from a single country. Another commenter said that mandatory COOL will restrict trade by restricting flexibility of ground beef processors.

Agency Response: Both importers and domestic suppliers will be required to meet the requirements of the rule. In the long run, the Agency believes that firms will find efficient ways to comply with the requirements of the rule. Resulting small trade impacts as estimated by the Economic Research Service (ERS) computable general equilibrium (CGE) model stem from general increases in production costs for the covered commodities, rather than any provision of the rule.

Summary of Comments: A number of commenters stated that mandatory COOL will restrict trade. One commenter said that COOL is a nontariff trade barrier intended to discriminate against imported products on the basis of nationality.

Agency Response: As previously mentioned, both importers and domestic suppliers will be required to meet the requirements of the rule, which is meant to provide accurate information to consumers with respect to the country of origin and the method of production of the fish and shellfish products they purchase. The Agency estimates that exports of fish and shellfish will

decline slightly and imports will increase slightly after 10 years of adjustment to the rule. This is a result of increased production costs for the covered fish and shellfish commodities regardless of origin, rather than any provision of the rule.

Summary of Comments: A commenter noted that the proposed rule will make domestic seafood canners less competitive with foreign producers of low-priced imports by increasing production costs and complicating the production process. The commenter said that plants must regularly use herring that are caught in both the U.S. and Canada to provide enough supplies, and that the rule will make processing sardines in Maine less competitive.

Agency Response: Because the interim final rule does not require labeling of canned fish and seafood products, these concerns have been addressed.

Summary of Comments: A commenter stated that mandatory COOL will add costs and reduce the abilities of U.S. industries to compete in international markets.

Agency Response: The Agency agrees that mandatory country of origin labeling will add costs to the covered commodities. The Agency assumes that producers and processors of the covered commodities will seek to maintain flexibility in marketing decisions. Thus, the Agency assumes that producers and processors will incur recordkeeping and associated operational

costs to make and substantiate country of origin claims for most, if not all, of their production even though most of the product ultimately will enter channels of distribution not covered by this rule. Higher costs will be passed forward in the form of higher prices, with the result that U.S. exports of the covered commodities are expected to decline slightly after 10 years of adjustment to the rule.

Summary of Comments: A commenter observed that implementation of mandatory COOL will add costs and complexities to all covered commodities regardless of where they are marketed.

Agency Response: The Agency agrees that mandatory COOL will add costs and complexities to the covered commodities regardless of where the products ultimately are marketed. First, the Agency expects that producers and intermediaries will seek to keep their marketing options flexible, and thus will take the steps necessary to implement COOL to allow their products to be labeled and sold at retail establishments covered by this rule. Second, covered commodities for which there is no verifiable country of origin information will no longer be fully fungible. That is, these products will not be able to be sold at retail establishments covered by this rule. These products will need to be segregated in the production and marketing

chain, resulting in reduced system wide efficiency and higher costs.

Preliminary Regulatory Flexibility Analysis

Summary of Comments: A commenter said that recordkeeping and other costs of compliance will fall disproportionately on smaller, independent farmers. Another commenter noted that the position of small, independent farmers may be weakened.

Agency Response: In the initial regulatory flexibility analysis, the Agency noted that costs of implementation may be proportionately higher for smaller versus larger firms given the potential scale economies associated with the operation of systems to comply with the requirements of mandatory country of origin labeling. In particular, larger firms would have the ability to spread fixed costs of implementation over a greater number of units of production, thereby incurring lower average costs per unit. Conversely, smaller farmers and other firms may have some implementation cost advantages over larger firms. Smaller farms and firms likely have simpler recordkeeping systems, and thus would incur lower development costs relative to larger firms. The rule does not prescribe a particular recordkeeping system; so for example, a small fishing operation likely would be able to maintain records in hardcopy form rather than developing a complicated electronic recordkeeping system.

Summary of Comments: A commenter stated that USDA's suggestion that a supplier could market covered commodities to other channels illustrates that mandatory COOL is an attempt to affect some supplier market preference with a discriminatory effect against the supermarket industry.

Agency Response: The intent of mandatory COOL is not to discriminate against the retailers subject to the law and the rule. Nonetheless, some retailers are required to provide country of origin information for the covered commodities, while foodservice establishments and other retailers not subject to the rule are not required to provide such information. The Agency's suggestion makes the point that producers and intermediaries could seek regulatory relief by selling their products through alternative marketing channels. As explained in the economic impact assessment, however, the Agency assumes that producers and intermediaries will seek to provide country of origin information for virtually all of their production so as to maintain maximum marketing flexibility.

Summary of Comments: A commenter said that requiring only PACA-licensed retailers to label may provide economic incentive for retailers not to be PACA licensed. Another commenter said that the exclusion of fish markets creates an un-level playing field.

Agency Response: PACA licensing is mandatory for retailers that purchase perishable agricultural commodities with an invoice value in excess of \$230,000 in a calendar year at retail. Adoption of this definition will assure that the vast majority of covered commodities will be subject to this rule without unduly burdening small businesses.

Fish markets and other retailers not subject to mandatory COOL may have a cost advantage over retailers subject to the rule, but the law defines explicitly which retailers are required to provide country of origin information.

Summary of Comments: A commenter said that the preliminary regulatory flexibility analysis is inadequate as the proposed alternatives will not decrease the burden on small entities. Another commenter said that AMS should further study its economic analysis and consider alternatives to minimize impacts on small entities.

Agency Response: The Agency's initial regulatory flexibility analysis examined potential viable alternatives for small entities, but found relatively little discretionary authority to provide additional regulatory relief. This interim final rule decreases the length of time that records are required to be kept, providing some relief to affected entities both large and small. The number of products required to be labeled is reduced because the definition of a processed food

item has been broadened, thus providing additional regulatory relief. The Agency will prepare a compliance guide to assist firms, both small and large, to comply with the requirements of the rule.

Summary of Comments: A commenter said that it is not reasonable for market participants to sell their products through other channels not subject to the proposed rule.

Agency Response: The Agency assumes that most entities will seek to maintain maximum marketing flexibility by complying with the requirements of this rule. Nonetheless, the Agency disagrees with the assertion that it would not be reasonable for some market participants to sell their products through channels other than retailers expressly required to provide country of origin information. As detailed in the economic impact assessment, the Agency estimates that 58 percent of fresh and frozen fish and 38 percent of shellfish are eaten at home, and that 65.8 percent of that at-home consumption of the covered commodities would be sold by retailers subject to the rule. Hence, most of the domestic market (62 percent for fish and 75 percent for shellfish) does not require country of origin information for the covered commodities, which includes retailers not subject to the rule and foodservice establishments. In addition, fish and shellfish defined as

ingredients in a processed food item and export sales are not subject to the requirements of this rule.

Summary of Comments: A commenter said that the notion is flawed that the proposed rule offers flexibility because it is a performance standard rather than a design standard.

Agency Response: The Agency's conclusion is based on the notion that each firm will be able to develop its own least-cost solution for complying with the rule, rather than having to meet a rigid design standard. This continues to be the case in this interim final rule, and the Agency continues to conclude that the performance standards of the rule allow firms to comply in the most cost effective way for their operations. Nonetheless, retailers, processors, and other affected firms may develop differing requirements for their suppliers. The Agency will issue a compliance guide to assist market participants in complying with the requirements of the rule.

Summary of Comments: A commenter questioned the assertion in the preliminary regulatory flexibility analysis that number of affected small entities is significantly reduced by the PACA definition of retailer.

Agency Response: The Agency disagrees with this comment. As detailed in the preliminary regulatory flexibility analysis, there were 67,916 food stores, warehouse clubs, and superstores operated the entire year according to the 1997 Economic Census,

and 66,868 of these firms are small. Based on PACA data, the Agency estimates that 4,512 retailers would be subject to this rule, with 3,464 of these being small. Thus, 63,404 smaller retailers, or 94.8 percent of all small food store retailers would not be affected. These are estimates of the number of firms and not the number of establishments. The Small Business Administration defines size standards based on the size of the business or firm, not the size of the establishments operated by the firm.

The Agency recognizes that all producers and intermediaries choosing to sell through marketing channels supplying the covered retailers would need to meet the requirements of the rule. The Agency did not assert that the number of small entities in these sectors would be reduced by the definition of a retailer. As noted previously, however, the majority of the sales of the covered commodities are through channels not affected by this rule, which provides substantial marketing opportunities for product without verifiable country of origin claims.

Summary of Comments: A commenter questioned the Agency's conclusion that costs for producers will be limited and will generally include costs involved in establishing and maintaining a recordkeeping system.

Agency Response: In its preliminary regulatory impact analysis, the Agency estimated a range of implementation costs. The lower-range estimates reflected the costs of implementing and maintaining a recordkeeping system. The upper-range costs reflected additional operational costs that would be incurred to comply with the rule. In the preliminary analysis, the Agency concluded that direct incremental costs likely would fall in the middle to upper end of the estimated range. In the interim final regulatory impact analysis, the Agency presents a single cost estimate to reflect its conclusion that costs for affected entities will be higher than the preliminary lower-range costs for recordkeeping activities alone.

Summary of Comments: A commenter said that the Agency should expand its analysis to take into consideration that the rule will likely impact all entities along the supply chain, not just those PACA licensed retailers.

Agency Response: The Agency's initial regulatory impact and regulatory flexibility analyses considered all potentially affected firms, from producer through intermediaries through retailers subject to this rule.

Summary of Comments: A commenter stated that the flexibility provided is not particularly helpful to small entities.

Agency Response: The Agency has provided as much regulatory relief for small entities as possible, within the limits of the discretionary authority provided by the law. The requirements of the rule flow from the law that requires retailers to inform consumers of the country of origin of the covered commodities. Information must flow throughout the supply chain to enable retailers to provide the required information to consumers, regardless of the size of the businesses participating in the supply chain. To ensure compliance and integrity of the program, the Agency has determined that these claims must be supported by a recordkeeping trail that can be audited.

Summary of Comments: A commenter noted that the Small Business Regulatory Enforcement Fairness Act requires publication of a compliance guide that explains the rule, provides compliance scenarios to illustrate and clarify any complexities, lessens small businesses' anxiety about complying with the rule, and provides suggestions on how to structure data collection and recordkeeping systems.

Agency Response: The Agency will develop a compliance guide to assist firms in complying with the rule.

Preliminary Paperwork Reduction Act

Summary of Comments: A commenter stated that wholesalers will have to develop new recordkeeping systems and that

substantial labor costs will be incurred because wholesalers are responsible for tracking the identity of both the prior seller and the subsequent buyer.

Agency Response: In the proposed rule, the Agency estimated the initial costs associated with recordkeeping, which includes the costs of maintaining country of origin information of the covered commodities purchased and subsequently furnishing that information to the next participant in the supply chain. For products that are not pre-labeled, this action would require adding information to a firm's bills of lading, invoices, or other records associated with movement of covered commodities from purchase to sale. The Agency believes that most wholesalers already have functioning recordkeeping systems and will require only modification of existing recordkeeping systems rather than the development of new systems. The Label Cost Model developed for FDA is used to estimate the cost of including additional country of origin information to an operation's records. The costs of labor in establishing and maintaining these records are included in these cost estimates. The Agency concludes that these costs will be substantial and will involve substantial labor costs.

Summary of Comments: A commenter strongly disagrees with the assumption that the recordkeeping for retailers and others will be accomplished primarily by electronic means. According

to the commenter's survey, 75 percent of retailers and wholesalers would have to keep manual records.

Agency Response: The Agency has made a number of visits to retailer and wholesaler facilities. Retailers covered by this rule must meet the definition of a retailer as defined by PACA. 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. Most small food store firms, which may keep manual records, have been excluded from mandatory COOL based on the PACA definition of a retailer. The Agency believes that most wholesalers and retailers covered by mandatory COOL already have established electronic recordkeeping systems and will only require the modification of existing recordkeeping systems rather than the development of new systems. Conceptually, the task of modifying a paper-based recordkeeping system is no different than the task of modifying an electronic recordkeeping system. Therefore, the Agency believes that its estimation represents a reasonable approximation of the variety of solutions that firms will undertake to comply with the rule.

Summary of Comments: A commenter said that if USDA is using the "FDA one pager" as a model, USDA should make it public and publish it in the Federal Register.

Agency Response: A more complete discussion of the Label Cost Model is available in the FDA proposed rule on "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (68 FR 25187).

Summary of Comments: A commenter noted that USDA uses contradictory assumptions—on the one hand USDA says industry will do electronic recordkeeping and on the other it bases cost estimates on a paper-based system.

Agency Response: As noted previously, the Agency believes that the task of modifying a recordkeeping system is similar conceptually regardless of whether the system is electronic or paper based. Therefore, the Agency believes that its approach to estimating costs adequately represents the variety of recordkeeping systems currently in place.

Summary of Comments: A commenter said that USDA has wrongly decreased the estimated recordkeeping costs for intermediaries like wholesalers (from the recordkeeping burden estimated for the voluntary guidelines).

Agency Response: In response to the estimated PRA burden published for the voluntary country of origin labeling guidelines, the Agency received numerous comments on its estimated costs and the number of enterprises impacted by the guidelines. As a result, the Agency carefully reconsidered its

estimates in preparing the preliminary paperwork burden estimate for the proposed rule. As a result of these revisions, the Agency has refined its estimates of the numbers of affected entities and the costs per entity. In addition, a further improvement from the voluntary country of origin recordkeeping cost estimates is the use of Bureau of Labor Statistics wage rates for tasks required by producers, distributors, handlers, packers, processors, wholesalers, and retailers for recordkeeping. Similarly, a more appropriate estimate is added to the wage rate to account for total benefits. All of this resulted in the reduction of the total estimated recordkeeping costs under mandatory COOL in comparison to the voluntary guidelines, and the Agency believes this is a more accurate assessment.

Summary of Comments: A commenter said that the assumed administrative hourly rate of \$16.05 ignores supervisory, professional, and management time required at the wholesale and retail level. This commenter further stated that if overhead costs are to equate fringe benefits, the rate should be 30-35 percent, not 25 percent.

Agency Response: The Agency believes that the administrative support occupations category represents a reasonable composite of the labor skills that will be involved in recordkeeping activities for wholesalers and retailers. The

Agency believes these responsibilities would be assumed under the current supervisory and management structure. For handlers, processors, wholesalers, and other intermediaries as well as retailers the Agency believes the maintenance activities for recordkeeping will include inputting, tracking, and storing country of origin information for each covered commodity. While the Agency acknowledges that supervisory and management input will be required, the Agency also notes that some labor will be supplied by workers receiving lower wages. In some of our visits to retailers, it was indicated that these firms were employing more high school and college students than in the past to reduce their costs.

Bureau of Labor Statistics (BLS) data are used for both the wage and for overhead costs (which include social security, unemployment insurance, workers compensation, and other benefits). In this interim final rule, the wage rates and fringe benefits rate are both updated to 2002 BLS figures, which results in increased wage rates and benefits. The Agency believes this is the most accurate and documented estimate of wages and additional employer paid benefits.

Summary of Comments: A commenter said that USDA has underestimated the number of hours needed for recordkeeping, noting that one hour per week for wholesalers is too low because

it will take more than one hour per day. This commenter also stated that one hour per day for retailers is also too low.

Agency Response: For fish and seafood wholesalers, the Agency estimates the maintenance burden for country of origin recordkeeping to be 52 hours per year per establishment, or one hour per week. The Agency recognizes that some of these wholesalers may require more than one hour a week to maintain country of origin information. However, a number of smaller wholesalers and those that do not operate continuously throughout the year will likely require less than an average of one hour per week. Therefore, the Agency believes an average of one hour per week per establishment is a reasonable estimate for these wholesalers. In the case of general line grocery wholesalers, the Agency reduced the maintenance burden from 52 to 12 hours annually per establishment because fish and shellfish represent only a portion of the commodities handled by these establishments.

Taking into account Agency reviews of retailers' operations, the Agency believes that an additional hour of recordkeeping activities for country of origin information will be incurred daily at each retail establishment. The Agency's estimate of one hour per day for retailers is only for the maintenance portion of the recordkeeping of country of origin information. Maintenance activities will include inputting,

tracking, and storing country of origin information for each covered commodity.

In summary, this interim final rule adopts the fish and shellfish provisions of the October 30, 2003, (68 FR 61944) proposed rule with the changes discussed herein and with other changes made for purposes of clarity and accuracy.

III. Impact Analysis

Executive Order 12866 - Interim Final Regulatory Impact Analysis

USDA has examined the economic impact of this interim final rule as required by Executive Order 12866. In its Preliminary Regulatory Impact Assessment (PRIA), USDA determined that the regulatory action was economically significant, as it was likely to result in a rule that would have an annual effect on the economy of \$100 million or more. Although the estimated annual effect on the economy of this interim final rule for fish and shellfish is less than \$100 million, it remains an economically significant regulatory action because it would adversely affect in a material way a sector of the economy and therefore has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12866 requires that a regulatory benefit-cost analysis be performed on all economically significant regulatory actions.

This interim final regulatory impact assessment reflects revisions to the PRIA (68 FR 61952). Revisions to the PRIA were

made as a result of changes to this rule relative to the proposed rule, in responses to comments on the PRIA itself, and as a result of narrowing the scope of covered commodities affected by the rule. Specifically, this interim final rule defines covered commodities as farm-raised and wild fish and shellfish.

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

Summary of the Economic Analysis

The estimated incremental benefits associated with this interim final rule are difficult to quantify, but current information indicates that they are not likely to be large. The estimated first-year incremental costs for fish and shellfish harvesters, producers, processors, wholesalers, and retailers are \$89 million. Maintenance costs beyond the first year are expected to be lower than the combined start up and maintenance costs required in the first year. The estimated cost to the U.S. economy in higher food prices and reduced food production (deadweight

loss) in the tenth year after implementation of the rule is \$6.2 million, or about two cents per person annually based on the current U.S. population. In other words, the U.S. economy would be worse off after implementing this rule.

Note that this analysis addresses implementation of labeling requirements for fish and shellfish destined for human consumption only. Note also that this analysis does not quantify certain costs of the interim final 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 interim final rule.

USDA finds little evidence that consumers are willing to pay a price premium for country of origin labeling. USDA also finds little evidence that consumers are likely to increase their purchase of food items bearing the U.S. origin label as a result of this rulemaking. Current evidence does not suggest that U.S. producers will receive sufficiently higher prices for U.S.-labeled products to cover the labeling, recordkeeping, and other related costs. The lack of participation in voluntary programs for labeling products of U.S. origin provides evidence

that consumers currently are unwilling to pay price premiums sufficient to recoup the costs of labeling.

Statement of Need

Justification for this interim final rule remains unchanged from the PRIA. This rule is the direct result of statutory obligations to implement the COOL provisions of the Farm Bill, which amended the Act by adding Subtitle D--Country of Origin Labeling. There are no alternatives to Federal regulatory intervention for implementing this statutory directive.

The country of origin labeling provisions of the Farm Bill change current Federal labeling requirements for muscle cuts of beef, pork, and lamb; ground beef, ground pork, and ground lamb; farm-raised fish; wild fish; perishable agricultural commodities; and peanuts (hereafter, covered commodities). Under current Federal laws and regulations, COOL is not universally required for covered commodities. Provisions concerning labeling requirements for farm-raised and wild fish are provided herein. Labeling requirements for the remaining covered commodities become effective on September 30, 2006. Therefore, this rule and economic impact analysis address requirements and impacts for farm-raised and wild fish and shellfish only.

As described in the PRIA, the conclusion remains that there does not appear to be a compelling market failure argument

regarding the provision of country of origin information. Comments received on the PRIA elicited no evidence of significant barriers to the provision of this information other than private costs to firms in the supply chain and low expected returns. Thus, market mechanisms likely would lead to the provision of the optimal level of country of origin information.

Alternative Approaches

The PRIA noted that many aspects of the mandatory COOL provisions of Pub. L. 107-171 are prescriptive and provide little regulatory discretion for this rulemaking. Some commenters suggested that USDA explore more opportunities for less costly regulatory alternatives. Specific suggestions focused on methods for identifying country of origin, recordkeeping requirements, and the scope of products required to be labeled.

A number of comments on the PRIA suggested that USDA adopt a "presumption of U.S. origin" standard for identifying commodities of U.S. origin. Under this standard, only imported covered commodities would be required to be identified and tracked according to their respective countries of origin. Any covered commodity not so identified would then be considered by presumption to be of U.S. origin. A presumption of origin standard would require mandatory identification of products not of U.S. origin. The law, however, specifically prohibits USDA

from using a mandatory identification system to verify the country of origin of a covered commodity. In addition, as discussed in the proposed rule (68 FR 61944), the Agency does not believe that a presumption of U.S. origin standard provides a means of providing country of origin information that is credible and can be verified. Comments on the proposed rule did not identify how to overcome these obstacles. Thus, a presumption of U.S. origin standard is not a viable alternative.

A number of commenters suggested that USDA reduce the recordkeeping burden for the rule. In this interim final rule, the recordkeeping retention period for retailers is reduced from 7 days following the retail sale of the product to the length of time the product is on hand. In addition, the overall recordkeeping retention period for retailers and suppliers is reduced from 2 years to 1 year.

The interim final rule also "streamlines" the required recordkeeping for items that are pre-labeled (i.e., labeled by the manufacturer/first handler) with the required country of origin and method of production (wild and/or farm raised) information. Records that demonstrate the chain of custody (immediate previous source and/or subsequent recipient, as applicable) for all covered items must be maintained, but the underlying records (e.g., invoices, bills of lading, production and sales records, etc.) do not need to identify the country of

origin and method of production (wild and/or farm-raised) of these pre-labeled products. For example, if a processor labels the country of origin and method of production on a package of salmon steaks, and the salmon steaks ultimately are sold in that package at retail, then that label may serve as sufficient evidence on which the retailer may rely to establish the product's origin and method of production. Thus, the retailer's records would not need to show country of origin and method of production information for that package of salmon, but the retailer's records would need to include information to allow the source of those salmon steaks to be tracked back through the system to allow the country of origin and method of production claims to be verified at the point in the system at which the claims were initiated. Under the proposed rule, the retailer would have also have been required to identify the country of origin and method of production of the package of salmon within its recordkeeping system; the information provided on the package itself would not have been sufficient. This change in recordkeeping requirements should lessen the number of changes that entities in the distribution chain need to make to their recordkeeping systems and should lessen the amount of data entry that is required.

The interim final rule changes the definition of a processed food item such that a greater number of products are

now exempt from country of origin labeling requirements. The fewer the number of products that must be labeled, the lower are implementation and maintenance costs for many affected entities.

Analysis of Benefits and Costs

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

Benefits: The expected benefits from implementation of this rule are difficult to quantify. The Agency's conclusion remains unchanged, which is that the estimated economic benefits will be small and will accrue mainly to those consumers who desire country of origin and method of production information. There clearly is some level of interest by consumers in the country of origin of food. In addition, the Agency received numerous comments expressing an interest in labeling of fish and shellfish as wild or farm-raised. The rule will provide 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 not be large. Additional information and studies cited by commenters were of the same type identified in the PRIA--namely, consumer surveys and willingness-to-pay studies. The Agency

does not believe that these types of studies provide a sufficient basis to estimate the quantitative benefits, if any, of COOL.

A number of commenters pointed to recent food safety incidents, suggesting that mandatory COOL would provide food safety benefits to consumers. As discussed in the PRIA, mandatory COOL does not address food safety issues. Appropriate preventative measures and effective mechanisms to recall products in the event of contamination incidents are more comprehensive means of protecting the health of the entire consuming public regardless of the form in which a product is consumed or where it is purchased. In addition, foods imported into the U.S. must meet food safety standards equivalent to those required of products produced domestically.

Costs: To estimate the costs of this rule, we employed a two-pronged approach. First, we estimated implementation costs for firms in the industries directly affected by the rule. 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, but are not necessarily costs to the U.S. economy as measured by the value of goods and services that are produced. We then applied the implementation cost estimates to a general equilibrium model

to estimate overall impacts on the U.S. economy after a 10-year period of economic adjustment. The model provides a means to estimate the change in overall consumer purchasing power after the economy has adjusted to the requirements of the rule.

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

In the PRIA, we developed a range of estimated implementation costs to reflect the likely range of first-year costs for directly affected firms to comply with the proposed rule. The lower range of incremental cost estimates reflected the costs to modify and maintain current recordkeeping systems, while the upper range of estimates reflected other capital and operational costs to comply with the proposed rule. We concluded in the PRIA that costs likely would fall in the middle to upper end of the range of estimated costs. Taking into account comments received on the proposed rule and the PRIA, this interim final regulatory impact assessment presents only a single set of estimates for anticipated costs. Comments representing affected entities clearly described that compliance with the rule would require changes beyond recordkeeping alone. Thus, the revised incremental cost estimates reflect not only additional recordkeeping costs, but also additional payments by

the directly affected firms for capital, labor, and other expenses that will be incurred as a result of operational changes to comply with the rule.

First-year incremental costs for directly affected firms are estimated at \$89 million. The large change relative to the estimate of \$3.9 billion for the proposed rule is attributable to the fact that this interim final rule covers only fish and shellfish. Costs per firm are estimated at \$241 for fish and shellfish harvesters and producers, \$1,890 for intermediaries (such as handlers, importers, processors, and wholesalers), and \$12,600 for retailers.

To estimate the overall impacts of the higher costs of production resulting from the interim final rule, we used a model of the entire U.S. economy. We adjusted the model by imposing the estimated implementation costs on the directly impacted segments of the economy in a computable general equilibrium model developed by the Economic Research Service (ERS). 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 (namely, 10 years). Because the model covers the whole U.S. economy, it also 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.

This general equilibrium analysis is developed from the standpoint that only farm-raised and wild fish and shellfish products will be directly affected by the interim final rule. Implementation and economic costs for the other covered commodities are not included in this analysis. Thus, this analysis illustrates the relative scale of the overall impacts of this rule on the U.S. economy, but does not represent the impacts of mandatory COOL requirements for all covered commodities.

Note that a general equilibrium analysis differs from a partial equilibrium analysis in that a partial equilibrium analysis would examine the effects of the mandatory COOL on consumers and producers of fish and shellfish. The general equilibrium approach is a more encompassing analytic approach. However, the gains and losses to consumers and producers of fish and shellfish are not identified separately from the rest of the economy.

Annual costs to the U.S. economy in terms of reduced purchasing power resulting from a loss in productivity after a 10-year period of adjustment are estimated at \$6.2 million. Domestic production of fish and shellfish at the producer and retail levels is estimated to be lower and prices to be higher. U.S. exports of fish and shellfish are estimated to decrease,

while U.S. imports of fish and shellfish are estimated to increase.

The findings indicate that 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 fish and shellfish. Overall, however, the fish and shellfish account for a small portion of the U.S. economy and of consumers' budgets. Thus, the "deadweight" economic burden of the rule is considerably smaller than the incremental costs to directly affected firms.

Estimated impacts of this interim final rule are subject to uncertainties inherent in this type of prospective economic analysis. Firms directly affected by this interim final rule differ considerably in size and in their operational characteristics. Actual impacts on individual firms and on the overall economy resulting from the interim final rule may vary from the average estimated impacts presented herein.

The remainder of this section describes in greater detail how we developed the estimated direct, incremental costs and the overall costs to the U.S. economy.

Cost assumptions: This interim final 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 and method of production (wild and/or farm-raised) information for fish and shellfish products that they sell, and firms that supply these products to these retailers must provide them with this information. In addition, all other firms in the supply chain for the relevant fish and shellfish products are potentially affected by the rule because country of origin and method of production (wild and/or farm-raised) information will need to be maintained and transferred along the entire supply chain to enable retailers to correctly label the products at the point of final sale.

Number of firms and number of establishments affected: We estimate that approximately 125,000 establishments owned by approximately 91,000 firms would be either directly or indirectly affected by this rule. Table 1 provides estimates of the affected firms and establishments.

Table 1. Estimated Number of Affected Entities		
Type	Firms	Establishments
Fish		
Farm-Raised Fish and Shellfish	3,540	3,540
Fishing	76,499	76,452
Fresh & Frozen Seafood Processing	582	653
Fish & Seafood Wholesale	2,897	2,980
General Line Grocery Wholesalers	3,183	3,993
Retailers	4,512	37,176

Totals		
Producers	80,039	79,992
Intermediaries	6,662	7,626
Retailers	4,512	37,176
Grand Total	91,213	124,794

In contrast to the PRIA, the beef, pork, lamb, perishable agricultural commodity and peanut sectors are no longer directly affected by this interim final rule. Thus, entities in these sectors are removed from the estimated number of affected entities. In addition, the numbers of affected entities in the seafood processing industry are lowered. Canned seafood products would have required labeling under the proposed rule, but are exempt under the interim final rule because of the revised definition of a processed food item. While there may be fishing operations that harvest fish destined exclusively for canning, data on the number of such operations are unavailable. In addition, fishing vessels that target a particular species destined for canning often have a by-catch of other species that would be destined for fresh or frozen end uses. Thus, we believe that keeping the estimated number affected fishing operations unchanged is a reasonable assumption. In the PRIA, the seafood product preparation and packing industry included fresh and frozen seafood processing and seafood canning. Because the interim final rule exempts canned seafood products, the number of affected seafood processing firms is reduced from 741 to 582 and the number of establishments from 823 to 653. We

assume that all of these remaining fresh and frozen seafood processing firms prepare at least some covered commodities, although there may be some firms that prepare fish and shellfish exclusively into items that would be exempt from this rule under the definition of a processed food item. For example, a firm that produces only breaded shrimp would not be subject to the requirements of this interim final rule.

We assume that all firms and establishments identified in Table 1 will be impacted 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, we believe 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, we reviewed the comments received on the voluntary guidelines (67 FR 63367), the comments received on the proposed rule for mandatory COOL (68 FR 61944), and available economic studies. No single source of information, however, provided comprehensive coverage of all economic benefits and costs associated with mandatory COOL. We applied available information and our knowledge about the operation of the supply chains for the covered commodities to synthesize the

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

Cost drivers: This interim final rule is a retail labeling requirement. Retail stores subject to this rule will be required to inform consumers as to the country of origin and method of production (wild and/or farm-raised) of the covered fish and shellfish products 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 method of production (wild and/or farm-raised) information through other point-of-sale materials. This may require additional retail labor and personnel training. A recordkeeping system will be required to ensure that products are labeled accurately and to permit compliance and enforcement reviews. For most retail firms of the size defined by the statute (i.e., those retailing fresh and frozen fruits and vegetables with an invoice value of at least \$230,000), we assume that recordkeeping will be accomplished primarily by electronic means. Modifications to recordkeeping systems will require software programming, but in most cases should not entail additional computer hardware. We expect that retail stores will also undertake efforts to ensure

that their operations are in compliance with the interim final rule.

Prior to reaching retailers, most covered fish and shellfish products move through distribution centers or warehouses. Direct store deliveries are an exception. Distribution centers will be required to provide retailers with country of origin and method of production (wild and/or farm-raised) information. This will require additional 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 method of production (wild and/or farm-raised) information through the distribution system. There may be a need to further segregate products within the warehouse, add storage slots, and alter product stocking, sorting, and picking procedures.

Processors of covered fish and shellfish products will also need to inform retailers and wholesalers as to the country of origin and 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 method of production (wild and/or farm-raised) of the products that they sell. Maintaining country of origin and method of

production (wild and/or farm-raised) identity through the processing phase is more complex if products from more than one country or from more than one method of production are involved. For example, the identity of wild shrimp from the U.S. and farm-raised shrimp from Thailand entering the same processing facility would need to be maintained throughout the packing operation. The efficiency of operations may be affected if products are segregated in receiving, storage, processing, and shipping operations. For processors handling products from multiple origins, there may also be a need to 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 method of production (wild and/or farm-raised) information is retained throughout the process and to permit compliance and enforcement reviews.

Processors handling only domestic origin products or products from a single country of origin and a single method of production may have lower implementation costs compared with processors handling products from multiple origins and methods of production. A processor that already sources products from a single country would not face additional costs associated with product segregation and tracking, provided that the products also have the same method of production (wild or farm-raised).

Procurement costs also may be unaffected in this case, if the processor is able to continue sourcing products from the same suppliers. Alternatively, a processor that currently sources products from multiple countries may choose to limit its source to a single country to avoid costs associated with product segregation and tracking. In this case, such cost avoidance would be partially offset by 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, and having the same method of production, whether wild or farm-raised.

At the production level, fish producers and harvesters will need to create and maintain records to establish country of origin and method of production (wild and/or farm raised) information for the products they sell. Country of origin and method of production (wild and/or farm-raised) information will need to be transferred to the first handler of their products, and records sufficient to allow the source and method of production of the product to be traced back will need to be maintained as the products move through the supply chains. In general, additional producer and harvester costs include the cost of establishing and maintaining a recordkeeping system for

country of origin and method of production (wild and/or farm-raised) information, product identification, and labor and training.

Incremental cost impacts on affected entities: To estimate direct costs of this rule, we focus on units of production that are impacted (Table 2). Relative to the PRIA, estimated quantities are reduced for fish and shellfish at the intermediary and retailer levels.

Table 2. Estimated Annual Units of Fish and Shellfish Production Affected by Mandatory Country of Origin Labeling		
	Million Pounds	
Producer		7,707
Intermediary		
Fresh and Frozen Fish:		
U.S. Food Disappearance	1,617	
Adjustments for Fish Sticks & Portions:		
U.S. Production	-232	
Imports	-16	
Exports	5	
Adjusted Subtotal	1,374	
Fresh and Frozen Shellfish:		
U.S. Food Disappearance	1,304	
Adjustments for Breaded Shrimp:		
U.S. Production	-152	
Imports	-7	
Adjusted Subtotal	1,145	
Total, Intermediary		2,519
Retailer		
At-Home Consumption		
Fish	797	
Shellfish	435	
Total	1,232	
Total, Affected Retailers		811

For fish producers, production is measured by round weight (live weight) pounds of fish, except mollusks, which excludes the weight of the shell. Wild caught fish and shellfish production is measured by U.S. domestic landings for fresh and frozen human food. The PRIA estimate inadvertently omitted landings of fish for canned human food, which would have required labeling under the proposed rule. Canned fish, however, is exempt from this interim final rule. We assume 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. Total estimated fish production is unchanged from the PRIA.

We assume that all sales by intermediaries such as handlers, packers, processors, wholesalers, and importers will be impacted by the rule. Although some product is destined exclusively for foodservice or other channels of distribution not subject to the interim final rule, we assume that these intermediaries will seek to keep their marketing options open for possible sales to subject retailers. Among other adjustments, fish and shellfish production at the intermediary level is reduced by 1.2 billion pounds from the PRIA estimate to account for the removal of canned fish and shellfish (Ref. 1).

Further adjustments to intermediary volume are made to remove other major categories of products exempt from labeling -

fish sticks, fish portions, and breaded shrimp. Fish sticks and portions are shaped masses of cohering fish flesh, and are thus defined as a processed food item. The volume of affected fish production is computed separately from shellfish production. As shown in Table 2, U.S. disappearance of fresh and frozen fish is estimated at 1,617 million pounds in 2001 (Ref. 1), which includes imports but excludes exports. This figure is reduced by the estimated U.S. production of fish sticks and portions (232 million pounds, Ref. 2) and by imports of fish sticks (16 million pounds, Ref. 3), as these items would be exempt from the requirements of this rule. Exports of fish sticks (5 million pounds, Ref. 3) are added back to U.S. production to estimate net U.S. supplies of these exempt products (i.e., domestic production plus imports minus exports). Similar calculations are applied to fresh and frozen shellfish to account for breaded shrimp. In the case of shellfish, however, U.S. trade data (Ref. 3) do not identify exports of breaded shrimp. Accordingly, exports of breaded shrimp are treated as zero for purposes of the calculations shown in Table 2.

PRIA estimates of the volume of affect product at the retail level are revised to reflect changes in the definition of a processed food item and to improve the accuracy of the estimates. First, estimated fish and shellfish retailer volume is reduced by 493 million pounds from the PRIA estimate to

remove canned fish and shellfish (Ref. 1, which is exempt from the requirements of this rule under the revised definition of a processed food item. Second, revised factors are used to estimate the volume of product requiring labeling at retailers subject to this rule.

In the PRIA, food disappearance figures were multiplied by 0.414 to represent the estimated share of production sold through retailers covered by the proposed rule. To derive this share, the factor of 0.629 was used to remove the 37.1 percent food service quantity share of total food in 2002. This factor was then multiplied by 0.658, which was the share of sales by supermarkets, warehouse clubs and superstores of food for home consumption in 2002. In other words, we assumed supermarkets, warehouse clubs and superstores represent the retailers as defined by PACA, and these retailers were estimated to account for 65.8 percent of retail sales of the covered commodities.

Compared to other food products, greater proportions of fish and shellfish are eaten away from home, and smaller proportions are eaten at home. We estimate that 58 percent of fresh and frozen fish and 38 percent of shellfish are eaten at home. These proportions are based on estimated at-home and away-from-home the National Seafood Consumption Survey conducted by the National Marine Fisheries Service (Ref. 4). Based on these percentages, at-home consumption is estimated at 797

million pounds for covered fresh and frozen fish products and 435 million pounds for covered shellfish products (Table 2). Total at-home consumption of covered fresh and frozen shellfish products is estimated at 1.2 billion pounds. As in the PRIA, 65.8 percent of at-home consumption is estimated to be sold by retailers subject to this rule. As a result, the total volume of fresh and frozen fish and shellfish products affected by this rule is estimated to be 811 million pounds at retail. Total fish and shellfish volume at retail is thus reduced 891 million pounds from the PRIA estimate.

Table 3 summarizes the direct, incremental costs that we believe firms will incur during the first year as a result of this interim final rule. These estimates are derived primarily from the available studies that addressed cost impacts of mandatory COOL, coupled with our estimates of the volume of affected production at each level of the supply chain.

Table 3. Estimates of First-Year Implementation Costs for Fish and Shellfish, per Affected Industry Segment

	<i>Million dollars</i>
Producer	19
Intermediary	13
Retailer	57
Total	89

Assumptions and procedures underlying the cost estimates are described fully in the discussion of the upper range

estimates presented in the PRIA. Changes from the PRIA estimates are highlighted herein.

As in the PRIA (68 FR 61952), we estimate costs to fish and shellfish producers at \$0.0025 per pound. Total costs for fish and shellfish producers are thus estimated at \$19 million, unchanged from the PRIA upper range estimate. As mentioned previously, the PRIA estimated of fish landings inadvertently omitted U.S. domestic landings used for canned human food. Thus, the estimated volume of fish is unchanged at the producer level even though the interim final rule now exempts canned fish. With the same estimate of the number of affected producers, the estimated cost per producer remains unchanged.

Consistent with the PRIA (68 FR 61952), we adopt \$0.005 per pound as an estimate of costs for intermediaries in the fish and shellfish sector. Processors will need to collect country of origin and method of production (wild and/or farm-raised) information from producers, maintain this information, and supply this information to other intermediaries or directly to retailers. In addition, there may need to be segregation of the product before and after processing to facilitate tracking of country of origin and method of production (wild and/or farm-raised) identity. There will also be labeling costs associated with providing country of origin and method of production (wild and/or farm-raised) information on consumer-ready packs of

frozen and fresh fish that are labeled by processors. Total costs for fish and shellfish intermediaries are thus estimated at \$13 million, a reduction of \$8 million from the upper range PRIA estimate. The reduction is attributable to the lowered estimate of the volume of production affected by the rule.

As discussed in the PRIA (68 FR 61952), we adopt \$0.07 per pound as an estimate of costs for retailers of fish and shellfish. This estimate results in total costs of \$57 million for retailers of fish and shellfish, a reduction of \$62 million from the PRIA upper range estimate. As with intermediaries, the reduction stems from the lowered estimate of the volume of production affected by the rule.

Total costs for fish and shellfish are estimated at \$89 million, \$70 million less than the PRIA upper range estimate.

We estimate total incremental costs for this interim final rule of \$19 million for fish producers and harvesters, \$13 million for intermediaries, and \$57 million for retailers for the first year. Total incremental costs for all supply chain participants are estimated at \$89 million for the first year. The large reduction from the PRIA upper range estimate of \$3.9 billion is attributable to the fact that this interim final rule covers only wild and farm-raised fish and shellfish products. The proposed rule also covered beef, pork, lamb, fruits, vegetable, and peanuts.

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, producer operations are single-establishment firms. Thus, average estimated costs per firm and per establishment are the same after rounding to the nearest dollar. In contrast, retailers subject to the rule operate an average of just over eight establishments per firm. As a result, average estimated costs per retail firm also are just over eight times larger than average costs per establishment.

Table 4. Estimated First-Year Implementation Costs per Firm and Establishment

	Firm	Establishment
Producer	\$241	\$241
Intermediary	1,890	1,650
Retailer	12,600	1,530

Average estimated implementation costs per fish and shellfish producer are relatively small at \$241. Costs per fish operation are lowered slightly from the PRIA upper-range estimates due to a correction in the number of fishing operations used to calculate the average cost per operation (the estimated number of operations is unchanged from the PRIA). Estimated costs for intermediaries are substantially larger, averaging \$1,890 per firm and \$1,650 per establishment. The

average cost per firm is much less than the PRIA upper range estimated cost, with the lower cost attributable to the sharp reduction in the volume of production subject to this interim final rule. Similarly, the average cost per intermediary establishment is considerably less than PRIA the upper range estimate. At an average of \$12,600 retailers have the highest average estimated costs per firm. This is much less than the PRIA upper range estimate because of the reduction in the estimated volume of production subject to the interim final rule. Retailers also have the highest average estimated costs per establishment, \$1,530.

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.

We believe that the major cost drivers for the rule occur when covered commodities are transferred from one firm to

another, when covered commodities are commingled in the production or marketing process, and when products are assembled and then redistributed to retail stores. In part, we believe that 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 and method of production (wild and/or farm-raised) 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 plant may need to sort incoming products by country of origin and method of production (wild and/or farm-raised) in addition to weight, size, color, or other quality factors. This may require adjustments to plant operations, line processing, product handling, and storage. Ultimately, we anticipate that a mix of solutions will be implemented by industry participants to effectively meet the requirements of the rule. Therefore, we anticipate that direct, incremental costs for the interim final rule likely will fall within a reasonable range of the estimated total of \$89 million.

In the PRIA, one regulatory alternative considered by AMS would be to narrow the definition of a processed food item, thereby increasing the scope of commodities covered by the rule.

This alternative is not adopted in this interim 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 resulting from fewer exempted items may also slow some of the innovation that is occurring with various types of value-added, further processed products.

A converse 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. 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 fish and shellfish harvesters and

producers would not be affected by a change in the definition of a processed food item. This is because we assume that virtually all affected producers would seek to retain the option of selling their products through supply channels for retailers subject to the rule.

The definition of a processed food item developed for this interim final rule has taken into account comments from potentially affected entities and has resulted in excluding products that would be more costly and troublesome for retailers and suppliers to provide country of origin and method of production (wild and/or farm-raised) information. Total incremental costs for this interim final rule are estimated at \$70 million less than the upper range costs estimated in the PRIA for fish and shellfish because of the exemption of canned items under the revised definition of a processed food item.

Another alternative considered by AMS would be to require that suppliers provide an affidavit for each transaction to the immediate subsequent recipient certifying that the country of origin and method of production (wild and/or farm-raised) claims being made are truthful and that the required records are being maintained. We do not have an estimate of the number of transactions that would be impacted. Assuming, however, costs of just \$0.001 per pound of product sold by producers and intermediaries, and assuming that commodities are transferred at

least twice between intermediaries, costs for fish and shellfish would increase by nearly \$13 million, or almost 15 percent, compared to the alternative of having no affidavits. Taking into consideration probable cost impacts, comments received on the proposed rule, and the structure and needs of the industry, we rejected this alternative.

Effects on the economy: The previous section estimated the direct, incremental costs of the interim final 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 U.S. 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 do not represent losses to the economy but rather transfers of money from one economic agent to another. As a result, the direct costs incurred by the participants in the supply chains for the covered commodities do not measure the impact of this

rule on the economy as a whole. Instead, the relevant measure is the extent to which the interim final rule reduces the amount of goods and services that can be produced throughout the U.S. 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 bear the full cost of implementing the interim final rule. However, over time as the economy adjusts to the requirements of the interim final rule, the burden facing suppliers will be reduced as their production level and the prices they receive change. What is critical in assessing the 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 this 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 U.S. 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 U.S. economy in a global context, we utilized a computable general equilibrium (CGE) model developed by ERS. In the PRIA, the ERS CGE model includes all the covered commodities and the products from which they are derived, as well as non-covered commodities that would be indirectly affected by the proposed rule, such as poultry and feed grains. For purposes of this interim final rule, the same model structure is used, but direct, incremental cost increases are assumed to occur for fish and shellfish products only.

The ERS CGE model traces the impacts from an economic "shock," in this case an incremental increase in operating costs, 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 U.S. and world economies, a comprehensive assessment can be made of the economic impact on the U.S. economy of the rule implementing COOL. The model reports resulting economic changes after a ten-year period of adjustment.

The results of this analysis indicate that the interim final rule implementing COOL after the economy has had a period of ten years to adjust will have a more limited impact on the overall U.S. economy than the direct costs for the first year, alone, would suggest. Under the assumption that COOL will not change consumers' preferences for the covered fish and shellfish commodities, we estimate that the overall costs to the U.S. economy of the interim final rule, in terms of a reduction in consumers' purchasing power, will be \$6.2 million. This represents the cost to the U.S. economy after all transfers and adjustments in consumption and production patterns have occurred.

Overall costs to the U.S. economy after a decade of adjustment are significantly smaller than the first-year 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. Prior to full economic adjustment, economic impacts on directly affected firms in the short term are expected to be larger than impacts on the economy after adjustment has taken place.

Our estimates of the overall costs to the U.S. economy are based on our 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 and method of production 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 5 reports these adjusted estimates in terms of their percentage of total operating costs for each of the directly impacted sectors. The percentages used are based on our estimate of the percentage change in operating costs for the entire supply channel and are adjusted between the various segments of the fish and shellfish supply chain (harvesters and producers, processors, importers, and retailers) based on our estimate of how the costs of the regulation will be distributed among them. As a result, the cost changes shown in

Table 5 only approximate the direct cost estimates previously described.

Table 5. Estimated Increases in Fish and Shellfish Industry Operating Costs by Supply Chain Segment		
		Percent change
Farm Supply	Domestic	0.6
	Imported	0.6
Processing	Domestic	(¹)
	Imported	(¹)
Retail	Domestic	0.4
	Imported	0.4
¹ Due to the structure of the model, costs increases for the processing segment are included in the retail segment.		

In addition, we assume that domestic and foreign suppliers of the affected commodities located at the same level or segment of the supply chain face the same percentage increases in their operating costs. In reality, imported covered commodities likely would enjoy some measure of competitive advantage as a portion of those products already enter the United States with country of origin labels. Labeling and country of origin notification necessary to satisfy existing U.S. Customs and Border Protection requirements could be used to implement the country of origin requirements of this rule, but importers also would need to provide method of production information (wild and/or farm-raised) for covered fish and shellfish commodities destined for retail.

The percentage changes in operating costs reported in Table 5 differ from the percentage changes in operating costs reported for the High Cost scenario as listed in Table 8 in the PRIA. The differences in percentage changes reported in the PRIA and those reported here are attributable to changes in implementation costs of the interim final rule as well as recalibration of our estimates of total operating costs for the various segments of the supply channels of the directly impacted sectors.

As discussed above, consumption and production patterns will change as the incremental increases in operating costs outlined above are passed on, at least partially, to consumers in the form of higher prices by the affected firms. The increases in the prices of the covered fish and shellfish commodities will in turn cause exports and domestic consumption and ultimately domestic production to fall.

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

Table 6 contains the percentage changes in prices, production, exports, and imports for the three main segments of the marketing chain for fish and shellfish. Results for potential substitute products are not shown in Table 6 because impacts of the interim final rule on these products are estimated to be minimal. Percentage changes in U.S. production, prices, exports, and imports of cattle and sheep, broilers, hogs, beef and lamb, chicken, and pork are estimated to be 0.001 percent or less. Because of the negligible impacts on these other commodities, Table 6 shows results for fish and shellfish only.

Table 6. Estimated Impact of Interim Final Rule on U.S. Production, Prices and Trade of Fish and Shellfish	
Item	Percent Change from the Base Year
Price	0.36
Production	-0.46
Exports	-0.56
Imports	0.18

The rule increases operating costs for the supply chains for the covered fish and shellfish commodities. As shown in Table 6, the increased costs result in higher prices for these products. The quantity demanded at these higher prices falls, with the result that the U.S. production of fish and shellfish decreases.

Demand for U.S. fish production is particularly sensitive to increases in prices in the model, suggesting that U.S. fish suppliers face a degree of competitive disadvantage relative to

their foreign counterparts. As a result, fish imports increase as a result of the estimated cost increases, while U.S. production to falls. Evidently, U.S. domestic suppliers of fish respond more to changes in their operating costs than do foreign suppliers. The resulting gap between the supply response of U.S. and foreign producers provides foreign suppliers of fish with a competitive advantage in U.S. markets that enables them to increase their exports to the U.S. even though they face similar increases in operating costs.

To put these impacts in more meaningful terms, the percentage changes reported in Table 6 were converted into changes in current prices and quantities produced, imported, and exported (Table 7). The base values in Table 7 differ from those reported in Table 2 above because they are derived from projected levels reported in the USDA Agricultural Baseline for 2003, while values in Table 2 represent actual reported values for 2002 as compiled by USDA's National Agricultural Statistical Service. Baseline values were used to accommodate the structure of the model.

Table 7. Estimated Changes in U.S. Production, Prices, and Trade for Fish and Shellfish

Indicator	Units	Base	Change
U.S. Production^a	Mil. Lbs.	10,204	-46.94
U.S. Price^b	\$/Lb.	0.41	0.0015
U.S. Exports	Mil. Lbs.	2,565	-14.36
U.S. Imports	Mil. Lbs.	4,102	7.38

Sources: Changes are derived from applying percentage changes obtained from

the ERS CGE model to the base values. ^aBase values for fish come from Fisheries of the United States, 2001. National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 2002. ^bFish price derived by dividing total value of commercial and aquaculture production, excluding other, by total commercial and aquaculture production.

U.S. prices for covered fish and shellfish commodities increase by a very small amount, less than two-tenths of a cent per pound. U.S. production declines by 47 million pounds. The estimated changes in prices and production cause revenues for the fish industry to fall by \$4 million. The increase in the price of the affected fish and shellfish commodities cause exports to decline by about 14 million pounds. Imports of fish and shellfish increase and as costs imposed on importers are relatively less than those imposed on domestic producers.

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, for example, 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 interim final rule on the United States are based on the assumption that country of origin and method of production (wild and/or farm-

raised) labeling does not shift consumer demand toward the covered fish and shellfish commodities of U.S. 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 U.S. products. An increase in the demand for commodities of U.S. origin increase would have to occur to offset the costs imposed on the economy by the interim final rule.

As previously mentioned, our estimates of the overall economic effects of the interim final 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). In reality, 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. In addition, these results assume that the only changes that are occurring in the agriculture sector or the economy as a whole are those that are driven by COOL. 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 U.S. economy and capture the direction of the changes.

The ERS CGE model is global in the sense that all regions in the world are covered. Production and consumption decisions in each region are determined within the model following behavior that is consistent with economic theory. Multilateral trade flows and prices are determined simultaneously by world market clearing conditions. This permits prices to adjust to ensure that total demand equals total supply for each commodity in the world.

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

The model is static and this implies that gains (or losses) from stimulating (or inhibiting) investment and productivity growth are not captured. The model allows the existing resources to move among sectors, thereby capturing the effects of re-allocation of resources that results due to policy changes. However, because the model fixes total available resources it underestimates the long-run effects of policies on aggregate output.

Regulatory Flexibility Analysis

This interim final 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 interim final regulatory analysis of the rule's likely economic impact on small entities pursuant to the RFA. The Comments and Responses section lists the comments received on the preliminary RFA and provides the Agency's responses to the comments.

The interim final rule is the direct result of statutory obligations to implement the COOL provisions of the Farm Bill, which amended the Act by adding Subtitle D--Country of Origin Labeling. The COOL provisions of the Farm Bill require covered fish and shellfish commodities to be labeled beginning September 30, 2004. 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 included in this interim final rule are farm-raised fish and shellfish and wild fish and shellfish.

Under preexisting Federal laws and regulations, COOL is not universally required for the commodities covered by this rule. In particular, labeling of U.S. origin and method of production (wild and/or farm-raised) 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 interim final 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 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 interim final rule provides flexibility in allowing market participants to decide how best to implement mandatory COOL in their operations. Market participants other than those retailers defined by the statute may decide to sell products through marketing channels not subject to the rule. Taking into account comments received on

the proposed rule, the interim final rule decreases the length of time that records are required to be kept, providing some relief to affected entities both large and small. A complete discussion of the information collection and recordkeeping requirements and associated burdens appears in the Paperwork Reduction Act section below. In addition, the number of products required to be labeled is reduced because the definition of a processed food item has been broadened, thus providing additional regulatory relief.

The objective of the interim final 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 interim final rule requires retailers to provide country of origin and method of production (wild and/or farm-raised) information for all of the covered fish and shellfish 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 and method of production (wild and/or farm-raised) information will need to be maintained and transferred along the entire supply chain. In general, the supply chains for the covered fish and shellfish

commodities consist of farms, fishing operations, processors, wholesalers, and retailers. A listing of the number of entities in the supply chains for the covered fish and shellfish commodities can be found in Table 1 above in the Interim Final Regulatory Impact Analysis (IFRIA).

Retailers covered by this interim final rule must meet the definition of a retailer as defined by PACA. The PACA definition includes only those retailers handling fresh and frozen fruits and vegetables with an invoice value of at least \$230,000 annually. Therefore, the number of retailers impacted 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 interim final rule.

Because country of origin and method of production (wild and/or farm-raised) information will have to be passed along the supply chain and made available to consumers at the retail level, we assume 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, we assume that all such entities will be affected to some extent even though some fish and shellfish harvesters, producers and suppliers may choose to

market their products through channels not subject to the requirements of this interim final rule. Therefore, we estimate that nearly 125,000 establishments owned by approximately 91,000 firms will be either directly or indirectly impacted by this rule. Changes from the PRIA are reductions in the numbers of affected firms and establishments due to the exclusion of covered commodities other than wild and farm-raised fish and shellfish in this interim final rule.

This interim final 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 fish and shellfish harvesters and producers is likely to be relatively small.

As shown in Table 3 and discussed in the *Costs* section of the IFRIA, we estimate direct incremental costs for the interim final rule at approximately \$89 million. The decrease in the direct incremental cost in the interim final rule as compared to the proposed rule is the result of excluding commodities other than fish and shellfish from this interim final rule. In addition, broadening the definition of a processed food item

exempts items such as canned fish and shellfish, fish sticks, and breaded shrimp from the labeling requirements of the rule.

There are two measures used by the Small Business Administration (SBA) to identify businesses as small: sales receipts or number of employees. In terms of sales, SBA classifies as small those grocery stores with less than \$23 million in annual sales and specialty food stores with less than \$6 million in annual sales (13 CFR 121.201). Warehouse clubs and superstores with less than \$23 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 impacted by the interim final 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 82.5 percent of all food consumed at home (Ref. 5). Therefore, the number of these stores provides an indicator of the number of entities *potentially* impacted by this interim final rule. The 1997 Economic Census (Ref. 6) shows there were

67,916 food store, warehouse club, and superstore firms operated for the entire year. Most of these firms, however, would not be subject to the requirements of this interim final rule.

Retailers covered by this interim final rule must meet the definition of a retailer as defined by PACA. The number of such businesses is estimated from PACA data (Ref. 7). A PACA license is required for all retailers having an invoice cost of fresh and frozen fruits and vegetables exceeding \$230,000 in a calendar year. Licensee data is entered and maintained in USDA's PACA database. Among other required information, the PACA license application includes the name of the business and the number of branches where the business handles fruits and vegetables. In the case of retailers, most branch locations represent retail stores. There is an active USDA compliance program to ensure compliance with licensing requirements, and the industry is monitored to keep the licensing data current when there are changes in firms' operations (such as the opening of new branch locations). Thus, the PACA data provide a reliable estimate of the number of retail firms that would be affected by this regulatory action.

Because 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, the number of retailers impacted by this rule is considerably smaller than

the number of food retailers nationwide. USDA data indicate that there are 4,512 retail firms as defined by PACA that would thus be subject to the interim final rule. As explained below, most small food store firms have been excluded from mandatory COOL based on the PACA definition of a retailer.

The 1997 Economic Census data provide information on the number of food store firms by sales categories. Of the 67,916 food store, warehouse club, and superstore firms, we estimate that there are 66,868 firms with annual sales meeting the SBA definition of a small firm and 1,048 other firms. 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 1,048 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, we estimate that 77 percent (3,464 out of 4,512) of the retailers subject to the interim final rule are small. However, this is only 5.2 percent of the estimated total number of small food store retailers. In other words, an estimated 94.8 percent of small food store retailers would not be subject to the requirements of this interim final rule.

As discussed in the *Costs* section of the IFRIA, we estimate retailer costs under this interim final rule at approximately \$57 million (Table 3). Costs are estimated at \$12,600 per retail firm and \$1,530 per retail establishment (Table 4). These estimated costs are lower than the PRIA upper range estimates because of the exclusion of commodities other than fish and shellfish from this interim final rule and because of the exemption of additional products under the revised definition of a processed food item.

Retailers will face recordkeeping costs, costs associated with supplying country of origin and method of production (wild and/or farm-raised) information to consumers, costs associated with segmenting products by country of origin and method of production (wild or farm-raised), and possibly additional handling costs. These cost increases may result in changes to retailer business practices, such as additional time devoted to labeling and signage needed to provide required information for products sold from in-store seafood department operations. The interim final 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 their own systems to comply with this rule. There are many ways in which the interim final rule's requirements may be met and firms

will likely choose the least cost method in their particular situation to comply with the interim final 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 method of production (wild and/or farm-raised) information so that retailers can accurately supply that information to consumers. Of wholesalers potentially impacted by the interim final rule, SBA defines those having less than 100 employees as small. Importers of covered commodities will also be impacted by the interim final rule and are categorized as wholesalers in the data.

The 2000 Statistics of U.S. Businesses (Ref. 8) provides information on wholesalers by employment size. For fish and seafood wholesalers there are a total of 2,897 firms. Of these, 2,837 firms have less than 100 employees. Therefore, approximately 98 percent of the fish and seafood wholesalers could be considered as small firms.

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. For purposes of this analysis, we assume that these general-line wholesalers handle at least some of the covered fish and shellfish commodities. Therefore, we include the number of general-line wholesale businesses among entities affected by the interim

final rule. The 2000 Statistics of U.S. Businesses provides information on general-line grocery wholesalers by employment size. There were 3,183 firms in total, and 2,983 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, 5,820 of 6,080 or 96 percent of the wholesalers are classified as small businesses. This indicates that most of the wholesalers impacted by this interim final rule may be considered as small entities as defined by SBA.

As discussed in the *Costs* section of the IFRIA, we estimate that intermediaries (importers and domestic wholesalers, handlers, and processors) will incur costs under the interim final rule of approximately \$13 million (Table 3). Costs are estimated at \$1,890 per intermediary firm and \$1,650 per establishment (Table 4). These costs are lower than the upper range costs estimated in the PRIA because of the omission of commodities other than fish and shellfish from this interim final rule and because of the revised definition of a processed food item.

Wholesalers will encounter increased costs in complying with this interim final rule. Wholesalers will likely face increased recordkeeping costs, costs associated with supplying country of origin and method of production (wild and/or farm-

raised) information to retailers, costs associated with segmenting products by country of origin and method of production (wild or farm-raised), and possibly additional handling costs. Some of the comments received from wholesalers and retailers on the proposed rule and voluntary guidelines 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. In the case of fish and shellfish, this type of change in procurement practices could extend to sourcing products having only one method of production (wild or farm-raised). These changes in business practices could lead to the further consolidation of firms in the wholesaling sector. The interim final 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 interim final 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 interim final rule.

Manufacturers: Any manufacturer that supplies retailers or wholesalers with a covered commodity will be required to provide country of origin and method of production (wild and/or farm-

raised) 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 method of production (wild and/or farm-raised) information on retail packages supplied to retailers. Of the manufacturers potentially impacted by the interim final rule, SBA defines those having less than 500 employees as small.

The 2000 Statistics of U.S. Businesses (Ref. 8) provides information on manufacturers by employment size. For seafood product preparation and packaging there is a total of 741 firms. Of these, 714 have less than 500 employees and thus, 96 percent are considered to be small firms. This indicates that most of the manufacturers of covered commodities impacted by the interim final 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 this interim final rule. Like wholesalers, manufacturers will likely face increased recordkeeping costs, costs associated with supplying country of origin and method of production (wild and/or farm-raised) information to retailers, costs associated with segmenting products by country of origin and method of

production, and possibly additional handling costs. Some of the comments received from manufacturers on the proposed rule and the voluntary guidelines indicated that they may limit the number of sources from which they procure raw products. These changes in business practices could lead to decreased operational efficiency and the further consolidation of firms in the manufacturing sector. The interim final 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 interim final rule's requirements may be met.

Producers: Harvesters and producers of the covered fish and shellfish commodities are directly impacted by this interim final rule. These harvesters and producers will more than likely be required by handlers and wholesalers to create and maintain country of origin and method of production (wild and/or farm-raised) information and transfer it to them so that they can readily transfer this information to retailers.

SBA defines a small agricultural producer as having annual receipts less than \$750,000. Based on 1998 Census of Aquaculture data (Ref. 9), we estimate that at least 90 percent of the 3,540 fish and shellfish farming operations are small. The manner in which the data are reported, however, does not

allow the precise number of small producers to be calculated. Similar information on the size of fishing operations is not known to exist. However, it is assumed that the majority of these producers would be considered small businesses. We estimate that there are 76,499 firms engaged in fishing (Refs. 8 and 10).

At the production level, fish and shellfish producers and harvesters will need to create, if necessary, and maintain records to establish country of origin and method of production (wild and/or farm-raised) 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 method of production (wild and/or farm-raised) information, product identification, and labor and training. Based on our knowledge of the affected industries as well as comments received on the proposed rule and the voluntary guidelines, we believe that producers and harvesters already have much of the information available that could be used to substantiate country of origin and method of production (wild and/or farm-raised) claims.

The costs for producers and harvesters are expected to be relatively limited and should not have a larger impact on small producers than large producers. As discussed in the *Costs*

section of the IFRIA, producer costs are estimated at \$19 million (Table 3), or an estimated \$241 per firm (Table 4). In the case of producers, the firm and the establishment are considered as one and the same, with the exception of a small number of fishing operations. Thus, costs per firm and per establishment are the same after rounding to the nearest dollar.

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 interim final 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 impacted if products are segregated in receiving, storage, processing, and shipping operations. For processors handling products sourced from multiple countries and multiple methods of production (wild and/or farm-raised), there may also be a need 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 method of production (wild and/or farm-raised) information is retained throughout the process and to permit compliance and enforcement reviews. A complete discussion of the recordkeeping

burden associated with this rule is contained in the Paperwork Reduction Act section below.

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. In the case of fish and shellfish, such "single-sourcing" of products extends to method of production (wild or farm-raised) in addition to 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, and with a particular method of production (wild or farm-raised).

These additional costs may result in a number of consolidations within the processor, manufacturer, and wholesaler sectors for these covered fish and shellfish commodities. Also, to comply with the interim final rule, retailers may seek to limit the number of entities from which they purchase covered commodities as a means to simplify recordkeeping and labeling tasks.

Additional alternatives considered: As previously mentioned, the COOL provisions of the Farm Bill 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 (wild and/or farm-raised) 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, in the case of fish and shellfish products, method of production (wild and/or farm-raised) of the covered commodity. Again, the law provides no discretion regarding this requirement for suppliers of covered commodities to provide information to retailers.

The interim final rule has no mandatory requirement, however, for any firm other than statutorily defined retailers to make country of origin and method of production (wild and/or farm-raised) claims. In other words, no harvester, producer, processor, wholesaler, or other supplier is required to make and substantiate a country of origin and method of production (wild and/or farm-raised) 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 interim final rule. Thus, for example, a processor and its suppliers may elect neither to maintain country of origin and method of production (wild and/or farm-raised) information nor to make country of origin and method of production (wild and/or farm-raised)

claims, but instead sell products through marketing channels not subject to the interim final rule. Such marketing alternatives include foodservice, export, and retailers not subject to the interim final rule. We estimate that about 38 percent of U.S. fresh and frozen fish and about 25 percent of fresh and frozen shellfish sales occur through retailers subject to the interim final rule, with the remainder sold by retailers not subject to the interim final rule or sold as food away from home.

Additionally, producers and intermediaries may have opportunities to market their products to export markets, which are not subject to the provisions of the interim final 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 effective date of this regulation is six months following the date of publication of this interim final rule. The country of origin statute provides that "not later than September 30, 2004, the Secretary shall promulgate such regulations as are necessary to implement this subtitle." Many of the covered commodities sold at retail are in a frozen or otherwise preserved state (i.e., not sold as "fresh"). Thus, many of these products would already be in the chain of commerce

prior to September 30, 2004, and for these products, origin/production information may not be known. Therefore, it is reasonable to delay the effective date of this interim final rule for six months to allow existing inventories to clear through the channels of commerce and to allow affected industry members to conform their operations to the requirements of this rule. During this time period, AMS will conduct an industry education and outreach program concerning the provisions and requirements of this rule. AMS also plans to focus its enforcement resources for the six months immediately following the effective date of this interim final rule on industry education and outreach. After a careful review of all its implications, AMS has determined that its allocation of enforcement resources will ensure that the rule is effectively and rationally implemented. This AMS plan of outreach and education, conducted over a period of one year, should significantly aid the industry in achieving compliance with the requirements of this rule.

The interim final rule does not dictate systems that firms will need to put in place to implement the requirements of the rule. 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 interim final 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 interim final rule provides flexibility regarding where records may be kept. If the product is pre-labeled with the necessary country of origin and method of production (wild and/or farm-raised) information, records documenting the immediate previous source and immediate subsequent recipient 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 interim final rule.

In effect, the interim final rule is a performance standard rather than a design standard. The interim final rule requires that covered fish and shellfish commodities at subject retailers be labeled with country of origin and method of production (wild and/or farm-raised) 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 interim final rule provides flexibility regarding the manner in which the required information may be provided by retailers to consumers. The interim final rule provides flexibility in the manner in which required country of origin and method of production (wild and/or farm-raised) information is provided by suppliers to retailers, and in the manner in which records and information are maintained to substantiate country of origin and method of production claims. Thus, the interim final rule provides the maximum flexibility practicable to enable small entities to minimize the costs of the interim final rule on their operations.

Paperwork Reduction Act

Pursuant to PRA (44 U.S.C 3501-3520) the information collection provisions contained in this interim final rule have not yet been approved by OMB and will not take effect until such approval is received. The Comments and Responses section lists the comments received on the preliminary PRA analysis and provides the Agency's responses to the comments. A description of these provisions is given below with an estimate of the annual recordkeeping burden.

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

OMB Number: 0581-new

Type of Request: New collection.

Expiration Date: Three years from the date of approval.

Abstract: The COOL provision in the Farm Bill requires that specified retailers inform consumers as to the country of origin and, in the case of fish and shellfish, method of production (wild and/or farm-raised) of covered commodities. This interim final rule requires that records and other documentary evidence used to substantiate an origin and method of production (wild and/or farm-raised) claim must, upon request, be made available to USDA representatives in a timely manner during normal business hours and at a location that is reasonable in consideration of the products and firm under review. Any person engaged in the business of supplying a covered commodity to a retailer (i.e., including but not limited to harvesters, producers, distributors, handlers, packers, and processors), whether directly or indirectly, must make country of origin and method of production (wild and/or farm-raised) 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, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, for a period of one year from the date of the transaction. For an imported covered commodity, 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 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. Records and other documentary evidence (e.g., shipping receipt from central warehouse) relied upon at the point of sale to establish a product's country of origin and designation of production method (wild and/or farm-raised) must be available during normal business hours to any duly authorized representative of USDA at the facility for as long as the product is on hand. In addition, records that identify the retail supplier, the product unique to that transaction by means of a lot number or other unique identifier, and for products that are not pre-labeled the country of origin and method of production (wild and/or farm-raised) information, must be maintained for a period of one year from the date the origin declaration is made at retail. Such records may be located at the retailer's point of distribution, or at a warehouse, central office or other off-site location.

Description of Recordkeepers: Individuals who supply covered fish and shellfish commodities, whether directly to retailers or indirectly through other participants in the marketing chain, are required to establish and maintain country

of origin and method of production (wild and/or farm-raised) information for the covered commodities and supply this information to retailers. As a result, producers, handlers, manufacturers, wholesalers, importers, and retailers of covered fish and shellfish commodities will be impacted by this interim final rule.

Burden: We estimate that nearly 125,000 establishments owned by approximately 91,000 firms would be either directly or indirectly impacted by this rule. Changes from the PRIA are reductions in the numbers of affected entities due to the omission of commodities other than fish and shellfish in this interim final rule.

In general, the supply chain for the covered fish and shellfish commodities includes fish and shellfish producers and harvesters, processors, wholesalers, importers, and retailers. Imported products may be introduced at any level of the supply chain. Other intermediaries, such as markets, may be involved in transferring products from one stage of production to the next. We estimate that the interim final rule's paperwork burden will be incurred by the number and types of firms and establishments listed in Table 8.

Table 8. Paperwork Burden Estimates.					
Type	Firms	Initial Costs	Establishments	Maintenance Costs	Total Costs
Producers:					

Farm-Raised Fish & Shellfish	3,540	245,895	3,540	466,876	712,772
Fishing	76,499	5,313,774	76,452	3,360,983	8,674,756
Intermediaries:					
Fresh & Frozen Seafood Processing	582	761,838	653	580,571	1,342,409
Fish & Seafood Wholesale	2,897	3,792,173	2,980	2,649,467	6,441,640
General Line Grocery Wholesalers	3,183	4,166,547	3,993	819,256	4,985,803
Retailers:	4,512	5,906,208	37,176	16,526,275	22,432,483
Totals:					
Producers	80,039	5,559,669	79,992	3,827,859	9,387,528
Handlers, Processors, & Wholesalers	6,662	8,720,558	7,626	4,049,294	12,769,852
Retailers	4,512	5,906,208	37,176	16,526,275	22,432,483
Grand Total	91,213	20,186,435	124,794	24,403,428	44,589,863

The impacted firms and establishments will broadly incur two types of costs. First, firms will incur initial or start-up costs to comply with the interim final rule. We assume that 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. We assume that these activities will take place in each establishment operated by each affected business.

Compared to the proposed rule, this interim final rule reduces the length of time that records must be kept and revises the recordkeeping requirements for pre-labeled products. Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must maintain records to establish and identify the immediate previous source

and immediate subsequent recipient of a covered commodity, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, for a period of 1 year from the date of the transaction. Under the proposed rule, records would have been required to be kept for 2 years. For retailers, this interim final rule requires records and other documentary evidence relied upon at the point of sale by the retailer to establish a product's country of origin and method of production, to be available to any duly authorized representatives of USDA for as long as the product is on hand. Under the proposed rule, retailers would have to have maintained these records for 7 days following the sale of the product. For pre-labeled products, the interim final rule provides that the label itself is sufficient evidence on which the retailer may rely to establish a product's origin and method of production (wild and/or farm-raised). The proposed rule would not have provided for this method of substantiation. Under the interim final rule, records that identify the supplier, the product unique to that transaction by means of a lot number or other unique identifier, and for products that are not pre-labeled, the country of origin and the method of production (wild and/or farm-raised) information must be maintained for a period of 1 year from the date the origin and production designations are made at retail. Under the proposed

rule, these records would have been required to be maintained for 2 years.

With respect to initial recordkeeping costs, we believe that most fish and shellfish harvesters and producers currently maintain many of the types of records that would be needed to substantiate country of origin and method of production (wild and/or farm-raised) claims. However, harvesters and producers are not typically required to pass along country of origin and method of production (wild or farm-raised) information to subsequent purchasers. Therefore, harvesters and producers will incur some additional incremental costs to record, maintain, and transfer country of origin and method of production (wild or farm-raised) information to substantiate required claims made at retail. Because much of the necessary recordkeeping is already developed during typical fishing and aquaculture operations, we estimate that the incremental costs for harvesters and producers to supplement existing records with country of origin and method of production (wild or farm-raised) 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 method of production (wild or farm-raised) information and transfer this information to handlers, processors, wholesalers, or retailers.

We estimate that producers will need 4 hours to establish a system for organizing records to carryout the purposes of these regulations. 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 fish and shellfish products ultimately will be sold at retail establishments covered by this interim final rule, we assume that virtually all producers will wish to keep their marketing options as flexible as possible. Thus, we assume that all harvesters and producers of covered fish and shellfish commodities will establish recordkeeping systems sufficient to substantiate country of origin and method of production claims. We also recognize that some operations will require substantially more than 4 hours to establish their recordkeeping systems. Overall, we believe that 4 hours represents a reasonable estimate of the average additional time that will be required across all types of harvesters and producers.

In estimating initial recordkeeping costs, we used 2001 wage rates and benefits published by the Bureau of Labor statistics from the National Compensation Survey. Subsequently, the National Compensation Survey has been updated and 2002 wage rates and benefits are now available. These updated wage rates and benefits are used in estimating the interim final

recordkeeping costs and results in an increase in the estimated costs.

For harvesters and producers, we assume that the added work needed to initially set up a recordkeeping system for country of origin and method of production (wild or farm-raised) 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, will require equivalent skills. The Bureau of Labor Statistics (BLS) (Ref. 11) publishes wage rates for bookkeepers, accounting, and auditing clerks. We assume 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, we assume that this wage rate represents the opportunity cost of the producers' time for performing these tasks. The July 2002 wage rate, the most recent data available, is estimated at \$13.62 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. 11). At 4 hours per firm and a cost of \$17.37 per hour, initial recordkeeping costs to harvesters and producers are estimated at approximately \$5.6 million to modify existing recordkeeping systems in order to

substantiate country of origin and method of production (wild or farm-raised) 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 method of production (wild and/or farm-raised) 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 harvesters and producers, however, we believe that most of these operations already maintain many of the types of necessary records in their existing systems. Thus, we assume that country of origin and method of production (wild and/or farm-raised) 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 (Refs. 12 and 13) is used to estimate the cost of including additional country of origin and method of production (wild and/or farm-raised) information to an operation's records. We assume a limited information, one-color redesign of a paper document will be sufficient to comply with the interim final

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, we believe that \$1,309 represents a reasonable estimate of average cost for all firms. We thus estimate that the initial recordkeeping costs to intermediaries such as handlers, processors, and wholesalers (importers are included with wholesalers) will be approximately \$8.7 million, and initial recordkeeping costs at retail will be approximately \$5.9 million. The initial recordkeeping cost to intermediaries declines from the initial recordkeeping cost estimate in the proposed rule due to the reduction in the number of affected intermediaries associated with commodities other than fish and shellfish. The total initial recordkeeping costs for all firms are thus estimated at approximately \$20 million.

In addition to these one-time costs to establish recordkeeping systems, enterprises will incur additional recordkeeping costs associated with storing and maintaining records. These costs are referred to as maintenance costs in Table 8. Again, the marginal cost for harvesters and producers to maintain and store any additional information needed to substantiate country of origin and method of production (wild or farm-raised) claims is expected to be relatively small.

For wild fish harvesters, country of origin and method of production (wild) generally is established at the time that the product is harvested, and thus there is no need to track country of origin and method of production information throughout the production lifecycle of the product. 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 method of production information. Maintenance costs for fish harvesters are estimated to be \$3.4 million.

Compared to wild fish harvesters, we expect that fish farmers will incur higher costs to maintain country of origin and method of production (farm-raised) information. Wild fish are generally harvested once and then shipped by the producer to the first handler. In contrast, farm-raised fish and shellfish can and often do move through several geographically dispersed operations prior to final sale for processing. Fish and shellfish may be acquired from other countries by U.S. producers, complicating the task of tracking country of origin and method of production information. Because farmed fish and shellfish may change ownership several times prior to harvest, will need to be maintained to substantiate country of origin information as the animals move through their lifecycle. Thus, we expect that the recordkeeping burden for fish and shellfish farmers will be higher than it will be for harvesters of wild

fish and shellfish. We estimate that these producers will require an additional 12 hours a year, or 1 hour per month, to maintain country of origin and method of production records. Again, this is an average for all enterprises. Some will require substantially more time, while others will require little additional time to maintain country of origin and method of production information.

We assume that farm labor will primarily be responsible for maintaining country of origin information at producers' enterprises. NASS data (Ref. 14) are used to estimate average farm wage rates--\$8.62 per hour for livestock workers. (Wage rates for fish workers were unavailable, so the average wage rate for livestock workers is used.) Applying the rate of 27.5 percent to account for benefits results in an hourly rate of \$10.99 for livestock workers. Assuming 12 hours of labor per year for farmed fish operations results in estimated annual maintenance costs to producers of \$467,000 which is slightly higher than the estimated maintenance costs in the proposed rule for this group of producers. The increase in the estimated maintenance cost is due to the higher estimated benefits.

We expect that intermediaries such as handlers, processors, and wholesalers will face higher costs per enterprise to maintain country of origin and method of production (wild and/or farm-raised) 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.

We estimate the maintenance burden hours for country of origin and method of production (wild and/or farm-raised) recordkeeping to be 52 hours per year per establishment for fresh and frozen seafood processors and fish and seafood wholesalers. For general line grocery wholesalers, we estimate the maintenance burden hours to be 12 hours per year per establishment. The burden estimate for general line grocery wholesalers is reduced from the 52 hours estimated in the proposed rule because fish and shellfish represent only a portion of the commodities handled by these establishments.

Maintenance activities will include inputting, tracking, and storing country of origin and method of production (wild and/or farm-raised) information for each covered fish and shellfish commodity. Since this is mostly an administrative task, we estimate the cost using the July 2002 BLS wage rate from the National Compensation Survey for administrative support occupations (\$13.41 per hour with an additional 27.5 percent added to cover overhead costs for a total of \$17.10 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 \$4.0 million.

Retailers will need to supply country of origin and method of production (wild and/or farm-raised) information for each covered fish and shellfish commodity sold at each store. Therefore, additional recordkeeping maintenance costs are believed to impact each establishment. Because fish and shellfish represent only a portion of the covered commodities included in the proposed rule, estimated recordkeeping maintenance burden is lowered from 365 hours to 26 hours per year per retail establishment. This represents 30 minutes per week. Using the BLS wage rate for administrative support occupations (\$13.41 per hour with an additional 27.5 percent added to cover overhead costs for a total of \$17.10 per hour) results in total estimated annual maintenance costs to retailers of \$16.5 million.

The total maintenance recordkeeping costs for all producer, intermediary, and retail enterprises are thus estimated at approximately \$24.4 million.

The total first-year recordkeeping burden is calculated by summing the initial and maintenance costs. The total recordkeeping costs are estimated for harvesters and producers

at approximately \$9.4 million; for handlers, processors, and wholesalers at approximately \$12.8 million; and for retailers at approximately \$22.4 million. We estimate the total recordkeeping cost for all participants in the supply chain for covered fish and shellfish commodities at \$44.6 million for the first year, with subsequent maintenance costs of \$24.4 million per year.

Annual Reporting and Recordkeeping Burden for the First Year (Initial): Public reporting burden for this initial recordkeeping set up is estimated to average 7.1 hours per year per individual recordkeeper.

Estimated Number of Firms Recordkeepers: 91,213.

Estimated Total Annual Burden: 644,202 hours.

Annual Reporting and Recordkeeping Burden (Maintenance): Public reporting burden for this recordkeeping storage and maintenance is estimated to average 12.4 hours per year per individual recordkeeper.

Estimated Number of Establishments Recordkeepers: 124,794.

Estimated Total Annual Burden: 1,551,696 hours.

AMS is committed to implementation of the Government Paperwork Elimination Act (GPEA) to provide the public with the option to submit or transact business electronically to the extent practicable. This new information collection has no forms and is only for recordkeeping purposes. Therefore, the

provisions of an electronic submission alternative is not required by GPEA.

AMS is soliciting comments from all interested parties concerning these recordkeeping requirements. Comments are specifically invited on: (1) Whether the recordkeeping is necessary for the proper operation of this program, including whether the information would have practical utility; (2) the accuracy of USDA's estimate of the burden of the recordkeeping requirements, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the records to be maintained; and (4) ways to minimize the burden of the recordkeeping on those who are to maintain and/or make the records available, including the use of appropriate automated, electronic, mechanical, or other technological recordkeeping techniques or other forms of information technology. Comments concerning the recordkeeping requirements contained in this interim final rule should reference the date and page number of this issue of the Federal Register and should be sent to Country of Origin Labeling Program, Room 2092-S; Agricultural Marketing Service (AMS), USDA; STOP 0249; 1400 Independence Avenue, SW.; Washington, D.C. 20250-0249, or by facsimile to 202/720-3499, or by e-mail to cool@usda.gov.

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

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12. 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.
13. RTI, International 2000. FDA Labeling Cost Model: Final Report. Revised April 2002.
14. NASS, USDA. Farm Labor, August 15, 2003.

Executive Order 12988

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

Civil Rights Review

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

any persons or groups the benefits of the program or subject any persons or groups to discrimination.

Executive Order 13132

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

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 which are not governed by this regulation, the States may continue to operate them. For those State country of origin labeling programs that encompass commodities which are governed by this regulation, these programs are preempted. In most cases, the requirements contained within this rule are more stringent and prescriptive than the requirements of the State programs. With regard to consultation with States, as directed by the law, AMS has consulted with the States that have country of origin labeling programs. Further, States were expressly invited to comment on the proposed regulation as it related to existing State programs. No States submitted any comments pertaining to this issue.

This interim final rule contains those provisions of the October 30, 2003, (68 FR 61944) proposed rule that pertain to fish and shellfish covered commodities. Modifications to these provisions have been made as discussed herein. The implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish has been delayed until September 30, 2006. The provisions for the other covered commodities, including muscle cuts of beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; perishable agricultural commodities; and peanuts are not made

final in this action. In view of the changes made in this interim final rule to fish and shellfish covered commodities, interested persons should examine provisions concerning their respective covered commodities in light of these changes. Assuming that provisions of the interim final rule would be applied to all covered commodities, the Agency specifically invites comments on the issues described below.

In this regard, particular attention is drawn to the changes made for fish and shellfish with respect to definition of a processed food item and recordkeeping. Under this interim final rule, all cooked products (e.g., canned fish) are considered processed food items and are excluded from labeling under this regulation. Cooked products have a character that is different than that of the covered commodity and have a somewhat limited functionality. Also excluded under this interim final rule are breaded products, which in the case of shrimp can account for up to 50 percent of the finished product. In addition, retail items that have been given a distinct flavor (e.g., Cajun marinated catfish) are also considered processed food items. The Agency believes that these exclusions are consistent in that these products all have a limited range of use.

AMS has reduced the recordkeeping retention requirement for suppliers and centrally-located retail records to one year and

reduced the retail level record retention requirement to while the product is on hand. In addition, the interim final rule clarifies that only those suppliers responsible for initiating an origin and method of production claim would have to possess records to substantiate those claims (e.g., where it was harvested). Intermediate suppliers and retailers would be required to have documentation that identifies the product with either a lot number or other unique identifier and illustrates the immediate previous supplier and subsequent recipient (as applicable) of that uniquely identified product. Thus, only origin/production identification must travel with the product either on the product itself, on the shipping container, or in some other fashion. In performing an audit, AMS would be able to track that product back through the marketing chain to the supplier responsible for initiating the origin/production designation claims.

With respect to costs, modifications in this interim final rule resulted in lower estimates of first-year implementation costs for affected entities in the fish and shellfish sector, relative to the upper range estimates of first-year implementation costs presented in the proposed rule. If applied to the other covered commodities, corresponding changes to the proposed rule would result in lowered estimates of first-year implementation costs for those commodities relative to the

upper-range estimates presented in the PRIA. In the PRIA, upper-range first-year implementation costs for all covered commodities (including fish and shellfish) were estimated at \$3.9 billion. Preliminary analysis suggests that requirements in this interim final rule, if applied to all covered commodities, would result in a reduction on the order of 20 to 30 percent in estimated first-year implementation costs relative to the PRIA upper-range estimate.

This interim final rule is made effective 180 days after the date of publication in the Federal Register. The requirements of this rule do not apply to frozen fish or shellfish caught or harvested before [Insert date 60 days after date of publication in the Federal Register]. This will allow existing product to clear through the channels of commerce and permit AMS to conduct an industry education and outreach program concerning the provisions contained within this rulemaking.

Further, pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impractical, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect. This action is authorized under the Agricultural Marketing Act of 1946, as amended. After issuance of a proposed rule, the Department has decided to provide further opportunity to comment due to the changes made as a result of comments received and the cost

associated with this rule. Further, this rule provides for a 90-day comment period.

List of Subjects in 7 CFR Part 60

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

For the reasons set forth in the preamble, 7 CFR chapter I is amended by adding part 60 to read as follows:

PART 60--COUNTRY OF ORIGIN LABELING FOR FISH AND SHELLFISH

Subpart A--General Provisions.

Definitions

Sec.

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- 60.102 AMS.
- 60.103 [Reserved]
- 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.
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- 60.117 [Reserved]
- 60.118 [Reserved]
- 60.119 Processed food item.
- 60.120 [Reserved]
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- 60.122 Production step.
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- 60.127 United States.
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60.129 USDA.
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Country of Origin Notification

60.200 Country of origin notification.
60.300 Markings.

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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 [Reserved]

§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 Legibly.

Legibly means text that can be easily read by a consumer.

§60.115 [Reserved]

§60.116 Person.

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

§60.117 [Reserved]

§60.118 [Reserved]

§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., 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, 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, salmon that has been smoked, 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."

(h) Blended Products (Commingling of the same covered commodity).

(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 Markings.

(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) Abbreviations and variant spellings that unmistakably indicate the country of origin, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland" 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 and other documentary evidence that will permit substantiation of an origin claim and method(s) of production (wild and/or farm-raised), in a timely manner during

normal hours of business and at a location that is reasonable in consideration of the products and firm under review.

(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, unique to that transaction by means of a lot number or other unique identifier. 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.

(2) Any intermediary supplier (i.e., not the supplier responsible for initiating a country of origin declaration and designation of wild and/or farm-raised) handling a covered commodity that is found to be designated incorrectly for 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 could not

have been reasonably expected to have had knowledge of the violation.

(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, in such a way that identifies the product unique to that transaction by means of a lot number or other unique identifier, 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) 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 be available during normal business hours to any duly authorized representative of USDA at the facility for as long as the product is on hand. For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish the product's origin and method(s) of production (wild and/or farm-raised).

2) Records that identify the retail supplier, the product unique to that transaction by means of a lot number or other unique identifier, 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. Such records may be located at the retailer's point of distribution, warehouse, central offices or other off-site location.

(3) Any retailer handling a covered commodity that is found to be designated incorrectly as to country of origin and/or the method of production (wild and/or farm-raised), or for frozen fish and shellfish covered commodities caught or harvested before [insert 60 days after publication in the Federal Register] for the date of harvest, shall not be held liable for a violation of the Act by reason of the conduct of another if

the retailer could not have been reasonably expected to have had knowledge of the violation.

Subpart B [Reserved]

Dated:

/s/ A. J. Yates

A. J. Yates
Administrator
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