



Country of Origin Labeling Compliance Guide

1 Purpose

This document summarizes the requirements for compliance to the Interim Final Rule (IFR) for the mandatory country of origin labeling (COOL) and the procedures to be followed in enforcing the COOL provisions of the Farm Security and Rural Investment Act of 2002 (Farm Bill).

2 Reference Documents

- *Federal Register Part IV USDA AMS 7 CFR Part 60 Mandatory Country of Origin Labeling of Fish and Shellfish; Interim Rule*, dated October 5, 2004
- *Country of Origin Labeling Surveillance Review Procedures for Retail Facilities*
- *Country of Origin Labeling Supplier Traceback Audit Procedures*
- <http://www.ams.usda.gov/cool/index.htm>
- *Bureau of Customs and Border Protection Service Form 7501*

3 COOL Summary

The Farm Bill and the 2002 Supplemental Appropriations Act amended the Agricultural Marketing Act of 1946 (Act) to require retailers to notify their customers of the country of origin of covered commodities beginning September 30, 2004. 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 (fresh and frozen fruits and vegetables); and peanuts. The effective date for all covered commodities except fish and shellfish was subsequently postponed until September 30, 2006 and later delayed until September 30, 2008.

On April 4, 2005, the provisions of the IFR for the mandatory country of origin labeling of fish and shellfish covered commodities became effective. The IFR was published in the Federal Register on October 5, 2004, and requires designated retailers to label fish and shellfish covered commodities for country of origin and method of production (i.e., wild or farm raised).

The full text of the IFR can be found at: <http://www.ams.usda.gov/cool/index.htm>.

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To convey the country of origin and method of production 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. This information 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 Federal regulation. In addition, this information may be combined or listed separately and 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. Food service establishments, such as restaurants, cafeterias, food stands, and other similar facilities are exempt from these labeling requirements.

The law also requires that any person engaged in the business of supplying a covered commodity to a retailer 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 the document identifies the product unique to that transaction by means of a lot number or other unique identifier, the country(ies) of origin, and method(s) of production.

In addition, the law states the Secretary of Agriculture (Secretary) 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 and also encourages the Secretary to enter into partnerships with States with enforcement infrastructure to the extent possible to assist in the program's administration.

4 Definitions

- 4.1** USDA – The responsible authority for enforcing the requirements of the COOL regulation is the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed Program (LSP), Standards, Analysis, and Technology Branch, referred to as USDA in this document.
- 4.2** Retailer – Seller of a covered commodity that is licensed under the Perishable Agricultural Commodities Act (PACA) of 1930. They are subject to the law and are required to label covered commodities for country of origin and method of production. This definition excludes butcher shops, fish markets, and exporters that are not PACA licensees.
- 4.3** Supplier – Any organization or person engaged in the business of supplying a covered commodity to a retailer either directly or indirectly. Suppliers must make



available information to the purchaser about the country or origin and method of production of the covered commodity.

- 4.4** Foodservice Establishment – 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 including salad bars and delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods. Foodservice establishments are exempt from labeling by the COOL statute.
- 4.5** Covered Commodities – Specific products that fall under the COOL statute. Under the IFR, this currently includes wild and farm-raised fish and shellfish. Items are excluded from labeling under this regulation when a covered commodity is an ingredient in a processed food item. An ingredient is a component either in part or in full of a finished retail food product.
- 4.6** Processed Food Item – 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 component (e.g., breadings, tomato sauce, marinade), 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 excluded items include fish sticks, surimi, mussels in tomato sauce, seafood medley, coconut shrimp, soups, stews, chowders, sauces, pates, salmon that has been smoked, marinated fish fillets, canned tuna, canned sardines, canned salmon, crab salad, shrimp cocktail, gefilte fish, sushi, breaded shrimp, and cooked shrimp, lobster or crab.
- 4.7** Pre-labeled – Covered commodity packaging (i.e., consumer packages or shipping containers) that is labeled for country of origin and/or method of production by the firm or entity responsible for making the initial claim for these attributes or by a further processor repacker (i.e., firms that receive bulk products and package the products as covered commodities in a form suitable for the retailer).
- 4.8** Remotely Purchased Products (e.g., Internet sales) – Covered commodities that are sold through “non-traditional” retail channels. The retailer will provide country of origin and method of production information on the sales vehicle (e.g., website) or at the time the product is delivered to the consumer.



- 4.9 Retail Notification to the Consumer – The declaration for the country of origin and method of production must be legible and placed in a conspicuous location, so as to render it likely to be read and understood by a customer under normal conditions of purchase. Retailers may commingle covered commodities from more than one country of origin and/or method of production in a single sales container (e.g., package of product or bulk bin) provided all possible origins and methods of production are listed.
- 4.10 State and Regional Labeling Programs - Marketing programs (e.g., Alaskan salmon, “Go Texan”) which are not affected by the COOL regulations. State and regional label designations cannot replace country of origin labeling required by this rule.

5 Country of Origin and Method of Production Designations

- 5.1 United States (U.S.) Country of Origin:
- Wild fish and shellfish must be derived exclusively from fish or shellfish harvested in the waters of the U.S. or by a U.S. flagged vessel and processed in the U.S. or aboard a U.S. flagged vessel that has not undergone a substantial transformation outside of the U.S.
 - Farm-raised fish and shellfish must be derived exclusively from fish or shellfish hatched, raised, harvested, and processed in the U.S. that has not undergone a substantial transformation outside of the U.S.
- 5.2 Imported Covered Commodities *not* Substantially Transformed in the U.S.:
- Imported covered commodities shall retain the origin as declared to U.S Customs and Border Protection (CBP) at the time the product entered the U.S.
- 5.3 Imported Covered Commodities Substantially Transformed in the U.S.:
- The origin for a covered commodity imported from country X, then substantially transformed in the U.S. or aboard a U.S. flagged vessel, shall be “From country X, processed in the U.S.”
- 5.4 Method of Production – Farm-raised fish and shellfish:
- Harvested in controlled or selected environments, including ocean-ranched (e.g., penned) fish and shellfish harvested from leased beds that have been subjected to production enhancements such as providing protection from predators, the addition of artificial structures, and/or providing nutrients.
- 5.5 Method of Production – Wild fish and shellfish:
- Naturally-born or hatchery-originated fish or shellfish released in the wild and caught, taken or harvested from non-controlled waters or beds.

6 Recordkeeping Requirements

- 6.1 All records must be legible and may be maintained in either electronic or hard copy formats.

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- 6.2 Upon request by USDA representatives, suppliers and retailers subject to the IFR shall make available to USDA representatives records and other documentary evidence that will permit substantiation of an origin and method(s) of production claim, 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.
- 6.3 The supplier of a covered commodity that is responsible for initiating a country of origin and method of production claim must possess or have legal access to records that are necessary to substantiate the claims for 1 year from the date the product is sold.
- 6.4 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 1 year from the date of the transaction.
- 6.5 Intermediary suppliers (i.e., suppliers other than those responsible for initiating a country of origin or method of production declaration) will not be held liable for erroneous information if they could not have been reasonably expected to have had knowledge of the violation from the information provided by the previous supplier.
- 6.6 For an imported covered commodity, the importer of record must ensure that records provided clear product tracking from the port of entry into the U.S. to the immediate subsequent recipient. Records must accurately reflect the country of origin and method of production of the item as identified in relevant U.S. CBP entry documents. These records must be maintained for a period of 1 year from the date of the transaction.
- 6.7 For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish the product's origin and method of production. Once the pre-labeled covered commodity leaves the possession of the retailer, no further recordkeeping documenting country of origin and method of production is required to be kept at the point of sale.
- 6.8 Retailers shall maintain 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. These records must be maintained for a period of 1 year from the date of 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.



- 6.9 Retailers will not be held liable for the accuracy of the information provided by suppliers. However, they will be responsible if they use erroneous information that could reasonably be determined to be incorrect (e.g., contrary to the normal harvesting season of a particular product).

7 Enforcement Policy

- 7.1 Retail and supplier surveillance audits shall be conducted by USDA or State employees operating under cooperative agreements between the appropriate State agencies and USDA
- 7.2 USDA will develop the procedures to be followed while conducting the retail and supplier surveillance audits.
- 7.3 USDA will select and assign the retail facilities to be reviewed.
- 7.4 In order to ensure that suppliers are in compliance with the COOL regulations, USDA shall randomly select retail surveillance reviews to gather additional information on covered commodities so that USDA officials can conduct tracebacks to the firm or entity responsible for importing the covered commodity or for initiating the country of origin and method of production claims.
- 7.5 The law contains enforcement provisions for both retailers and suppliers that include civil penalties of up to \$10,000 for each violation. For retailers and suppliers that are determined to be in violation of the COOL requirements, they shall be notified of the violation(s) and provided with a 30-day period to take the necessary steps to comply.
- 7.6 When violations are observed, the matter will be referred to the USDA Office of the General Counsel for further action, as appropriate. Only USDA will be able to initiate enforcement actions against a person found to be in violation of the law.
- 7.7 Audits conducted to determine compliance with the COOL requirements will occur:
- a) During a random retail surveillance review.
 - b) During a random supplier traceback audit in which a product sold at retail is traced back through the marketing chain.
 - c) When possible violations by a supplier are observed during the course of an review of a retailer.
 - d) As warranted, when USDA receives allegations of violations.
- 7.8 In addition to the COOL enforcement provisions, statements regarding a product's origin and method of production 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 labeling of country of origin and method of production of covered commodities may lead to penalties under other statutes.



- 7.9 In addition to conducting routine retail and supplier surveillance audits, USDA will also respond to consumer complaints. Any consumer that wishes to file a complaint should send an email to COOLAudit@usda.gov that includes the following information: the name and address of the store in which the apparent violation occurred, a detailed description of the product and the apparent violation, and the date the product was observed. USDA personnel will investigate all complaints received and take the appropriate action.

8 Procedures

Retail and supplier surveillance audits shall be conducted in accordance with procedures developed by the USDA, AMS, LSP, Standards, Analysis, and Technology Branch. The procedures for conducting surveillance reviews of retail facilities are detailed in the document entitled, *Country of Origin Labeling Surveillance Review Procedures for Retail Facilities*. The procedures for random supplier surveillance tracebacks in which a product sold at retail is traced back through the marketing chain are detailed in the document entitled, *Country of Origin Labeling Supplier Traceback Audit Procedures*.

9 Types of Violations

- 9.1 Failure to Label Product - It is a violation for a retailer to fail to identify the country of origin and method of production of a covered commodity at the final point of sale to consumers.

Country of origin declarations and method of production 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. This information 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 Federal regulation. In addition, origin and production information may be combined or provided separately and 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.

- 9.2 Misabeled Product - It is a violation for a retailer to incorrectly identify the country of origin and method of production of a covered commodity. Retailers are required to provide accurate notification to consumers about the country of origin and method of production of covered commodities. Any retailer that is found to have provided inaccurate information will not be held in violation if the information provided by the supplier(s) was inaccurate and the retailer could not have been reasonably expected to have had knowledge of the violation.

- 9.3 Failure to Maintain Records - It is a violation for retailers and their suppliers to fail to maintain records that permit substantiation of origin and method of production claims.



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 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 record on which the intermediary supplier and retailer may rely while the product is in their possession. Once the pre-labeled covered commodity leaves the possession of an intermediary supplier or retailer, no further recordkeeping documenting country of origin and method of production is required. The documentation for covered commodities that are not pre-labeled for country of origin or method of production must be maintained at the retail site while the product is on hand and for a period of 1 year by both the retailer and their suppliers.

Attached to this compliance guide in Appendix 1 are lists providing examples of the types of records that may be useful to comply with the record keeping requirements for Country of Origin labeling.

9.4 Failure to Provide COOL Information - It is a violation for suppliers of covered commodities to fail to provide information to the customer that accurately identifies the country of origin and method of production of a covered commodity.

Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must provide complete and accurate country of origin and, if applicable, method of production information to their customers.

Intermediary suppliers that distribute covered commodities to other suppliers, which in turn may or may not distribute them to covered retailers, may not be required to provide COOL information. However, if the intermediary supplier possesses knowledge, through contract or other arrangement, that the product is destined for retail sale by a covered retailer they are required to provide COOL information. Further, even if the intermediary supplier does not know the covered commodity will be distributed to a covered retailer, if COOL information is relied upon by a covered retailer, it must be accurate and will be subject to enforcement.



10 Specific Examples of Violations

The following are examples of different types of violations and corrective steps that may be taken. These examples are illustrative only, and not intended to cover every possible violation. The corrective actions are suggested steps that may be taken and are not intended to be a complete list of the measures that may be taken to comply with the country of origin requirements.

Action Resulting in a Violation	Type of Violation	Corrective Action
Farm-raised tuna steaks in display case with no information regarding country of origin.	Failure to label product with the country of origin.	Provide country of origin declaration on sign over display or on the product.
Wild shrimp from the U.S., Ecuador, and Chile in a retail bulk bin labeled with a sign above the bin stating, "Product of U.S.A."	Mislabeled product for countries of origin. Failure to label product for method of production	Include all possible countries origin and method of production on the sign above the bin or on the product.
A Canadian supplier of lobster to a retailer does not provide method of production information (farm-raised or wild).	Failure of supplier to provide COOL information to retailer.	Supplier must provide complete and accurate COOL information to their customers.
A wild-caught cod supplier does not use unique identifier for product tracking purposes to determine source of bulk packed cod that is not pre-labeled.	Failure to maintain records that substantiate COOL claims.	Supplier must use a unique identifier that provides for a verifiable record keeping audit trail, such as a container number, lot number, or product ID code that would identify the product unique to that transaction.



11 Action in Response to Violations:

- 11.1** Retailers: When a retailer is found to have an apparent violation of the COOL requirements, the agent conducting the review will immediately notify the appropriate store personnel. USDA will notify the retailer in writing of the nature of the violation, the date the violation was discovered, and request the submission of corrective actions to address the violation. A USDA representative may conduct a follow-up compliance audit to ensure that violations of the type specified in the letter are not continuing to occur. If requested, USDA personnel will provide additional information to educate the retailer on the COOL requirements.
- 11.2** Suppliers: When suppliers are found to have an apparent violation of the COOL requirements, the agent conducting the audit will immediately notify the appropriate supplier personnel. USDA will also notify the supplier in writing of the nature of the violation, the date the violation was discovered, and request corrective actions that will be taken to remedy the violation. A USDA representative may conduct a follow-up compliance audit to ensure that violations of the type specified in the warning letter are not continuing to occur. If requested, USDA personnel will provide additional information to educate the supplier on the COOL requirements.

These guidelines are effective immediately.

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Appendix 1

The examples of documents and records listed in the attached tables, although extensive, are not inclusive of all documents and records that may be useful to verify compliance with the Country of Origin Labeling provisions of the 2002 Farm Bill. Additionally, maintaining documents and records such as those listed as examples will not necessarily ensure compliance. The documents listed are examples only and are for the sole purpose of providing information for producers, processors, and retailers to consider when establishing records for verification purposes. During a compliance audit conducted by USDA, auditors will review any and all documents to the extent necessary to arrive at an accurate decision on the level of compliance.

In terms of the requirements to substantiate origin and method of production (wild and/or farm-raised) claims for imported fish and shellfish covered commodities, a declaration of these claims on the Bureau of Customs and Border Protection Service Form 7501 or other official entry document will be considered sufficient evidence.



Wild Fish

Harvesting Fish /US Flagged Vessel	US Flagged Ship/Slaughter/ Processor	Further Processor	Distributor
Responsibility			
Maintain records of location where wild fish are being harvested. Maintain harvesting documentation from US Flagged ship.	Segregate fish according to the country designation. Segregate and control throughout the system and properly label product according to the country designation. Document origin of all products.	Transfer labels and identification of all products processed. Operate under a labeling program. Inventory all products according the origin.	Maintain the integrity of the product. If repackaged, transfer the original identification.
Examples of Records and Activities that may be useful.			
Site maps	Transportation records	Product inventory	Invoices
Vessel records	Receiving Records	Receiving Records	Receiving Records
Harvesting records	Purchase Records	Purchase Records	Purchase Records
Brood stock records	Plant ID system	Production Records	Sales records
US Flagged Vessel ID	Sales Receipts	Sale Receipts	Sales Receipts
Production records	Shipping manifest	Label Inventory	Labeling requirements
Sales receipts	Inspection records	Labeling requirements	Inventory
Purchase records	Quality Control records	Yield sheet	Segregation plan
Receiving records	Segregation plan	UPC codes	UPC codes
	Production records	Segregation plan	
	Inventory records		
	UPC codes		
	Sampling Records		
	Yield Records		
	Location of harvest		



Farm-Raised Shellfish

Hatchery/Nursery	Grow-out	Processor/Dealer	Further Processor/Dealer	Distributor
Responsibility				
Provide adequate information for an auditor to verify the origin of all seed, eyed larvae and set cultch. Record all origin information according to the designation.	Identify and segregate seed according to the origin designation and manner of production. Maintain and identify designation information. Maintain ownership and transfer records.	Maintain segregation of shellfish according to origin and manner of production designation and properly label throughout the system. Document origin and manner of production of all products.	Transfer labels, tags and identification of all products processed. Operate under a labeling program. Include origin and manner of production information in inventory records.	Maintain integrity of the product. If repackaged, transfer original identification.
Examples of Records and Activities that may be useful				
Spawning records	Seed/eyed larvae records	Landings reports	Landings reports	Invoices
Brood stock records	Cultch purchase records	Harvest records	Harvest records	Purchase records
Seed/eyed larvae purchase records	Seed transfer records	HACCP Records	Purchase records	HACCP Records
Feeding records	Inspection/monitoring records	Processing records	HACCP Records	Processing records
Ploidy records	Dive records	Receiving logs	Processing records	Receiving logs
Cultch purchase records	Transfer permits	Tags	Receiving logs	Tags
Growth records	Transplant records	Shipping records/Bills of lading	Tags	Shipping records/Bills of lading
Spat collection records	Site maps	Shucking records	Shucking records	Inventory records
Site maps	Harvest records	Inventory records	Shipping records/Bills of lading	Order sheets
Production records	Landings reports	Order sheets	Inventory records	Invoices
Import permits	Crop records and reports	Invoices	Order sheets	Sales records
Health records		Sales records	Invoices	Yield records
Crop records and reports		Yield records	Sales records	UPC codes
		UPC codes	Yield records	Sampling records
		Sampling records	UPC codes	Plant ID system
		Plant ID system	Sampling records	
		Bulk Tagging Transaction Record	Plant ID system	Bulk Tagging Transaction Record
			Bulk Tagging Transaction Record	



Farm-Raised Fish

Hatchery /Nursery Pond	Grow-out Ponds	Slaughter/ Processor	Further Processor	Distributor
Responsibility				
Provide enough information for an auditor to verify the origin and ownership of all shipments of fry /fingerlings. Properly record all hatching production according to the designation.	Identify and segregate fingerlings as to the origin designation. Properly label and identify all marketable size fish sold. Maintain the integrity of the identification. Maintain ownership transfer records.	Segregate fish according to the country designation. Segregate and control throughout the system and properly label product according to the country designation. Document origin of all product.	Transfer labels and identification of all products processed. Operate under a labeling program. Inventory all products according to the origin.	Maintain the integrity of the product. If repackaged, transfer the original identification.
Examples of Records and Activities that may be useful.				
Hatching records	Transportation records	Transportation records	Product inventory	Invoices
Brood stock records	Receiving Records	Receiving Records	Receiving Records	Receiving Records
Receiving records	Purchase Records	Purchase Records	Purchase Records	Purchase Records
Purchase records	Sales Receipts	Plant ID system	Production Records	Sales records
Sales receipts	Feed bills	Sales Receipts	Sale Receipts	Sales Receipts
Feed bills	Feeding records	Shipping manifest	Label Inventory	Labeling requirements
Feeding records	Stocking records	Inspection records	Labeling requirements	Inventory
Site maps	Replacement activities	Quality Control records	Yield sheet	Segregation plan
Production estimates	Segregation plan	Segregation plan	UPC codes	UPC codes
Health records	Feed per acre rate	Production records	Segregation plan	
Owner ship records	Pond yield records	Inventory records		
Replacement activities	Locations	UPC codes		
Site maps	Sampling Records			
Pond acreage	Yield Records			
Harvesting records	Location of harvest			