

SUPPORTING STATEMENT

Mandatory Country of Origin Labeling of Muscle Cuts and Ground Beef, Lamb, Pork, Chicken, and Goat; Wild and Farm-raised Fish and Shellfish; Perishable Agricultural Commodities; Peanuts; Macadamia Nuts; Pecans; and Ginseng Under the Authority of the Agricultural Marketing Act of 1946

**OMB NO. 0581-0250
(Final Rule)**

A. Justification

- 1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.**

The Farm Security and Rural Investment Act of 2002 (2002 Farm Bill)(Pub. L. 107-171), the 2002 Supplemental Appropriations Act (2002 Appropriations)(Pub. L. 107-206), and the Food, Conservation and Energy Act of 2008 (2008 Farm Bill)(Pub. L. 110-234) amended the Agricultural Marketing Act of 1946 (Act)(7 U.S.C. 1621 *et seq.*) to require retailers to notify their customers of the country of origin of covered commodities. Covered commodities include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.

- 2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.**

To facilitate the mandatory country of origin labeling of covered commodities, the final rule includes definitions that can be used by retailers and their suppliers and understood by other market participants. The final rule also outlines the framework of a consumer notification, product marking, and recordkeeping program that will be required to carry out this program. There is no submission requirement associated with this mandatory program per se. Records maintained in the normal course of business by market participants will be used by the Agency in conducting enforcement activities to verify compliance with the law. The types of market participants affected by this rule are producers, handlers, processors and wholesalers, and retail facilities.

- 3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G.**

PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.

There are no submission requirements associated with this mandatory program per se. Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location. These records may be in any form that is auditable and verifiable, which would include those records maintained electronically.

4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.

The final rule is not prescriptive as to the form that records must take. Further, records maintained in the normal course of business are acceptable for verifying origin claims under this rule. In addition, the law prohibits the Secretary from requiring the creation of new records.

5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-1), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.

The law specifically exempts many retailers by choosing to cover only those retailers already covered by the Perishable Agricultural Commodities Act of 1930 (PACA) (7 U.S.C. 499a(b)). In addition, the 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 final rule. Taking into account comments received on the interim final rules for fish and shellfish and the remaining covered commodities, the final rule decreases the length of time that records are required to be kept, providing some relief to affected entities both large and small.

6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.

The law requires the Agency to establish a program that requires retailers to label covered commodities with country of origin information. If such products are not produced under a system that ensures that their source of origin is maintained, it will not be possible for retailers to accurately label covered commodities, and consumers will not be able to purchase such products by their country of origin with any degree of confidence.

Accordingly, the Agency has drafted the final rule in a manner that meets the requirement of the law with the minimum burden imposed on the industry.

The Agency has made several changes in this final rule compared to the proposed rule to further minimize the burden on regulated entities. These changes are discussed more fully below in the responses to question numbers 8 and 12. In addition, the 2008 Farm Bill contained a number of amendments to the COOL provisions of the Act, which further reduce the burden on regulated entities. Therefore, any further reduction in the burden imposed by this mandatory program would result in a program that would not achieve the objective of the authorizing legislation and could result in a program that would provide unverifiable and even misleading information to consumers.

7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:

- **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**
- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**
- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**
- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**
- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**
- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**
- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**
- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS**

THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES TO PROTECT THE INFORMATION'S CONFIDENTIALITY TO THE EXTENT PERMITTED BY LAW.

There are no special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.6.

8. IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.

The interim final rule for fish and shellfish was published in the October 5, 2004, Federal Register. (69 FR 59708). In addition, the interim final rule for the remaining covered commodities was published in the August 1, 2008 Federal Register (73 FR 45106) with a 60-day request for comments. Comments can be viewed at <http://www.reginfo.gov> (Docket AMS-LS-07-0081; Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts)

Summary of Comments and Responses

Supplier Responsibilities

Summary of Comments: Several commenters expressed concerns with the Agency's assertion in the interim final rule that "the supplier of a covered commodity that is responsible for initiating a country of origin claim...must possess or have legal access to records that are necessary to substantiate that claim." The commenters maintained that the Agency's jurisdiction stops with the initiator of the origin claim of a covered commodity, which in the case of meat products is the slaughter facility. The commenters further stated that the COOL law authorizes only the Secretary of Agriculture to conduct an audit for verification purposes, not the packer, and that furthermore, the Secretary may not require a person that prepares, stores, handles, or distributes a covered commodity to maintain a record of the country of origin of a covered commodity other than those maintained in the course of the normal conduct of the business of such person. The commenters argued that the 2008 Farm Bill language states that producer affidavits are sufficient in making a country of origin claim; therefore, packers or processors should not be given legal access to producers' records. The commenters recommended that the Agency eliminate language referencing "legal access" from the final regulation as they contend it is not authorized by the law.

Two commenters suggested that the Agency should require the original suppliers of covered products to substantiate the chain of custody and the accuracy of country of origin

information. One commenter expressed the opinion that it is unreasonable that the liability ultimately is placed on the meat processor to provide country of origin information when they are relying on the word of livestock producers, who may or may not be providing accurate information.

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

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

One commenter noted that while producers are not directly affected by the COOL law, Section 282 (3) of the statute expressly requires that "anyone engaged in the business of supplying a covered commodity provide country of origin information." The commenter further stated that in the case of animals imported from Canada, this necessarily implicates Canadian producers who must present health papers to APHIS at the border. The commenter suggested further clarification is needed about the manner in which that origin will be tracked and conveyed to AMS should proof of origin be required further down the supply chain.

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

One commenter stated that the most practical approach to meeting the COOL requirements for most covered commodities is for those producers to print the country of origin on all retail packaging for case and consumer ready, and on all case end labels for all products destined to be store processed or packaged by the retailer. The commenter suggested that producers will not need to continuously transmit country of origin information to the retailer on an order by order basis. Instead, package and case labeling in conjunction with the USDA

establishment number (used to identify producer) and the lot or batch number (used to identify the specific lot of live animals from which products are derived) will already be on pre-packaged labels and case end codes. The commenter further stated that retailers already retain invoices to meet other reporting requirements, which identify the producers of the product, and can be used to satisfy the COOL recordkeeping obligation. The commenter also stated that there will be no required change in business processes for retailers but producers will be required to add accurate origin information to the retail packaging and/or case end labels.

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

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

Agency Response: It is correct to say that the Agency's authority to audit ends at the slaughter facility as the slaughter facility is the first handler of the covered commodity and the Agency has deleted the requirement that suppliers have legal access to records from this final rule. However, as initiators of origin claims, packers must have records to substantiate those claims. With regard to records maintained in the course of the normal conduct of the business of such person and producer affidavits, the final rule states that producer affidavits shall be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction. With regard to the commenter's assertion that producers not be asked for unreasonable information that goes beyond what would be considered acceptable, the Agency has provided examples of records kept in the normal course of business that may be used to substantiate origin claims. As previously stated, packers can utilize producer affidavits to obtain origin information. This final rule has been drafted to minimize the recordkeeping burden as much as possible while still providing the Agency with the information necessary to verify origin claims.

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

Ultimately, retailers must ensure that covered commodities displayed for retail sale have country of origin designations.

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

Visual Inspection

Summary of Comments: Several commenters expressed support for the Agency policy to accept visual inspection as a means to verify the origin of livestock during the period between July 15, 2008 and July 15, 2009. Specifically, the majority of commenters supported the Agency's decision to authorize sellers of cattle to conduct a visual inspection of their livestock for the presence or absence of foreign marks of origin, and that such visual inspection constitutes firsthand knowledge of the origin of their livestock for use as a basis for verifying origin and to support an affidavit of origin. They noted that visual inspection for verification of origin is particularly important to the trade during the period between July 15, 2008, and whenever the final regulation is published. The commenters stated that producers now have livestock without all of the origin documentation that may be necessary and that it would be very difficult, and in some cases impossible, to recreate the paper trail on many of these animals. Other commenters noted that the visual inspection of animals for import markings is a highly reliable, cost effective method of verification of origin and will significantly reduce compliance costs for livestock producers. The commenters recommend that visual inspection be made a permanent method on which to base origin claims.

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

Producer Affidavits

Summary of Comments: Numerous commenters expressed support for the "Universal Country of Origin Affidavit/Declaration" that was developed by consensus across the livestock and chicken industry to serve as verification from producers to slaughter facilities for the country of origin of livestock. Several commenters requested that these agreed-upon documents be incorporated in the final rule. Several commenters also argued that producers should not be

asked for unreasonable information. They urged AMS to consider a standardized producer affidavit that would accompany an animal from its first sale throughout the chain of custody.

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

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

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

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

National Animal Identification System (NAIS)

Summary of Comments: Commenters had mixed opinions about relying on NAIS as a safe-harbor for COOL compliance. Numerous commenters supported the provision in the interim final rule stating that voluntary participation in NAIS program will comply with COOL verification requirements. The commenters that support the use of NAIS stated that official USDA 840-tags can serve as a universal passport for an animal during its lifetime indicating the animal is of U.S. origin, no matter how many times ownership of the animal changes during its lifetime. Commenters strongly encouraged the Agency to utilize Radio Frequency Identification (RFID) tags in NAIS to allow verification of country of origin at the speed of commerce and stated that official NAIS USDA 840-RFID tags for livestock represent the simplest way for producers to assist in the marketing of their animals to ensure compliance with COOL.

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

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

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

A final commenter warned that the acceptance of an ear tattoo does not meet the needs of modern industry practices. Due to issues associated with the speed of commerce, record keeping, accuracy and overall effectiveness of the program, the commenter stated that the Agency should only allow a hot iron brand on all live foreign cattle.

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

just one option that can be utilized to obtain origin information.

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

Retailer Responsibilities

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

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

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

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

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

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

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

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

- **DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.**

- **CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS.**

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CIRCUMSTANCES SHOULD BE**

**CIRCUMSTANCES THAT MAY
SPECIFIC SITUATION. THESE
EXPLAINED.**

In order to gain as much public input into this rulemaking as possible, the Agency plans to hold three formal listening sessions across the country to explain the rule's requirements and provide participants with an opportunity to submit comments that will be included in the formal record.

The Agency also toured the facilities of a local retailer to gain a better understanding of how the retail segment will be affected by this rule.

Primary Contacts:

Food Marketing Institute
Deborah White
2345 Crystal Drive, #800
Arlington, VA 22202
202-452-8444

American Meat Institute
Mark Dopp
1150 Connecticut Ave. NW
12th Floor
Washington, DC 20036
202-587-4229

Produce Marketing Association
Kathy Means
302-738-7100
P.O. Box 6036
Newark, DE 19714

9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.

No payments or gifts are provided to respondents.

10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.

There are no assurances of confidentiality being provided to respondents under this program.

11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO

OBTAIN THEIR CONSENT.

There are no questions of a sensitive nature in this information collection.

12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION. THE STATEMENT SHOULD:

- **INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**

- **IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN OF OMB FORM 83-I.**

ITEM 13

Estimates of the recordkeeping burden have been summarized on the AMS-71 form.

- **PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

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

In general, the supply chain for each of the covered commodities includes agricultural producers or fish harvesters, processors, wholesalers, importers, and retailers. Imported products may be introduced at any level of the supply chain. Other intermediaries, such as auction markets, may be involved in transferring products from one stage of production to the next. The rule's paperwork burden will be incurred by the number and types of firms and establishments listed in Table 9, which follows.

Table 9.--Costs Associated with Paperwork Burden

| Type | Firms | Initial Costs | Establishments | Maintenance Costs | Total Costs |
|--|------------------|--------------------|------------------|--------------------|--------------------|
| Producers | | | | | |
| Cattle & Calves | 971,400 | 75,699,259 | 971,400 | 145,651,716 | 221,350,975 |
| Sheep & Lambs | 69,090 | 5,384,046 | 69,090 | 10,359,355 | 15,743,400 |
| Hogs & Pigs | 65,540 | 5,107,401 | 65,540 | 9,827,068 | 14,934,469 |
| Goats | 9,146 | 712,745 | 9,146 | 1,371,381 | 2,084,126 |
| Chicken Producer and Processor | 38 | 2,961 | 168 | 25,190 | 28,151 |
| Farm-Raised Fish & Shellfish | 3,752 | 292,386 | 3,752 | 562,575 | 854,961 |
| Fishing | 71,128 | 5,542,863 | 71,142 | 3,555,677 | 9,098,540 |
| Fruits & Vegetables | 79,800 | 6,218,654 | 79,800 | 3,788,984 | 10,007,638 |
| Ginseng | 190 | 14,806 | 190 | 9,021 | 23,828 |
| Peanuts | 650 | 50,653 | 650 | 30,863 | 81,516 |
| Pecans | 1,119 | 87,192 | 1,119 | 53,130 | 140,323 |
| Macadamia | 53 | 4,130 | 53 | 2,516 | 6,647 |
| Handlers, Processors, & Wholesalers | | | | | |
| Stockyards, Dealers & Market Agencies | 6,807 | 8,910,363 | 6,807 | 6,589,040 | 15,499,403 |
| Livestock Processing & Slaughtering | 2,943 | 3,852,387 | 3,207 | 62,086,237 | 65,938,624 |
| Meat & Meat Product Wholesale | 2,509 | 3,284,281 | 2,706 | 2,619,354 | 5,903,635 |
| Chicken Processor and Wholesaler | 510 | 667,590 | 564 | 545,941 | 1,213,531 |
| Fresh & Frozen Seafood Processing | 516 | 675,444 | 590 | 571,108 | 1,246,552 |
| Fish & Seafood Wholesale | 2,254 | 2,950,486 | 2,330 | 2,255,393 | 5,205,879 |
| Frozen Fruit, Juice & Vegetable Mfg | 155 | 202,895 | 247 | 239,091 | 441,986 |
| Fresh Fruit & Vegetable Wholesale | 4,654 | 6,092,086 | 5,016 | 4,855,388 | 10,947,474 |
| Ginseng Dealers | 46 | 60,214 | 46 | 44,527 | 104,741 |
| Roasted Nuts & Peanut Butter Mfg | 8 | 10,472 | 9 | 8,712 | 19,184 |
| Peanut, Pecans, & Macadamia Nut Wholesalers | 5 | 6,545 | 5 | 4,840 | 11,385 |
| General Line Grocery Wholesalers | 3,037 | 3,975,433 | 3,436 | 3,325,979 | 7,301,412 |
| Retailers | 4,040 | 5,288,360 | 36,392 | 247,264,534 | 252,552,894 |
| Totals | | | | | |
| Producers | 1,271,906 | 99,117,097 | 1,272,050 | 175,237,476 | 274,354,573 |
| Handlers, Processors, & Wholesalers | 23,444 | 30,688,196 | 24,963 | 83,145,610 | 113,833,806 |
| Retailers | 4,040 | 5,288,360 | 36,392 | 247,264,534 | 252,552,894 |
| Grand Total | 1,299,390 | 135,093,653 | 1,333,405 | 505,647,620 | 640,741,274 |

The affected firms and establishments will broadly incur two types of costs. First, firms will incur initial or start-up costs to comply with the rule. Initial costs will be borne by each firm, even though a single firm may operate more than one establishment. Second, enterprises will incur additional recordkeeping costs associated with storing and maintaining records on an ongoing basis. These activities will take place in each establishment operated by each affected business.

Initial Recordkeeping Costs

With respect to initial recordkeeping costs, it is believed that most producers currently maintain many of the types of records that would be needed to substantiate country of origin and, if applicable, method of production claims. However, producers do not typically record or pass along country of origin and, if applicable, method of production information to subsequent purchasers. Therefore, producers will incur some additional incremental costs to record, maintain, and transfer country of origin and, if applicable, method of production information to substantiate required claims made at retail. Because much of the necessary recordkeeping has already been developed during typical farm, ranch, and fishing operations, it is estimated that the incremental costs for producers to supplement existing records with country of origin and, if applicable, method of production information will be relatively small per firm. Examples of initial or start-up costs would be any additional recordkeeping burden needed to record the required country of origin and, if applicable, method of production information and transfer this information to handlers, processors, wholesalers, or retailers via records used in the normal course of business.

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

In estimating initial recordkeeping costs, 2006 wage rates and benefits published by the Bureau of Labor statistics from the National Compensation Survey are used.

For producers, it is assumed that the added work needed to initially adapt an existing recordkeeping system for country of origin and, if applicable, method of production information is primarily a bookkeeping task. This task may be performed by independent bookkeepers, or in the case of operations that perform their own bookkeeping, an individual with equivalent skills. The Bureau of Labor Statistics (BLS) publishes wage rates for bookkeepers, accounting, and auditing clerks (Ref. 15). It is assumed that this wage rate represents the cost for producers to hire an independent bookkeeper. In the case of producers who currently perform their own bookkeeping, it is assumed that this wage rate represents the opportunity cost of the producers' time for performing these tasks. The May 2006 wage rate is estimated at \$15.28 per hour. For

this analysis, an additional 27.5 percent is added to the wage rate to account for total benefits which includes social security, unemployment insurance, workers compensation, etc. The estimate of this additional cost to employers is published by the BLS (Ref. 15). At 4 hours per firm and a cost of \$19.48 per hour, initial recordkeeping costs to producers are estimated at approximately \$135.1 million to modify existing recordkeeping systems in order to substantiate country of origin and, if applicable, method of production claims.

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

The Label Cost Model Developed for FDA by RTI International (Ref. 16; Ref. 17) is used to estimate the cost of including additional country of origin and, if applicable, method of production information to an operation's records. It is assumed that a limited information, one-color redesign of a paper document will be sufficient to comply with the rule's recordkeeping requirements. The number of hours required to complete the redesign is estimated to be 29 with an estimated cost at \$1,309 per firm. While the cost will be much higher for some firms and lower for others, it is believed that \$1,309 represents a reasonable estimate of average cost for all firms. Based on this, it is estimated that the initial recordkeeping costs to intermediaries such as handlers, processors, and wholesalers (importers are included with wholesalers) will be approximately \$31 million, and initial recordkeeping costs at retail will be approximately \$5 million. The recordkeeping cost to producers increases due to the inclusion of fish and shellfish.

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

Storage and Maintenance Costs

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

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

of the product. Likewise, this is also the case for chicken as the vast majority of chicken products sold by covered retailers are from chickens that are produced in a controlled environment in the United States. This group of producers is estimated to require an additional 4 hours a year, or 1 hour per quarter, to maintain country of origin and, if applicable, method of production information.

Compared to wild fish harvesters, chicken, fruit, vegetable, ginseng, peanut, macadamia nut, and pecan producers, it is expected that fish farmers and livestock producers will incur higher costs to maintain country of origin and, if applicable, method of production information. Wild fish, chicken, fruits, vegetables, ginseng, peanuts, and macadamia nuts are generally harvested once and then shipped by the producer to the first handler. In contrast, farm-raised fish and livestock can and often do move through several geographically dispersed operations prior to sale for processing or slaughter. Cattle, for example, typically change ownership between 2 to 3 times before they are slaughtered and processed. Fish and livestock may be acquired from other countries by United States producers, which may complicate the task of tracking country of origin and, if applicable, method of production information. Because animals are frequently sorted and regrouped at various stages of production and may change ownership several times prior to slaughter, country of origin information will need to be maintained on animals as they move through their lifecycle. Thus, it is expected that the recordkeeping burden for fish farmers and livestock producers will be higher than it will be for producers of other covered commodities. It is estimated that these producers will require an additional 12 hours a year, or 1 hour per month, to maintain country of origin and, if applicable, method of production records. Again, this is an average for all enterprises.

It is assumed that farm labor will primarily be responsible for maintaining country of origin information at producers' enterprises. NASS data (Ref. 18) are used to estimate average farm wage rates--\$9.80 per hour for livestock workers and \$9.31 per hour for other crops workers. Applying the rate of 27.5 percent to account for benefits, this results in an hourly rate of \$12.50 for livestock workers and \$11.87 for other crops workers. Wage rates for fish workers were unavailable, so the average wage rate for livestock workers is used. Assuming 12 hours of labor per year for livestock and farmed fish operations and 4 hours per year for all other operations, the estimated total annual maintenance costs to producers is \$175 million which is higher than the initial maintenance costs in the interim final rule. The increase in the estimated maintenance cost is due to the inclusion of fish and shellfish in this final rule.

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

With the exception of livestock processing and slaughtering establishments, the maintenance burden hours for country of origin and, if applicable, method of production recordkeeping is estimated to be 52 hours per year per establishment. For this part of the supply chain, the recordkeeping activities are on-going and are estimated to require an additional hour a week. It is expected, however, that livestock processing and slaughtering enterprises will

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

Maintenance activities will include inputting, tracking, and storing country of origin and, if applicable, method of production information for each covered commodity. Since this is mostly an administrative task, the cost is estimated by using the May 2006 BLS wage rate from the National Compensation Survey for administrative support occupations (\$14.60 per hour with an additional 27.5 percent added to cover benefit costs for a total of \$18.62 per hour). This occupation category includes stock and inventory clerks and record clerks. Coupled with the assumed hours per establishment, the resulting total annual maintenance costs to handlers, processors, and wholesalers and other intermediaries are estimated at approximately \$83 million.

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

The total maintenance recordkeeping costs for all enterprises are thus estimated at approximately \$506 million. The increase in the total maintenance cost over the maintenance cost estimate in the interim final rule is due to the inclusion of fish and shellfish in this final rule. The total first-year recordkeeping burden is calculated by summing the initial and maintenance costs. The total recordkeeping costs are estimated for producers at approximately \$274 million; for handlers, processors, and wholesalers at approximately \$114 million; and for retailers at approximately \$253 million. The total recordkeeping cost for all participants in the supply chain for covered commodities is estimated at \$641 million for the first year, with subsequent maintenance costs of \$506 million per year.

13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).

- **THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND**

MAINTENANCE AND COMPONENT. THE ESTIMATES SHOULD COSTS ASSOCIATED WITH GENERATING, DISCLOSING OR PROVIDING THE INCLUDE DESCRIPTIONS OF METHODS USED TO MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.

- IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.

- GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND USUAL BUSINESS OR PRIVATE PRACTICES.

There is no other capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT

WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.

Beginning in FY 2009, AMS must deploy an effective surveillance and enforcement program. A primary component of the enforcement program will be surveillance activities performed by State governments. This will require AMS to enter into cooperative agreements with each state and transfer sufficient funds to cooperating State agencies to conduct the surveillance activities. The estimated costs are as follows:

| | |
|---|-------|
| Retail Surveillance Reviews | |
| 5000/year x \$900/Review | \$4.5 |
| Primarily paid to States | |
| Supplier Trace-back Audits | 1.3 |
| 100 Retail Audits @ 3 items per review | |
| 300 items/year \$4,320/audit | |
| \$4,320 = 40 hours x \$108/hour | |
| Administration-Salary and Benefits | 1.2 |
| 10 Staff Years x 120,000 | |
| Miscellaneous Costs | 0.8 |
| rent/utilities/phones/Dept. | |
| assessments/ | |
| travel/printing/equipment | |
| Computer System (annual) | 1.8 |

The total annual cost to the Government to implement this regulation is \$9.6 million.

15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-I.

There is an increase of +861,282 burden hours due to the inclusion of wild and farm-raised fish and shellfish covered commodities.

16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.

Information obtained under this information collection is not published.

17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.

There is no form submission requirement associated with this collection.

18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-I.

The Agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection does not employ statistical methods.